Section A7.4.3.5.2 Aquatic plant toxicity

Annex Point IIIA, XIII.3.4 *Lemna gibba*

	substance	
3.4	**Testing procedure**	
3.4.1	Dilution water Test Sediment	*Lemna* culture techniques were based on those described in ASTM Standard E1415 (1991): Standard Guide for Conducting Static Toxicity Tests with *Lemna gibba* G3. The test suspensions contain the following (based on 1 litre): 243 mg $MgCl_2$ x6H_2O, 88.2 mg $CaCl_2$ x2H_2O, 294 mg $MgSO_4$ x7H_2O, 20.8 mg KH_2PO_4, 3.2 mg $FeCl_3$ x6H_2O, 6 mg Na_2EDTA x2H_2O, 3.71 mg H_3BO_3, 8.3 µg $MnCl_2$ x4H_2O, 28 µg $CoCl_2$ x6H_2O, 240 ng $CuCl_2$ x2H_2O, 145.2 µgNa_2MoO_4 x2H_2O, 300 mg $NaHCO_3$, 65.4 µg $ZnCl_2$, 0.2 µg Na_2SeO_3 x2H_2O
3.4.2	Test organisms	see table A7_4_3_5_2-2
3.4.3	Test system	see table A7_4_3_5_2-3
3.4.4	Test conditions	see table A7_4_3_5_2-4 Test was conducted under static-renewal conditions. The test solutions were renewed on day 7.
3.4.5	Duration of the test	14 days
3.4.6	Test parameter	Frond count endpoint and biomass endpoint.
3.4.7	Sampling	The **frond count** in each vessel was determined on Day 0, 2, 5, 7, 9, 12 and 14. On day 14, the plants from each replicate were dried at 60°C, cooled to ambient temperature and then weighted to determine the dry weight. The dry weight data were used for the analysis of **biomass**.
3.4.8	Monitoring of TS concentration	Yes; Samples of test solutions, including controls, were taken on day 0, day 7 (new solution), and day 14 (old solution) to measure actual exposure concentrations. Furthermore, pH Values and conductivity of test solutions were measured on day 0, day 7 and day 14.
3.4.9	Statistics	Growth data was analysed using the following statistical tests: - t-Test to determine if control and solvent control data could be pooled, - Chi-square test for normality, Bartlett test for homogeneity of variance - ANOVA followed by Dunnett's test or Bonferroni test - Probit analysis to estimate slope of dose-response curve, - Linear interpolation according to US-EPA (Inhibition concentration approach, 1993) to estimate EC25/EC50
		4 RESULTS
4.1	**Limit test**	A range find test was conducted with two replicates at each test concentration
4.1.1	Concentration	Control, solvent control (acetone), 0.01, 1.0, and 100 mg a.i./L
4.1.2	Number/ percentage of	The 100 mg/L test level had visible precipitates in the test solution. The frond counts at the 1 mg/L and 100 mg/L test levels indicated 80% and

Section A7.4.3.5.2 Aquatic plant toxicity

Annex Point IIIA, XIII.3.4 *Lemna gibba*

	animals showing adverse effects	100% inhibition in frond growth, respectively, compared to solvent control. Dry weight (biomass) was also measured: The 0.01, 1.0 and 100 mg/L test levels resulted in 13%, 81% and 99% inhibition, respectively, as compared to the solvent control.
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	Nominal concentrations: control, solvent control 31.3, 62.5, 125, 250 and 500 µg a.i./L.
4.2.2	Actual concentrations of test substance	Samples of test solutions, including controls, were taken on day 0, day 7 (new solution), and day 14 (old solution) to measure actual exposure concentrations. See table A7_4_3_5_2-5
4.2.3	Growth curves	Growth curves are plotted in the test report (page 22)
4.2.4	Concentration / response curve	Dose-response curves are given in the test report (page 23)
4.2.5	Cell concentration data	Not applicable
4.2.6	Effect data	See tables A7_4_3_5_2-6 and A7_4_3_5_2-7 for results of frond counts and biomass determinations. Frond count endpoint (in µg a.i./L): 14-day EC25 = 91.2 (95% CI = 81.2-97.1); 14-day EC50 = 144.4 (95% CI = 131.9-154.3); 14-day NOEC = 62.6. Biomass endpoint (in µg a.i./L): 14-day EC25 = 96.7 (95% CI = 57.9-124.8); 14-day EC50 = 179.8 (95% CI = 159.2-198.8); 14-day NOEC = 62.6.
4.2.7	Other observed effects	No
4.3	**Results of controls**	
4.4	**Test with reference substance**	Not performed
4.4.1	Concentrations	Not applicable
4.4.2	Results	Not applicable

Section A7.4.3.5.2 Aquatic plant toxicity

Annex Point IIIA, XIII.3.4 *Lemna gibba*

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The acute toxicity of tebuconazole (purity [redacted] to the aquatic plant *Lemna gibba* was studied for 14 days according to US-EPA FIFRA Guideline 123-2. The test was performed under static-renewal conditions with nominal test substance concentrations of 31.3; 62.5; 125; 250 and 500 µg a.i./L. Growth was determined by counting of fronds on days 2, 5, 7, 9, 12 and 14. Biomass was also determined at day 14.
5.2	**Results and discussion**	Frond count endpoint (in µg a.i./L): 14-day EC25 = 91.2 (95% CI = 81.2-97.1); 14-day EC50 = 144.4 (95% CI = 131.9-154.3); 14-day NOEC = 62.6. Biomass endpoint (in µg a.i./L): 14-day EC25 = 96.7 (95% CI = 57.9-124.8); 14-day EC50 = 179.8 (95% CI = 159.2-198.8); 14-day NOEC = 62.6.
5.3	**Conclusion**	Validity criteria can be considered as fulfilled. There is a clear dose-response relationship. Tebuconazole is toxic to *Lemna gibba* G3.
5.3.2	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	*April 2007*
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

COMMENTS FROM ...

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*

Section A7.4.3.5.2 Aquatic plant toxicity

Annex Point IIIA, XIII.3.4 *Lemna gibba*

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_4_3-5_2-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	No information
Vehicle	Yes, Acetone
Concentration of vehicle	Acetone was added to the test solutions to approximate the same solvent load at all concentration levels (100 µl acetone/L dilution water).
Vehicle control performed	Yes, growth inhibition test
Other procedures	No

Table A7_4_3_5_2-2: Test organisms

Criteria	Details
Species	Aquatic plant *Lemna gibba* G3
Strain	*Scenedesmus subspicatus* strain SAG 86/81
Source	Obtained from an in-house culture, which was maintained in the laboratory since 1996-10-23. The Lemna culture was obtained from Dr. J. Slovin, US Department of Agriculture, Beltsville, Maryland.
Laboratory culture	Yes
Method of cultivation	Under sterile conditions. *Lemna* culture techniques were based on those described in ASTM Standard E1415 (1991): Standard Guide for Conducting Static Toxicity Tests with *Lemna gibba* G3.
Pre-treatment	The batch culture was grown under test conditions. The density was documented to verify that the batch culture was in log-phase growth at study initiation.
Density	Each replicate was inoculated with three to four *Lemna* plants for a total of 12 to 14 fronds at study initiation.

Table A7_4_3_5_2-3: Test system

Criteria	Details
Volume of culture flasks	650 ml borosilicate glass crystallization dishes filled with approximately 260 ml of test solution and capped with sterile Petri dish lids.
Culturing apparatus	Controlled environment chamber
Light quality	Fluorescent lamps; photoperiod of 24 h light; light intensity of approximately 495 foot-candles (5.3 klux)
Procedure for suspending algae	Shaking
Number of vessels/ concentration	3 vessels per test substance concentration, 3 vessels control, 3 vessels solvent control, 1 vessel pooled controls
Test performed in closed vessels due to significant volatility of TS	No

Table A7_4_3_5_2-4: Test conditions

Criteria	Details
Test temperature	25 ± 2.0°C
pH	Day 1: 8.1; Day 7 (new solution): 8.1-8.2; Day 7 (old solution): 8.5-8.8; Day 14 (old solution): 8.6-9.4
Aeration of dilution water	No information
Light intensity	approximately 495 foot-candles (5.3 klux)
Photoperiod	Constant light (24 hour photoperiod)

Table A7_4_3_5_2-5: Measured test concentrations of Tebuconazole during the exposure to *Lemna gibba* G3

Test concentration level	Measured concentration (µg a.i./L)			Mean Standard deviation	Percent of nominal
	Day 0 (new test solution)	Day 7 (new test solution)	Day 14 (old test solution)		
Control	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Solvent control	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
31.3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
62.5	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
125	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
250	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
500	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Lab. Recovery**	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

* : Not detected at or above the validated limit of detection (3 µg/L)
** : Based upon a lab spike of 104.4 µg test substance/L media

Table A7_4_3_5_2-6: Test results for the exposure of Tebuconazole to *Lemna gibba* G3: Front counts at day 14

Mean measured concentration (µg/L)	Replicate	Day 14 (Number of Fronds)	Day 14 (Mean)	Percent of Pooled Control
Control	A B C	[redacted]	[redacted]	[redacted]
Solvent control	A B C	[redacted]	[redacted]	[redacted]
Pooled controls	--	[redacted]	[redacted]	[redacted]
30.7	A B C	[redacted]	[redacted]	[redacted]
62.3	A B C	[redacted]	[redacted]	[redacted]
127.9	A B C	[redacted]	[redacted]	[redacted]
208.6	A B C	[redacted]	[redacted]	[redacted]
488.5	A B C	[redacted]	[redacted]	[redacted]

* : Statistical analysis of day 14 growth indicated that these test levels were significantly different ($p < 0.05$) from the pooled controls.

\# : Statistical analysis indicated a significant difference at this concentration. However, the response at the 62.3 µg/L level and the slight difference from the pooled controls led to the conclusion that this lowest treatment was biologically similar and was not adversely affected by the exposure to Tebuconazole.

Table A7_4_3_5_2-7: Test results for the exposure of Tebuconazole to *Lemna gibba* G3: Biomass at day 14

Mean measured concentration (µg/L)	Replicate	Day 14 Dry Weight (grams)	Day 14 (Mean)	Percent of Pooled Control
Control	A B C	[redacted]	[redacted]	[redacted]
Solvent control	A B C	[redacted]	[redacted]	[redacted]
Pooled controls	--	[redacted]	[redacted]	[redacted]
30.7	A B C	[redacted]	[redacted]	[redacted]
62.3	A B C	[redacted]	[redacted]	[redacted]
127.9	A B C	[redacted]	[redacted]	[redacted]
208.6	A B C	[redacted]	[redacted]	[redacted]
488.5	A B C	[redacted]	[redacted]	[redacted]

* : Statistical analysis of day 14 growth indicated that these test levels were significantly different ($p < 0.05$) from the pooled controls.

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA7.4

Official use only

1 REFERENCE

1.1	**Reference**	a) Anderson, J.P.E.: Influence of Folicur (tebuconazole) EW 250 on glucose stimulated respiration in soils. Bayer AG, now Bayer CropScience AG, unpublished report No. AJO/217601, 2001-04-17. b) Anderson, J.P.E.: Influence of Folicur (tebuconazole) EW 250 on the microbial mineralization of nitrogen in soils. Bayer AG, now Bayer CropScience AG; unpublished report No. AJO/217701, 2001-04-17.
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	a) BBA Part VI 1-1 (2nd ed), ISO/DIS 1036-6, OECD/OCDE No. 217 b) BBA Part VI 1-1 (2nd ed), ISO/DIS 1036-6, OECD/OCDE No. 216
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

3.1	**Test material**	Folicur (tebuconazole) EW 250, containing [redacted] g tebuconazole/L
3.1.1	Lot/Batch number	Batch No. 233025507
3.1.2	Specification	technical active ingredient
3.1.3	Purity	Folicur (tebuconazole) EW 250, containing [redacted] g tebuconazole/L
3.1.4	Composition of Product	
3.1.5	Further relevant properties	
3.1.6	Method of analysis	a) For CO_2 in the respiration test: CO_2 was measured after absorption in NaOH and following titration b) For the determination of the nitrification: Two photometric methods were used to measure ammonium (colour complex at 660 nm) and nitrate plus nitrite (after reduction and formation of an azo dyestuff at 520 nm)
3.2	**Preparation of TS solution for poorly**	No

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA7.4

	soluble or volatile test substances	
3.2.1	Method of analysis for reference substance	n.a.
3.3	**Testing procedure**	
3.3.1	Soil sample / inoculum / test organism	see table A7_5_1_1-1
3.3.2	Test system	see table A7_5_1_1-2
3.3.3	Application of TS	see table A7_5_1_1-3 a) A silty sand soil was exposed for 28 d to concentrations of 3.29 and 32.93 mg tebuconazole EW 250/kg d.wt. soil (application rates were equivalent to 2.47 and 24.7 kg tebuconazole EW 250/ha, which is equivalent to 1x and 10x the maximum field rate, respectively). Glucose was added to soil samples to induce maximum respiration rate (3 g/kg d.wt. soil). b) A silty sand soil was exposed for 28 d to concentrations of 3.29 and 32.93 mg tebuconazole EW 250/kg d.wt. soil (application rates were equivalent to 2.47 and 24.7 kg tebuconazole EW 250/ha, which is equivalent to 1x and 10x the maximum field rate, respectively). Lucerne-grass green meal was added to soil (5 g/kg d.wt. soil) to stimulate nitrogen transformation.
3.3.4	Test conditions	Give relevant test conditions in tabular form (see table A7_5_1_1-4)
3.3.5	Test parameter	a) inhibition of microbial carbon transformation b) inhibition of nitrification of ammonia
3.3.6	Analytical parameter	a) CO_2 measurement b) Ammonia and nitrate (including nitrite) measurement
3.3.7	Duration of the test	a) 28 days b) 28 days
3.3.8	Sampling	Three samples each sampling a) CO_2 kinetics (2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 hours after addition of glucose) at day 0, 7, 14 and 28. b) Determination of ammonia and nitrate (including nitrite): after day 0 , 7, 14, and 28.
3.3.9	Monitoring of TS concentration	No
3.3.10	Controls	Carrier (quartz sand) control

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA7.4

3.3.11	Statistics	a) and b) mean value from three samplings, b) t-test with 5% probability level
		4 RESULTS
4.1	**Range finding test**	not performed for the a.i.
4.1.1	Concentration	n.a.
4.1.2	Effect data	n.a.
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	a) Concentrations of 3.29 and 32.93 mg tebuconazole EW 250/kg d.wt. soil (application rates were equivalent to 2.47 and 24.7 kg tebuconazole EW 250/ha, which is equivalent to 1x and 10x the maximum field rate, respectively). b) Concentrations of 3.29 and 32.93 mg tebuconazole EW 250/kg d.wt. soil (application rates were equivalent to 2.47 and 24.7 kg tebuconazole EW 250/ha, which is equivalent to 1x and 10x the maximum field rate, respectively).
4.2.2	Actual concentrations of test substance	No measurements were done (nominal concentrations), no volatility is assumed due to the low vapour pressure of tebuconazole, also major degradation processes are not expected according to the laboratory tests.
4.2.3	Growth curves	n.a.
4.2.4	Cell concentration data	n.a.
4.2.5	Concentration/ response curve	n.a.
4.2.6	Effect data	a) During the 28-day experiments, tebuconazole (Folicur) EW 250 had no influence at 0.625 and 6.25 kg a.s./ha on soil respiration after addition of glucose to a silty sand soil. b) During the 28-day experiments the maximum field rate of tebuconazole (Folicur) EW 250 had no influence on the turnover of nitrogen in a silty sand soil amended with lucerne-grass green meal. In samples treated with a 10-fold overdose of tebuconazole EW 250, there was a temporary increase in nitrate production 14 days after treatment. At the end of the 28-day experiment differences between treated soil samples and control soil samples were 10 %. During the 28-day experiments, tebuconazole (Folicur) EW 250 had no influence at 0.625 and 6.25 kg a.s./ha on the turnover of nitrogen in a silty sand soil amended with lucerne-grass green meal.

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA7.4

		See table A7_5_1_1-5 and table A7_5_1_1-6 for detailed results
4.2.7	Other observed effects	
4.3	**Results of controls**	See also table including data for all controls applied: e.g. control without test substance; abiotic control; carrier control
4.4	**Test with reference substance**	Not performed
4.4.1	Concentrations	n.a.
4.4.2	Results	n.a.

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA7.4

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	a) A silty sand soil was exposed for 28 d to concentrations of 3.29 and 32.93 mg tebuconazole EW 250/kg d.wt. soil (application rates were equivalent to 2.47 and 24.7 kg tebuconazole EW 250/ha, which is equivalent to 1x and 10x the maximum field rate, respectively). Glucose was added to soil samples to induce maximum respiration rate (3 g/kg d.wt. soil). b) A silty sand soil was exposed for 28 d to concentrations of 3.29 and 32.93 mg tebuconazole EW 250/kg d.wt. soil (application rates were equivalent to 2.47 and 24.7 kg tebuconazole EW 250/ha, which is equivalent to 1x and 10x the maximum field rate, respectively). Lucerne-grass green meal was added to soil (5 g/kg d.wt. soil) to stimulate nitrogen transformation. Tests were performed according to: a) BBA Part VI 1-1 (2nd ed), ISO/DIS 1036-6, OECD/OCDE No. 217 b) BBA Part VI 1-1 (2nd ed), ISO/DIS 1036-6, OECD/OCDE No. 216
5.2	**Results and discussion**	a) During the 28-day experiments, tebuconazole (Folicur) EW 250 had no influence at 0.625 and 6.25 kg a.s./ha on soil respiration after addition of glucose to a silty sand soil. b) During the 28-day experiments the maximum field rate of tebuconazole (Folicur) EW 250 had no influence on the turnover of nitrogen in a silty sand soil amended with lucerne-grass green meal. In samples treated with a 10-fold overdose of tebuconazole EW 250, there was a temporary increase in nitrate production 14 days after treatment. At the end of the 28-day experiment differences between treated soil samples and control soil samples were 10 %. During the 28-day experiments, tebuconazole (Folicur) EW 250 had no influence at 0.625 and 6.25 kg a.s./ha on the turnover of nitrogen in a silty sand soil amended with lucerne-grass green meal.
5.2.1	NOEC	NOEC was not calculated
5.2.2	EC_{10}	Not calculated
5.2.3	EC_{50}	Not calculated
5.3	**Conclusion**	Tebuconazole will not cause adverse effects to the soil carbon and nitrogen cycle at the concentration as for the recommended agricultural use or a 10-fold overdose.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA7.4

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*June 2004.*
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA7.4

[redacted]

[redacted]

	COMMENTS FROM ...
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_1_1-1: Properties of the soil sample

Criteria	Details
Nature	One soil sample (silty sand)
Sampling site:	Soil sample from Germany
Geographical reference on the sampling site	Bayer Experimental Farm Monheim/Laacher Hof (Field Plot F)
Data on the history of the site	History of the site from 1981 until now is given in report
Use pattern	Agricultural soil, plot is under grass since 1996
Depth of sampling [cm]	Not reported
Sand / Silt / Clay content [% dry weight]	77.5 / 18.0 /4.5 (loamy sand)
pH (KCl)	5.8
Organic carbon content [% dry weight]	0.6
Nitrogen content [% dry weight]	0.08
Cation exchange capacity [meq/100 g dry wt soil]	6.0
Initial microbial biomass [mg C/kg dry wt soil]	232
Reference of methods	J.P.E. Anderson, 1982, Soil Respiration, in: Page, A.L. et al. (eds.): Methods of Soil Analysis, Part 2 (Chemical and Microbiological Methods), Agronomy Monograph 9, 2nd ed., Madison, USA, pp. 831-871
Collection / storage of samples	The soils were sampled from the field, passed through a sieve (2 mm) and stored at 20 ± 2 °C for at least days but not for longer than 14 days. Sampling and storage according to ISO 1036-6 and BBA Guideline (Testing of Plant Protectants, Part VI, Influence on the activity of the Soil Microflora, BBA Braunschweig, Germany, March 1990)
Preparation of inoculum for exposure	n.a.
Pretreatment	n.a.

Table A7_5_1_1-2: Test system for soil respiration / nitrification tests

Criteria	Details
Culturing apparatus	After mixing, soil was incubated in 500 ml brown glass bottles
Number of vessels / concentration	3 replicates per application
Aeration device	The glasses were closed with PARAFILM
Measuring equipment	
Test performed in closed vessels	No

Table A7_5_1_1-3: Application of test substance and sampling

Criteria	Details
Application procedure	Addition of premixtures in a carrier and mixing the carrier with native soil
Carrier	Quartz sand
Concentration of liquid carrier [% v/v]	no
Liquid carrier control	n.a.
sampling procedure	Three 10 g dry wt. soil samples were taken at each sampling interval. The average from the three samples was taken for evaluation

Table A7_5_1_1-4: Test conditions

Criteria	Details
Organic (inorganic) substrate	Addition of a) 3000 mg glucose / kg dry wt. soil b) 5000 mg lucerne-grass-grean meal / kg dry wt. soil
Incubation temperature	20 ± 2 °C
Soil moisture	a) about 40% of the water holding capacity b) about 40% of the water holding capacity
Method of soil incubation	Bulk
Aeration	No

Table A7_5_1_1-5 (sampling after 14 days) **Typical Test Results from the Respiratory Test a) in silty sand**

Addition of Glucose	0 mg tebuconazole / kg[1] (quartz sand only)	3.29 mg tebuconazole[1]/ kg	32.93 mg tebuconazole / kg[1]
hours after addition	mg carbon dioxide / hour / kg dry wt soil		
1	[redacted]	[redacted]	[redacted]
2	[redacted]	[redacted]	[redacted]
3	[redacted]	[redacted]	[redacted]
4	[redacted]	[redacted]	[redacted]
5	[redacted]	[redacted]	[redacted]
6	[redacted]	[redacted]	[redacted]
7	[redacted]	[redacted]	[redacted]
8	[redacted]	[redacted]	[redacted]
9	[redacted]	[redacted]	[redacted]
10	[redacted]	[redacted]	[redacted]
11	[redacted]	[redacted]	[redacted]
12	[redacted]	[redacted]	[redacted]
Sum	[redacted]	[redacted]	[redacted]
% of control	[redacted]	[redacted]	[redacted]

1 = dry wt soil / average from three samples

TableA7_5_1_1-6 **Test Results from the Nitrification Test in silty sand**

Addition of Ammonium sulfate	0 mg tebuconazole / kg[1] (quartz sand only)		3.29 mg tebuconazole[1]/ kg		32.93 mg tebuconazole / kg[1]	
days after	mg ammonium or nitrate / kg dry wt soil					
	ammonium	nitrate	ammonium	nitrate	ammonium	nitrate
0	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
7	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
14	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
28	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

1 = dry wt soil / average from three samples

Section A7.5.1.1 Inhibition to microbial activity (terrestrial) of 1,2,4-triazole

Annex Point IIIA XIII.3.3

Official use only

	1 REFERENCE	
1.1	**Reference**	Völkel, W. The effects of CGA71019 on soil respiration and nitrification. RCC Project 763367, Novartis Crop Protection study number: 2003502. May 16, 2000.
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, OECD Draft Guideline 217 "Soil Microorganisms: Carbon transformation Test, August 1999 and OECD Draft Guideline 216 "Soil Microorganisms: Nitrogen transformation Test, August 1999
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]
	3 MATERIALS AND METHODS	
3.1	**Test material**	1,2,4-triazole
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	Pure substance
3.1.3	Purity	[redacted]
3.1.4	Composition of Product	n.a.
3.1.5	Further relevant properties	-
3.1.6	Method of analysis	n.a.
3.2	**Reference substance**	Dinoseb acetate (CAS 2813-95-8)
3.2.1	Method of analysis for reference substance	n.a.
3.3	**Testing procedure**	
3.3.1	Soil sample / inoculum / test organism	See table A7_5_1_1-1

Section A7.5.1.1 Annex Point IIIA XIII.3.3 — Inhibition to microbial activity (terrestrial) of 1,2,4-triazole

3.3.2	Test system	See OECD Draft Guideline quoted under 2.1
3.3.3	Application of TS	Addition of quartz sand to a pre-mixture in water and mixing with native soil
3.3.4	Test conditions	Fresh soil moistened to 42 % of its maximum water capacity
3.3.5	Test parameter	20 ± 2 °C
3.3.6	Analytical parameter	CO2 (IR detection) and photometric detection of nitrite/nitrate
3.3.7	Duration of the test	28 days
3.3.8	Sampling	Respiration and nitrification were measured at day 0 (0-3 h), day 7, day 14 and after 28 days
3.3.9	Monitoring of TS concentration	No monitoring
3.3.10	Controls	Untreated soil samples
3.3.11	Statistics	Probability analysis
		4 RESULTS
4.1	**Range finding test**	Not performed
4.2	**Results test substance**	See table 7_5_1_1-2
4.2.1	Initial concentrations of test substance	0.035 and 0.353 mg 1,2,4 Triazole / kg soil dry weight
4.2.2	Concentration/ response curve	Not determined
4.2.3	Effect data	There were no significant effect on carbon dioxide evolvement after addition of glucose and on the nitrification
4.2.4	Other observed effects	
4.3	**Results of controls**	Controls were used as 100 % reference
4.4	**Test with reference substance**	
4.4.1	Concentrations	25 mg Dinoseb acetate / kg soil dry weight
4.4.2	Results	CO_2 evolvement was diminished, nitrification was increased.

Section A7.5.1.1 Inhibition to microbial activity (terrestrial) of 1,2,4-triazole

Annex Point IIIA XIII.3.3

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The effect of 1,2,4-triazole was tested against
5.2	**Results and discussion**	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 turnover
5.2.1	NOEC	Should be equivalent to EC10
5.2.2	EC_{10}	0.353 mg 1,2,4-triazole/kg dry soil
5.2.3	EC_{50}	> 0.353 mg 1,2,4-triazole/kg dry soil
5.3	**Conclusion**	At the concentrations tested 1.2.4 triazole has no impact on the vitality of soil microorganisms involved in the carbon cycle and in nitrification.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	*April 07*
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

COMMENTS FROM ...

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_1_1-1: Microbial sample

Criteria	Details
Nature	Agricultural soil
Sampling site:	Soil samples from Germany, F 30200 Speyer 2.3
Geographical reference on the sampling site	Landwirtschaftliche Untersuchungs- und Forschungsanstalt, Speyer, Germany
Sand / Silt / Clay content [% dry weight]	66.2 / 26.5 / 7.4 (USDA)
pH (KCl)	6.5
Organic carbon content [% dry weight]	0.71
Nitrogen content [% dry weight]	0.09
Cation exchange capacity [meq/100g soil]	11
Maximum water holding capacity [ml H2O/100 g soil]	37
Microbial biomass [mgC/kg dry weight soil]	203
Bulk density of air dried an sieved soil [g/1000ml]	1328

Table A7_5_1_1-2: Test Results after 28 Days

		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	n.a.	n.a.
	NO_3-N	-5.2	-1.5

n.a. = not applicable

Section A7.5.1.2 Soil non-target organisms
Annex Point IIIA XIII 3.2

			Official use only
		1 REFERENCE	
1.1	**Reference**	Hoogendoorn, G.M., 1999, An extended laboratory dose-response study to evaluate the effects of HWG 1608 on the predaceous mite *Hypoaspis aculeifer Canestrini* (Acari: Gamasidae), Source: MITOX, Amsterdam, sponsored by Bayer AG, now Bayer CropScience AG; Report No. B052HAE (amended 2001).	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Lokke & van Gestel (1996), SETAC/ESCORT (1994)	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Tebuconazole tech.	
3.1.1	Lot/Batch number	Batch number [redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Purity	[redacted] of active substance	
3.1.4	Composition of Product		
3.1.5	Further relevant properties		
3.1.6	Method of analysis	GLC (int. Std.) (performed by Bayer AG, Germany)	
3.2	**Reference substance**	Yes Dimethoate	
3.2.1	Method of analysis for reference substance	GC PAM 695/1 (performed by Zeneca Agrochemicals, UK)	
3.3	**Testing procedure**		
3.3.1	Preparation of the test substance	Solution was made by dissolving test substance into Acetone	

Section A7.5.1.2 Soil non-target organisms
Annex Point IIIA XIII 3.2

3.3.2	Application of the test substance	The test substance was applied at concentrations ranging from 1 to 100 mg/kg soil to LUFA 2.2 soil by mixing solutions into the soil. The treated soil was placed into glass coffin cells.
3.3.3	Test organisms	see table A7_5_1_2-2
3.3.4	Test system	see table A7_5_1_2-3
3.3.5	Test conditions	see table A7_5_1_2-4
3.3.6	Test duration	24 days
3.3.7	Test parameter	Mortality and fecundity (i.e. egg production and egg hatch success)
3.3.8	Examination	After 14 and following 10 days
3.3.9	Monitoring of test substance concentration	No
3.3.10	Statistics	The LC50 was determined using Abbott's correction. Juvenile mortality, egg production and hatch were statistically analysed using Anova followed by a Fisher's LSD test for pairwise comparisons.
		4 RESULTS
4.1	**Test**	
4.1.1	Initial concentrations of test substance	See table A7_5_1_2-5
4.2.3	Effect data (Mortality)	see table A7_5_1_2-5and table A7_5_1_2-6
4.2.4	Other effects	None
4.3	**Results of controls**	
4.3.1	Mortality	See table A7_5_1_2-5
4.4	**Test with reference substance**	Performed, Dimethoate
4.4.1	Concentrations	3.3 resp. 6.5 mg/kg soil
4.4.2	Results	27% resp. 95% mortality
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	The test according to Lokke & van Gestel (1996), SETAC/ESCORT (1994). Test was developed within Mitox, guidelines served as general guidelines.
5.2	**Results and discussion**	
5.2.1	LC_{50}	521 mg/kg soil

Section A7.5.1.2 Soil non-target organisms
Annex Point IIIA XIII 3.2

5.2.2	NOEC	50 mg/kg soil
5.3	**Conclusion**	No biologically significant effects
5.3.1	Other Conclusions	none
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	[redacted]

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date September 2004

Materials and Methods [redacted]

Results and discussion [redacted]

Conclusion [redacted]

Reliability [redacted]

Acceptability

Remarks

COMMENTS FROM ... *(specify)*

Date

Materials and Methods

Results and discussion

Conclusion

Reliability

Acceptability

Remarks

Table A7_5_1_1-2: Test organisms

Criteria	Details
Species/strain	*Hypoaspis aculeifer* Canestrini (Acari: Gamasida)
Source of the initial stock	Department of Population Biology and Systematics (University of Amsterdam, The Netherlands)
Culturing techniques	Six days before exposure cohorts were putting into several jars with a plaster bottom, darkened with active carbon and supplied with an ample amount of food. Two days later all females were removed.
Age/weight	The eggs laid into the jars yielded juvenile mites used in the test. In addition due to the lack of mites protonymphs taken directly from the rearing of the University of Amsterdam were used.
Pre-treatment	none

Table A7_5_1_1-3: Test system

Criteria	Details
Test units	Glass cages ('coffin cells') filled with treated LUFA 2.2 soil
Size, volume and material of test container	Top glass plate (10x5x0.3 cm) with 3 holes (∅ = 0.6 cm) and side walls (3 mm high) and a bootom glass plate (10x5x0.15 cm) with side walls (3 mm high)
Nominal levels of test concentrations	1, 12.5, 25, 50 and 100 mg ai/kg artificial soil
Number of replicates/concentration	3 replicates
Number of insects/replicate	20
Number of insects/cage	Dose response: cohorts Repetition: 15 protonymphs and 5 larvae

Table A7_5_1_2-4: Test conditions

Criteria	Details
Test temperature	25 °C
Relative humidity	70%
Moist content	Dose response: Checked on day 3, 7, 10 and 10 (Only on day 10 water was added) Repetition: checked on day 3 and 10
Light intensity / photoperiod	Kept in the dark

Table A7_5_1_2-5: Mortality data

	Mortality after 14 days	Fecundity	
		(eggs/female)	(eggs hatched/female)
Control	18 % / repeat 8 %	23.5	20.9
Application rates	Corrected mortality after 14 days	Reproduction relative to the control	
1 mg /kg soil	[redacted]	[redacted]	[redacted]
12.5 mg /kg soil	[redacted]	[redacted]	[redacted]
25 mg /kg soil	[redacted]	[redacted]	[redacted]
50 mg /kg soil	[redacted]	[redacted]	[redacted]
100 mg /kg soil	[redacted]	[redacted]	[redacted]

1): Significantly different from the control. 2) not determined; 3) not statistically tested

Table A7_5_1_2-6: Effect data

LC_{50}	521 mg/kg soil
NOEC	50 mg /kg soil based on mortality

Section A7.5.1.2 Soil non-target organisms
Annex Point IIIA XIII 3.2

Official use only

		1 REFERENCE
1.1	**Reference**	Hoogendoorn, G.M., 1999, An extended laboratory dose-response study to evaluate the effects of HWG 1608 on the predaceous mite *Hypoaspis aculeifer Canestrini* (Acari: Gamasidae), Source: MITOX, Amsterdam, sponsored by Bayer AG, now Bayer CropScience AG; Report No. B052HAE (amended 2001).
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes Lokke & van Gestel (1996), SETAC/ESCORT (1994)
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]
		3 METHODS
3.1	**Test material**	Tebuconazole tech.
3.1.1	Lot/Batch number	Batch number [redacted]
3.1.2	Specification	[redacted]
3.1.3	Purity	[redacted] of active substance
3.1.4	Composition of Product	
3.1.5	Further relevant properties	
3.1.6	Method of analysis	GLC (int. Std.) (performed by Bayer AG, Germany)
3.2	**Reference substance**	Yes Dimethoate
3.2.1	Method of analysis for reference substance	GC PAM 695/1 (performed by Zeneca Agrochemicals, UK)
3.3	**Testing procedure**	
3.3.1	Preparation of the test substance	Solution was made by dissolving test substance into Acetone
3.3.2	Application of the	The test substance was applied at concentrations ranging from 1 to 100

Section A7.5.1.2 Soil non-target organisms
Annex Point IIIA XIII 3.2

	test substance	mg/kg soil to LUFA 2.2 soil by mixing solutions into the soil. The treated soil was placed into glass coffin cells.
3.3.3	Test organisms	see table A7_5_1_2-2
3.3.4	Test system	see table A7_5_1_2-3
3.3.5	Test conditions	see table A7_5_1_2-4
3.3.6	Test duration	24 days
3.3.7	Test parameter	Mortality and fecundity (i.e. egg production and egg hatch success)
3.3.8	Examination	After 14 and following 10 days
3.3.9	Monitoring of test substance concentration	No
3.3.10	Statistics	The LC50 was determined using Abbott's correction. Juvenile mortality, egg production and hatch were statistically analysed using Anova followed by a Fisher's LSD test for pairwise comparisons.
		4 RESULTS
4.1	**Test**	
4.1.1	Initial concentrations of test substance	See table A7_5_1_2-5
4.1.2	Effect data (Mortality)	see table A7_5_1_2-5and table A7_5_1_2-6
4.1.3	Other effects	None
4.2	**Results of controls**	
4.2.1	Mortality	See table A7_5_1_2-5
4.3	**Test with reference substance**	Performed, Dimethoate
4.3.1	Concentrations	3.3 resp. 6.5 mg/kg soil
4.3.2	Results	27% resp. 95% mortality
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	The test according to Lokke & van Gestel (1996), SETAC/ESCORT (1994). Test was developed within Mitox, guidelines served as general guidelines.
5.2	**Results and discussion**	
5.2.1	LC_{50}	521 mg/kg soil
5.2.2	NOEC	50 mg/kg soil

Section A7.5.1.2 Soil non-target organisms
Annex Point IIIA XIII 3.2

5.3	**Conclusion**	No biologically significant effects
5.3.1	Other Conclusions	none
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	[redacted]

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	September 2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	
Remarks	

COMMENTS FROM ... *(specify)*

Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A7_5_1_1-2: Test organisms

Criteria	Details
Species/strain	*Hypoaspis aculeifer* Canestrini (Acari: Gamasida)
Source of the initial stock	Department of Population Biology and Systematics (University of Amsterdam, The Netherlands)
Culturing techniques	Six days before exposure cohorts were putting into several jars with a plaster bottom, darkened with active carbon and supplied with an ample amount of food. Two days later all females were removed.
Age/weight	The eggs laid into the jars yielded juvenile mites used in the test. In addition due to the lack of mites protonymphs taken directly from the rearing of the University of Amsterdam were used.
Pre-treatment	none

Table A7_5_1_1-3: Test system

Criteria	Details
Test units	Glass cages ('coffin cells') filled with treated LUFA 2.2 soil
Size, volume and material of test container	Top glass plate (10x5x0.3 cm) with 3 holes (∅ = 0.6 cm) and side walls (3 mm high) and a bootom glass plate (10x5x0.15 cm) with side walls (3 mm high)
Nominal levels of test concentrations	1, 12.5, 25, 50 and 100 mg ai/kg artificial soil
Number of replicates/concentration	3 replicates
Number of insects/replicate	20
Number of insects/cage	Dose response: cohorts Repetition: 15 protonymphs and 5 larvae

Table A7_5_1_2-4: Test conditions

Criteria	Details
Test temperature	25 °C
Relative humidity	70%
Moist content	Dose response: Checked on day 3, 7, 10 and 10 (Only on day 10 water was added) Repetition: checked on day 3 and 10
Light intensity / photoperiod	Kept in the dark

Table A7_5_1_2-5: Mortality data

	Mortality after 14 days	Fecundity	
		(eggs/female)	(eggs hatched/female)
Control	18 % / repeat 8 %	23.5	20.9
Application rates	Corrected mortality after 14 days	Reproduction relative to the control	
1 mg /kg soil	[redacted]	[redacted]	[redacted]
12.5 mg /kg soil	[redacted]	[redacted]	[redacted]
25 mg /kg soil	[redacted]	[redacted]	[redacted]
50 mg /kg soil	[redacted]	[redacted]	[redacted]
100 mg /kg soil	[redacted]	[redacted]	[redacted]

1): Significantly different from the control. 2) not determined; 3) not statistically tested

Table A7_5_1_2-6: Effect data

LC_{50}	521 mg/kg soil
NOEC	50 mg /kg soil based on mortality

Section A7.5.1.2 Soil non-target organisms
Annex Point IIIA XIII 3.2

			Official use only
		1 REFERENCE	
1.1	**Reference**	Wilhelmy, G.M., 1999, HWG 1608: Inhibition of reproduction of Collembola (*Folsomia candida*), Source: Dr.U.Noack-Laboratorium für angewandte Biologie, sponsored by Bayer AG, now Bayer CropScience AG; Report No. ICR64011	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes ISO/FDIS 11267 (1998)	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 METHODS	
3.1	**Test material**	Tebuconazole tech.	
3.1.1	Lot/Batch number	batch number [redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Purity	[redacted] of active substance	
3.1.4	Composition of Product		
3.1.5	Further relevant properties		
3.1.6	Method of analysis	GLC (int. Std.) (performed by Bayer AG, Germany)	
3.2	**Reference substance**	Yes Parathion	
3.2.1	Method of analysis for reference substance		
3.3	**Testing procedure**		
3.3.1	Preparation of the test substance	Solution was made by dissolving test substance into Acetone	

Section A7.5.1.2 Soil non-target organisms
Annex Point IIIA XIII 3.2

3.3.2	Application of the test substance	The test substance was applied at concentrations ranging from 62.5 to 1,000 mg/kg d.w.s. to artificial soil by mixing test substance dispersed in quartz sand into the soil. The treated soil was placed into glass beakers.
3.3.3	Test organisms	see table A7_5_1_2-2
3.3.4	Test system	see table A7_5_1_2-3
3.3.5	Test conditions	see table A7_5_1_2-4
3.3.6	Test duration	28 days
3.3.7	Test parameter	Mortality and reproduction
3.3.8	Examination	After day 28
3.3.9	Monitoring of test substance concentration	No
3.3.10	Statistics	Anova, Dunett's test and t-test.
		4 RESULTS
4.1	**Test**	
4.1.1	Initial concentrations of test substance	See table A7_5_1_2-5
4.1.2	Effect data (Mortality)	see table A7_5_1_2-5 and table A7_5_1_2-6
4.1.3	Other effects	None
4.2	**Results of controls**	
4.2.1	Mortality	See Table A7_5_1_2-5
4.3	**Test with reference substance**	Performed, Parathion
4.3.1	Concentrations	0.05, 0.1, 0.2, 0.4 and 0.8 mg/kg dry weight soil
4.3.2	Results	LOEC 0.20 mg/kg (adult mortality) and 0.10 mg/kg (reproduction) LC_{50} 0.17 mg/kg (adult mortality) and 0.15 mg/kg (reproduction) NOEC 0.1 mg/kg (adult mortality) and 0.05 mg/kg (reproduction)
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	The test according to ISO/FDIS 11267 (1998). No significant derivation from the guideline.
5.2	**Results and discussion**	
5.2.1	LOEC	500 mg/kg soil (adult mortality and reproduction)

Section A7.5.1.2 Soil non-target organisms
Annex Point IIIA XIII 3.2

5.2.2	LC50/EC50	> 1,000 mg/kg soil (adult mortality and reproduction)
5.2.3	NOEC	250 mg/kg soil (adult mortality and reproduction)
5.3	**Conclusion**	
5.3.1	Other Conclusions	none
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	[redacted]

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]

Section A7.5.1.2 Soil non-target organisms
Annex Point IIIA XIII 3.2

Remarks	[redacted]
	COMMENTS FROM ... *(specify)*
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A7_5_1_1-2: Test organisms

Criteria	Details
Species/strain	*Folsomia candida* Willem (Mandibulata, Antennata, Apterigota, Collembola)
Culturing techniques	Bred in covered polyethylene flasks (height 7.5 cm, diameter 7 cm) on artificial soil containing 90% w/w calcium sulphate dihydrate and 10% w/w powdered activated charcoal.
Age/weight	Juvenile springtails (10-12 days old)
Pre-treatment	Egg clusters from breeding containers were transferred to freshly prepared containers. After 48 h egg clusters were removed and the hatched instars were fed. For the following 0-12 days overcrowding was avaoided.

Table A7_5_1_1-3: Test system

Criteria	Details
Test units	Glass beakers
Size, volume and material of test container	Glass beakers with a volume of 100 ml (diameter 4.3 cm) covered with Parafilm.
Nominal levels of test concentrations	62.5, 125, 250, 500 and 1,000 mg/kg dry weight
Number of replicates/concentration	5 replicates
Number of insects/replicate	10

Table A7_5_1_2-4: Test conditions

Criteria	Details
Test temperature	20 °C ± 2 °C
Moisture content	25%
pH	6.0 ± 0.5
Adjustment of pH	Yes, with calcium carbonate
Light intensity / photoperiod	400 – 800 lx (light/dark cycle of 16/8 h)

Table A7_5_1_2-5: Mortality data

	Adult mortality	Reproduction
LC_{50}/EC_{50} [mg/kg soil]	> 1,000	> 1,000
LOEC [mg/kg soil]	500	500
NOEC [mg/kg soil]	250	250

Table A7_5_1_2-6: Effect data

LC_{50}	> 1,000 mg/kg soil
NOEC	250 mg /kg soil

Section A7.5.1.2 Earthworm, acute toxicity test
Annex Point IIIA XIII 3.2

Official use only

		1 REFERENCE
1.1	**Reference**	Heimbach F., 1987, Acute Toxicity of HWG 1608 (tech) to Earthworms, Bayer AG,Report HBF/Rg 82.
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes OECD Guideline No.207
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]
		3 METHODS
3.1	**Test material**	As given in section 2
3.1.1	Lot/Batch number	batch number [redacted]
3.1.2	Specification	As given in section 2
3.1.3	Purity	[redacted] of active substance
3.1.4	Composition of Product	
3.1.5	Further relevant properties	
3.1.6	Method of analysis	
3.2	**Reference substance**	Yes Chloracetamide
3.2.1	Method of analysis for reference substance	
3.3	**Testing procedure**	
3.3.1	Preparation of the test substance	
3.3.2	Application of the test substance	The test substance was added into 5 g quartz sand and pounded well. From these mixtures, the concentrations were produced for the study by mixing into the test substrate thoroughly with a domestic mixer. At the same time, 100 ml deionised water was mixed into the test substrate in each test container. 500 g dry weight test substrate (equivalent to 775 g

Section A7.5.1.2 Earthworm, acute toxicity test
Annex Point IIIA XIII 3.2

		wet weight) was prepared for each test container.
3.3.3	Test organisms	see table A7_5_1_2-2
3.3.4	Test system	see table A7_5_1_2-3
3.3.5	Test conditions	see table A7_5_1_2-4
3.3.6	Test duration	14 days
3.3.7	Test parameter	Mortality and weight alteration of the survivors
3.3.8	Examination	After 7 and 14 days
3.3.9	Monitoring of test substance concentration	No
3.3.10	Statistics	The LC50 was determined by Probit-Analysis after the "Maximum-Likelihood" Method.

4 RESULTS

4.1	**Filter paper test**	Not performed
4.1.1	Concentration	
4.1.2	Number/ percentage of animals showing adverse effects	
4.1.3	Nature of adverse effects	
4.2	**Soil test**	
4.2.1	Initial concentrations of test substance	See table A7_5_1_2-5
4.2.2	Effect data (Mortality)	see table A7_5_1_2-5 and table A7_5_1_2-6
4.2.3	Concentration / effect curve	The line of regression (after Litchfield & Wilcoxon) has a gradient of s = 1.74
4.2.4	Other effects	Weight alteration of the survivors (%) after 14 days:

Concentrations (mg a.i./kg dry weight substrate)	
Control	- 8
100	- 16
562	- 33
1000	- 45
1780	- 47
3160	- 50

4.2 Results of controls

Section A7.5.1.2 Earthworm, acute toxicity test
Annex Point IIIA XIII 3.2

4.2.1	Mortality	See Table A7_5_1_2-5
4.2.2	Number/ percentage of earthworms showing adverse effects	0
4.2.3	Nature of adverse effects	-
4.3	**Test with reference substance**	Performed, chloracetamide
4.3.1	Concentrations	10, 18, 24, 32 and 56 mg/kg
4.3.2	Results	LC50 (14 days) 26.6 mg/kg dry weight substrate (95% confidence limits 24.9 – 28.4 mg/kg)
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	The test according to OECD 207. No significant derivation from the guideline.
5.2	**Results and discussion**	
5.2.1	LC_0	178 mg a.i. / kg dry weight substrate
5.2.2	LC_{50}	1381 mg a.i./ kg dry weight substrate
5.2.3	LC_{100}	> 3160 mg a.i./ kg dry weight substrate
5.3	**Conclusion**	Validity criteria can be considered as fulfilled (see validity criteria summarized in table A7_5_1_2-7).
5.3.1	Other Conclusions	-
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	[redacted]

Section A7.5.1.2 Earthworm, acute toxicity test
Annex Point IIIA XIII 3.2

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*02 04 04*
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	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_1_1-2: Test organisms

Criteria	Details
Species/strain	*Eisenia foetida andrei*
Source of the initial stock	Prof. Graff, D-3300 Brunswick
Culturing techniques	The animals are kept at 22 °C, 70-90% relative humidity, 12:12 hour light-dark cycle. The substrate consists of ca 70% by weight of natural soil, 25% peat and 5% straw (dry weight in each case). The animals are fed on ground, dried cattle manure at 14 day intervals. At the same time, the substrate is also replenished with water. The animals are transferred into fresh substrate at half-yearly intervals.
Age/weight	The adult worms used in the test were more than two months old. Average weight at the start of the study was 401 mg (minimum/maximum values were 350/470 mg)
Pre-treatment	On the day prior to the start of the study, they were removed from the breeding substrate for acclimatisation and kept in the test substrate (without test substance) under the test conditions until the start of the study.

Table A7_5_1_1-3: Test system

Criteria	Details
Artificial soil test substrate	Detailed composition of the test substrate (% clay, sand, sphagnum peat), pH, moisture etc. and give the used method The test substrate consists of 69% fine quartz sand (84% of the sand has a particle size of 0.06 – 0.2 mm), 10% dried, finely ground peat (spagnum peat; pH 2-4), 20% kaolin (kaolinite content of around 36%, pH value ca 7) and around 1% calcium carbonate (pure) to adjust the pH value to 6 +/- 0.5. The substrate was first of all mixed dry from these components in a mixer, and moistened with water. The water content in the test substrate was around 35% when the worms were introduced corresponding to 40.5% of the maximum water capacity.
Test mixture	Concentrations Level: mg/kg 100 mg /kg 51 562 mg/kg 288 1000 mg/kg 513 1780 mg/kg 913 3160 mg/kg 1621
Size, volume and material of test container	1.5 litre preserving jars, covered with glass lids

Criteria	Details
Amount of artificial soil (kg)/ container	0.5 kg dry weight (equivalent to 0.775 kg wet weight)
Nominal levels of test concentrations	100, 562, 1000, 1780 and 3160 mg/kg artificial soil
Number of replicates/concentration	4
Number of earthworms/test concentration	40
Number of earthworms/container	10
Light source	Light source? Constant light 400-800 lux
Test performed in closed vessels due to significant volatility of test substrate	No

Table A7_5_1_2-4: Test conditions

Criteria	Details
Test temperature	20 ± 2 °C
Moisture content	Water content in the substrate (%) 35.5 at the start of the study and 33 at the end
pH	5.8 at the start and 6.0 at the end
Adjustment of pH	Yes 1% calcium carbonate
Light intensity / photoperiod	Constant light (400 – 800 lux)
Relevant degradation products	?

Table A7_5_1_2-5: Mortality data

Test Substance Concentration nominal [1] [mg a.i. /kg dry weight artificial soil]	Mortality			
	Number		Percentage	
	7 d	14 d	7 d	14 d
Control				
100				
562				
1000				
1780				
3160				
Temperature [°C]	20	20		
pH	5.8	6.0		
Moisture content Water content in the substrate	35%			

[1] specify, if TS concentrations were nominal or measured

Table A7_5_1_2-6: Effect data

	14 d [mg/kg soil][1]	95 % c.l.
LC_0	100	
LC_{50}	1381	1225-1558
LC_{100}	> 3160	

[1] Effect data are based on nominal concentrations

Table A7_5_1_2-7: Validity criteria for acute earthworm test according to OECD 207

	fulfilled	Not fulfilled
Mortality of control animals < 10%	X	

Section A7.5.1.2 Acute toxicity test of 1,2,4-triazole to earthworm

Annex Point IIIA XIII 3.2

Official use only

		1 REFERENCE
1.1	**Reference**	Heimbach F: Acute toxicity of 1,2,4-triazole (technical) to earthworms. Bayer AG, Germany, unpublished report No. HBF/Rg 59; 1986-02-24.
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes, OECD Guideline No. 207 (1986)
2.2	**GLP**	Yes
2.3	**Deviations**	No
		3 METHODS
3.1	**Test material**	1,2,4-triazole
3.1.1	Lot/Batch number	batch No. [redacted]
3.1.2	Specification	Technical 1,2,4-triazole
3.1.3	Purity	[redacted]
3.1.4	Composition of Product	n.a.
3.1.5	Further relevant properties	n.a.
3.1.6	Method of analysis	Nominal concentrations
3.2	**Reference substance**	Yes, Chloracetamide
3.2.1	Method of analysis for reference substance	Nominal concentrations
3.3	**Testing procedure**	
3.3.1	Preparation of the test substance	The test substance weighted out and dissolved in water.
3.3.2	Application of the test substance	The test concentrations were prepared from aqueous stock solution by mixing the appropriate amounts into the test substrate.
3.3.3	Test organisms	See table A7_5_1_2-1

Section A7.5.1.2 Acute toxicity test of 1,2,4-triazole to earthworm
Annex Point IIIA XIII 3.2

3.3.4	Test system	See table A7_5_1_2-2
3.3.5	Test conditions	See table A7_5_1_2-3
3.3.6	Test duration	14 days
3.3.7	Test parameter	Mortality and weight alteration of the survivors
3.3.8	Examination	Give details on examination intervals after 7 and 14 days
3.3.9	Monitoring of test substance concentration	No
3.3.10	Statistics	n.a..

4 RESULTS

4.1	**Test**	Not performed
4.1.1	Concentration	
4.1.2	Number/ percentage of animals showing adverse effects	
4.1.3	Nature of adverse effects	
4.2	**Soil test**	
4.2.1	Initial concentrations of test substance	[mg/kg dry weight artificial soil] See table A 7 5 1 2-4
4.2.2	Effect data (Mortality)	See table A7_5_1_2-5)
4.2.3	Concentration / effect curve	n.a.
4.2.4	Other effects	Weight alteration of the survivors (%) after 14 days: Concentrations (mg a.i./kg dry weight substrate) Limit (main) test Control +17 1000 -12 Range finder test Control +1 1000 -14
4.3	**Results of controls**	
4.3.1	Mortality	No mortalities were observed

Section A7.5.1.2 Acute toxicity test of 1,2,4-triazole to earthworm
Annex Point IIIA XIII 3.2

4.3.2	Number/ percentage of earthworms showing adverse effects	-14%
4.3.3	Nature of adverse effects	Weight change at 1000 mg 1,2,4–triazole / kg dry weight substrate
4.4	**Test with reference substance**	Performed chloracetamide
4.4.1	Concentrations	10, 18, 24, 32 and 56 mg/kg
4.4.2	Results	LC50 (14 days) 24.4 mg/kg dry weight substrate

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	In a limit test, adult worms (mean weight 360 mg) were exposed to 1000 mg/kg 1,2,4-triazole for 14 days. This main test incorporated four replicate chambers of ten adult worms for the test substance treatment and for the untreated control. The LC50 for the reference compound chloracetamide p.a. was calculated to be 24.4 mg/kg, thus confirming that the sensitivity of the test system was acceptable.
5.2	**Results and discussion**	No mortalities were recorded in the test at 1000 mg 1,2,4-triazole/kg soil). Exposure to 1000 mg/kg soil caused a reduction in bodyweight compared to controls. o
5.2.1	LC_0	1000 mg 1,2,4-triazole / kg dry weight substrate
5.2.2	LC50	> 1000 mg 1,2,4-triazole / kg dry weight substrate
5.2.3	LC100	n.a.
5.3	**Conclusion**	
5.3.1	Other Conclusions	Non
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	[redacted]

Section A7.5.1.2 Acute toxicity test of 1,2,4-triazole to earthworm

Annex Point IIIA XIII 3.2

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*April 07*
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	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_1_1-1: Test organisms

Criteria	Details
Species/strain	Eisenia foetida andrei
Source of the initial stock	Prof. Graff, D-3300 Brunswick
Culturing techniques	The animals are kept at 22°C, 70-90% relative humidity, 12:12 hour light-dark cycle. The substrate consists of ca 70% by weight of natural soil, 25% peat and 5% straw (dry weight in each case). The animals are fed on ground, dried cattle manure at 14 day intervals. At the same time, the substrate is also replenished with water. The animals are transferred into fresh substrate at half-yearly intervals.
Age/weight	The adult worms used in the test were more than two months old. Average weight at the start of the study was 405 mg in the range finder study and 360 mg in the main test.
Pre-treatment	On the day prior to the start of the study, they were removed from the breeding substrate for acclimatisation and kept in the test substrate (without test substance) under the test conditions until the start of the study.

Table A7_5_1_1-2: Test system

Criteria	Details
Artificial soil test substrate	The test substrate consists of 69% fine quartz sand (84% of the sand has a particle size of 0.06 – 0.2 mm), 10% dried, finely ground peat (spagnum peat; pH 2-4), 20% kaolin (kaolinite content of around 36%, pH value ca 7) and around 1% calcium carbonate (pure) to adjust the pH value to 6 +/- 0.5. The substrate was first of all mixed dry from these components in a mixer, and moistened with water. The water content in the test substrate was around 35% when the worms were introduced corresponding to 40.5% of the maximum water capacity.
Test mixture	Give the relationship test substance : artificial soil (mg/kg) per concentration level Concentrations Level: mg/kg Range finder test 0.1 -1000 Main (limit test) 1000
Size, volume and material of test container	1.5 litre preserving jars, covered with glass lids
Amount of artificial soil (kg)/ container	0.5 kg dry weight (equivalent to 0.775 kg wet weight)
Nominal levels of test concentrations	*0.1-1000 resp. mg/kg artificial soil*
Number of replicates/concentration	*2*
Number of earthworms/test concentration	*20*
Number of earthworms/container	*10*

Criteria	Details
Light source	Constant light 400-800 lux

Table A7_5_1_2-3: Test conditions

Criteria	Details
Test temperature	20 ± 2°C
Moisture content (main test)	Water content in the substrate (%) about 24.3 at the start of the study and 32.9 at the end
pH	Between 5.59 and 6.35 in all tests.
Adjustment of pH	Yes, 1% calcium carbonate
Light intensity / photoperiod	Constant light (400 – 800 lux)
Relevant degradation products	No

Table A7_5_1_2-4: Mortality data

Test Substance Concentration nominal [1] [mg a.i. /kg dry weight artificial soil]	Mortality			
	Number		Percentage	
	7 d	14 d	7 d	14 d
Control	[redacted]	[redacted]	[redacted]	[redacted]
0.1 – 1000	[redacted]	[redacted]	[redacted]	[redacted]
1000	[redacted]	[redacted]	[redacted]	[redacted]
Temperature [°C]	20	20		
pH	5.8	6.0		
Moisture content Water content in the substrate	79.1 / 68.6 % of maximum water capacity[2]	82.5 / 68.9 of maximum water capacity[2]		

[1] based on nominal concentrations,
[2] range finder / limit test

Table A7_5_1_2-5: Effect data

	14 d [mg/kg soil][1]	95 % c.l.
LC_0	1000	
LC_{50}	> 1000	
LC_{100}	n.a.	

Table A7_5_1_2-6: Validity criteria for acute earthworm test according to OECD 207

	Fulfilled	Not fulfilled
Mortality of control animals < 10%	X	

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

Official use only

		1 REFERENCE
1.1	**Reference**	Seyfried B., 1999, Terrestrial plants, growth test with tebuconazole, RCC Ltd, 727907, august 1999.
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes OECD no. 208
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]
		3 METHODS
3.1	**Test material**	As given in section 2
3.1.1	Lot/Batch number	Batch number [redacted]
3.1.2	Specification	As given in section 2
3.1.3	Purity	Purity [redacted]
3.1.4	Composition of Product	
3.1.5	Further relevant properties	
3.1.6	Method of analysis	
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	see table A7_5_1_3-1
3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	
3.4	**Testing procedure**	
3.4.1	Dilution water	see table A7_5_1_3-2

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

3.4.2	Test plants	see table A7_5_1_3-3
3.4.3	Test system	see table A7_5_1_3-4
3.4.4	Test conditions	see table A7_5_1_3-5
3.4.5	Test duration	The tests were started when at least 50% of the control seedlings had emerged (7 days after sowing = Day 0) and were finished 14 days after this date
3.4.6	Test parameter	The number of plants emerged Phytotoxic symptoms (e.g. stunted growth, discoloration, necrosis) Fresh weight at the end of the study (day 14)
3.4.7	Sampling	See table A7_5_1_3-4
3.4.8	Method of analysis of the plant material	?
3.4.9	Quality control	OK
3.4.10	Statistics	For data evaluation, the mean values per plant at the different concentrations were calculated as percentage of untreated plants and their 95% confidence limits were calculated by Probit Analysis. For the determination of LOEC and NOEC, the rate of emergence and the mean shoot fresh weight per plant at the different concentrations were tested on significant differences to the control value by a Williams-test.
		4 RESULTS
4.1	**Results test substance**	
4.1.1	Applied initial concentration	0, 1, 10, and 100 mg/kg; for turnip 0, 0.5, 1, 10, and 100 mg/kg (nominal)
4.1.2	Phytotoxicity rating	**Oat:** Visual phytotoxic symptoms were observed at all three test concentrations. At 1 mg/kg 8 out of 20 plants showed minor necrosic. At 10 mg/kg 18 of 20 plants showed minor to medium necrosis. At 100 mg/kg all plants showed minor to intense extent: involuted and stunted leaves, necrosis and darker colour (dark bluish-green). **Turnip:** At 1 mg/kg two plants had minor respectively medium stunted leaves and 7 plants had shorter stems as the controls. At 10 and 100 mg/kg the plants showed the following symptoms at a medium to intense extent at the end of the test: stunted leaves, shorter and darker colour. **Cress**: At mg/kg10 plants showed shorter stems, 3 showed chlorosis and 5 darker colour. In 10 mg/kg all had shorter stems and darker collar, and 12 out of 13 showed stunted leaves. In 100 mg/kg all plants had died at the end of exposure.
4.1.3	Plant height	Not described
4.1.4	Plant dry weights	Not described
4.1.5	Root dry weights	Not described

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

4.1.6	Root length	Not described
4.1.7	Number of dead plants	For cress all plant dead at the end of the test at the highest concentration (100 mg/kg)
4.1.8	Effect data	See table **Oat:** Emergence LC50 > 100 mg/kg dry soil* Growth shoot fresh weight: 14-day NOEC were determined to be 10 mg/kg EC25= 57 mg/kg dry soil*; and EC50: > 100 mg/kg dry soil* **Cress:** Emergence: LC50* = 100mg/kg dry soil Growth; shoot fresh weight: 14 day NOEC and LOEC were calculated 10 and 100. At concentration of 1 and 10mg /kg dry soil, no statistically significant influence on growth was observed. At 100 mg/kg no plants had survived. EC25* = 6; EC50* = 14 mg/kg dry soil **Turnip:** Emergence: LC50* = > 100 mg/kg dry soil. Growth; shoot fresh weight: NOEC and LOEC for growth based on the plant fresh weight were determined to be 1 mg/kg and 10 mg/kg dry soil, respectively. EC25* = 7 mg/kg dry soil; EC50* = 41 mg/kg dry soil Growth; leaf fresh weight: 14-day NOEC and LOEC were determined to be 1 mg/kg and 10 mg/kg dry soil, respectively. EC25* = 15 mg/dry soil; EC50* =82 mg/kg dry soil Growth; stem length: NOEC and LOEC were determined to be 0.5 and 1 mg/kg dry soil. EC25* = 1 mg/kg dry soil; EC50* = 4 mg/kg dry soil * 95% confidence limits not calculated.
4.1.9	Concentration / response curve	
4.1.10	Other effects	
4.2	**Results of controls**	
4.2.1	Number/ percentage of plants showing adverse effects	Not described
4.2.2	Nature of adverse effects	Not described
4.3	**Test with reference substance**	Not performed
4.3.1	Concentrations	
4.3.2	Results	

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	OECD 208, No deviations from this guideline
5.2	**Results and discussion**	See point 4.1.8 For Turnip The EC25- and EC50-values obtained from stem length (1 and 4 mg/kg), shoot fresh weight (7 and 41 mg/kg) and leaf fresh weight (15 and 82 mg/kg) clearly show that the effect of the test item on turnip was mainly caused by its stem shortening effect. This effect is well known from other studies and without any negative ecological effect on reproduction and reproductively of affected plants. Therefore, the ecological relevant NOEC should be 1 mg/kg for turnip based on shoot and leaf fresh weight.
5.2.1	LC_{20}	Not described
5.2.2	LC_{50}	**Oat :**Emergence LC50 > 100 mg/kg dry soil Growth shoot fresh weight: EC50: > 100 mg/kg dry soil **Cress:** Emergence: LC50* = 100mg/kg dry soil Growth; shoot fresh weight: 14 EC50 = 14 mg/kg dry soil **Turnip:** Emergence: LC50* = > 100 mg/kg dry soil. Growth; shoot fresh weight: EC50 = 41 mg/kg dry soil Growth; leaf fresh weight: EC50 =82 mg/kg dry soil Growth; stem length: EC50 = 4 mg/kg dry soil
5.2.3	LC_{80}	Not described
5.3	**Conclusion**	There is a clear dose-response relationship for all 3 plants. The validity criteria can not be considered fulfilled according to the EPA guideline. However, the criteria can be considered as fulfilled according to the OECD guideline.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*02 04 04*
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

	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_1_3-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	Yes
Vehicle	Yes. 301 mg of tebuconazole is dissolved in 5 ml of acetone. For the preparation of the highest test concentration, the stock solution was quantitatively homogeneously distributed onto 29.7 g of sand. After complete evaporation of the acetone, the mixture was thoroughly ground in the mortar. The sand mixtures for the lower test concentrations were prepared by serial dilutions by sand. Aliquots of 10 g of sand mixtures were incorporated uniformly into 990 g of soil (dry weight basis)
Concentration of vehicle	0%
Vehicle control performed	No
Other procedures	

Table A7_5_1_3-2: Dilution water

Criteria	Details
Source	
Alkalinity / Salinity	
Hardness	
pH	
Oxygen content	
Conductance	
Holding water different from dilution water	

Table A7_5_1_3-3: Test plants

	Family	Species	Common name	Source (seed/plant)
Dicotyledonae		*Brassica rapa L.*	Turnip	H. Nebiker AG, Switzerland
		Lepidium sativum L.	Cress	UFA-Samen, Switzerland
Monocotyledonae		*Avena sativa L.*	oat	Landi Landesprodukte, Switzerland

Table A7_5_1_3-4: Test system

Criteria	Details
Test type	climatic chamber The test plants were grown at 20-25 °C during daytime and 17-20 at night.
Container type	Plastic pots (8 cm in diameter) containing 70 g dry soil
Seed germination potential	Rate of emergence at day 0 in the controls: Oat = 88% Turnip = 65% Cress = 50%
Identification of the plant species	
Number of replicates	4
Numbers of plants per replicate per dose	10 seeds were sowed in each replicate. To provide optimum growth conditions the seedlings were reduced to five plants per pot
Date of planting	Oat and cress: May 03, 1999 Turnip: June 21, 1999
Plant density	Five plants per replicate (plastic pots 8 cm in diameter with 70 g soil
Date of test substance application	Oat and cress: May 03, 1999 Turnip: June 21, 1999
High of plants at application	The test seeds were sowed in soil incorporated with the test item
Date of phytotoxicity rating or harvest	Days 0, 2, 7, 10 and 14 phytotoxic symptoms were assessed (e.g. stunted growth, discoloration, necrosis). Determination of shoot fresh weight was carried out at the end of the test (Day 14)
Dates of analysis	?

Table A7_5_1_3-5: Test conditions

Criteria	Details
Test type	Terrestrial plants, growth test according to OECD 208
Method of application	301 mg of tebuconazole is dissolved in 5 ml of acetone. For the preparation of the highest test concentration, the stock solution was quantitatively homogeneously distributed onto 29.7 g of sand. After complete evaporation of the acetone, the mixture was thoroughly ground in the mortar. The sand mixtures for the lower test concentrations were prepared by serial dilutions by sand. Aliquots of 10 g of sand mixtures were incorporated uniformly into 990 g of soil (dry weight basis). Immediately after incorporation of the test item, the soil was weighed into the bioassay pots at an amount corresponding to 70 g dry soil.
Application levels	See above
Dose rates	Three concentrations equivalent to 1, 10 and 100 mg test item per kg soil (dry weight) plus an untreated control. For turnip an additional concentration of 0.5 mg/kg was incorporated in the test design
Substrate characteristics	Soil Type (DIN): loamy sand pH (0.01M $CaCl_2$) 6.6 Organic carbon (g/100 g dry soil)%: 1.18 Particle size: < 0.02 mm: 19.2% Maximal water holding capacity 39 (MWC g/100 g dry soil)
Watering of the plants	A hole for a glass fibre wick was punched through the bottom of the pot. The wick served for the transport of water from a water reservoir to the soil. For some of the pots the water transport of the glass fibre wicks was insufficient. Those pots were additionally watered by carefully pouring deionised water on the soil surface as needed.
Temperature	The test plants were grown at 20-25 °C during daytime and 17-20°C at night
Thermoperiod	See above
Light regime	Illuminated for 16 hours per day, about 9000 Lux
Relative humidity	?
Wind volatility	?

Table A7_5_1_3-5: Test conditions (continued)

Observation periods and duration of test	The number of plants emerged per replicate was recorded on days –3, 0, 1 (cress only), 2,7,10 and 14 On Days 0, 2, 7, 10 and 14 phytotoxic symptoms were assessed Determination of shoot fresh weight was carried out at the end of the test (Day 14) for all plants of one pot as one replicate.
Pest control	?
Any other treatments and procedures	?

Table A7_5_1_3-6: Effective phytotoxicity after test termination

Test Substance Concentration (nominal)[1] [mg/l]	Absolute Numbers				Percent relative to control			
	Plant height	Plant dry weight	Root dry weight	Dead plants	Plant height	Plant dry weights	Root dry weight	Dead plants
Temperature [°C]								
Relative humidity								

[1] specify, if TS concentrations were nominal or measured

Table new: Effects at test termination

Test Substance Concentration (nominal)[1] [mg/kg]	Absolute Numbers				Percent relative to control			
	No emerg-ed	Plant fresh weight Per Plant (g)	Leaf fresh weight Per plant (g)	Stem length (cm) per plant	Ermergence	Plant fresh weights Per Plant	Leaf fresh weight Per plant	Stem length (cm) per plant
Oat								
Control	[redacted]	[redacted]			[redacted]	[redacted]		
1	[redacted]	[redacted]			[redacted]	[redacted]		
10	[redacted]	[redacted]			[redacted]	[redacted]		
100	[redacted]	[redacted]			[redacted]	[redacted]		
Turnip								
Control	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
0.5	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
10	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
100	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Cress								
Control	[redacted]	[redacted]			[redacted]	[redacted]		
1	[redacted]	[redacted]			[redacted]	[redacted]		
10	[redacted]	[redacted]			[redacted]	[redacted]		
100	[redacted]	[redacted] [redacted]			[redacted]	[redacted] [redacted]		
Temperature [°C]								
Relative humidity								

[1] specify, if TS concentrations were nominal or measured
n.s.: not significant lower than the control
s: significant lower than the control

Table A7_5_1_3-7: Validity criteria for terrestrial plant toxicity according to EPA OPPTS 850.4150 (vegetative vigor test)

	Fulfilled	Not fulfilled
Adverse effect > 25% on one or more plant species (EPA)	X	

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

Official use only

		1 REFERENCE
1.1	**Reference**	Meisner P (2001): Herbicidal screening data for HWG 1608, Bayer Crop Science AG, Report No. DOM 99106, June 19, 2001.
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes OECD Non-Target Plant Testing Guideline Proposal, 1999
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]
		3 METHODS
3.1	**Test material**	Tebuconazole (HWG 1608) tech.
3.1.1	Lot/Batch number	Batch No. [redacted]
3.1.2	Specification	As given in section 2
3.1.3	Purity	[redacted]
3.1.4	Composition of Product	-
3.1.5	Further relevant properties	-
3.1.6	Method of analysis	Not performed
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	For the pre-emergence test HWG 1608 was dissolved in DMF (N,N-dimethylformamide) with Emulgator (emulsifier) W and water. The test material was applied as a laboratory formulation with a spray volume of 1,000 L/ha. For the post-emergence test, 0.1 % Renex 36 was added as surfactant.
3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	-
3.4	**Testing procedure**	
3.4.1	Dilution water	-

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

3.4.2	Test plants	11 plant species, see table A7_5_1_3-1
3.4.3	Test system	see table A7_5_1_3-2
3.4.4	Test conditions	see table A7_5_1_3-3
3.4.5	Test duration	Plants were grown in the greenhouse for about 14 days prior to application of the test material. For the pre-emergence 10 seeds of each of the 11 species were placed within 24 hours prior to application of the test substance. The final evaluation for the pre-emergence test was done 21 days after treatment and for the foliar-applied test 17 days after treatment.
3.4.6	Test parameter	Phytotoxic effects
3.4.7	Sampling	The final evaluation for the pre-emergence test was done 21 days after treatment and for the foliar-applied test 17 days after treatment.
3.4.8	Method of analysis of the plant material	Not performed
3.4.9	Quality control	-
3.4.10	Statistics	Evaluation of phytotoxicity was done by visual observation using a rating scale of 0 – 100%
		4 RESULTS
4.1	**Results test substance**	
4.1.1	Applied initial concentration	Water application rate to the target area 1,000 L/ha; the test material was applied in single applications of 125, 250, 500 and 1,000 g a.s./ha. The application rates were up to 2.7 times higher than a maximal use rate in the fields of 375 g a.s./ha.
4.1.2	Phytotoxicity rating	When applied to soil (pre-emergence) no effect was observed on *Zea mays, Alopecurus myosuroides, Avena fatua* and *Xanthium spec.* Between the single and triple proposed maximum spray application rate phytotoxic effects from 20 to 95% were observed on *Echinochloa crus-galli, Setaria viridis, Abutilon theophrasti, Amaranthus retroflexus, Galium aparine, Sinapis arvensis* and *Beta vulgaris.* When applied to foliage (post-emergence) no (single application rate) or only weak (triple application rate) phytotoxicity in comparison to the pre-emergence test occurred.
4.1.3	lant height	Not described
4.1.4	Plant dry weights	Not described
4.1.5	Root dry weights	Not described
4.1.6	Root length	Not described
4.1.7	Number of dead plants	Not described

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

4.1.8	Effect data	Visual damage (% effect at the different application rates) observed at the completion of the pre-emergence test and after the completion of the foliar-applied test see table A7_5_1_3-4 and table A7_5_1_3-5. When applied to soil (pre-emergence) no effect was observed on *Zea mays, Alopecurus myosuroides, Avena fatua* and *Xanthium spec.* Between the single and triple proposed maximum spray application rate phytotoxic effects from 20 to 95% were observed on *Echinochloa crus-galli, Setaria viridis, Abutilon theophrasti, Amaranthus retroflexus, Galium aparine, Sinapis arvensis* and *Beta vulgaris.* When applied to foliage (post-emergence) no (single application rate) or only weak (triple application rate) phytotoxicity in comparison to the pre-emergence test occurred.
4.1.9	Concentration / response curve	Not given in report
4.1.10	Other effects	-
4.2	**Results of controls**	
4.2.1	Number/ percentage of plants showing adverse effects	Not described
4.2.2	Nature of adverse effects	Not described
4.3	**Test with reference substance**	Not performed
4.3.1	Concentrations	-
4.3.2	Results	-

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	OECD Non-Target Plant Testing Guideline Proposal: Spray treatments are applied in an automatic spray chamber for screening tests to the soil surface in which plants were subsequently grown, and to the foliage of emerged plants. For the testing of HWG 1608 as active substance a laboratory formulation was made. For the pre-emergence test HWG 1608 was dissolved in DMF (N,N-dimethylformamide) with Emulgator (emulsifier) W and water. For the post-emergence test, 0.1 % Renex 36 was added as surfactant. The test material was applied as a laboratory formulation with a spray volume of 1,000 L/ha. The spray chamber was adjusted as follows: Water application rate to the target area 1,000 L/ha; the material was applied in single applications of 125, 250, 500 and 1,000 g a.s./ha. The application rates were up to 2.7 times higher than a maximal use rate in the fields of 375 g a.s./ha. No significant deviation from the guideline.
5.2	**Results and discussion**	When applied to soil (pre-emergence) no effect was observed on *Zea mays, Alopecurus myosuroides, Avena fatua* and *Xanthium spec.* Between the single and triple proposed maximum spray application rate phytotoxic effects from 20 to 95% were observed on *Echinochloa crus-galli, Setaria viridis, Abutilon theophrasti, Amaranthus retroflexus, Galium aparine, Sinapis arvensis* and *Beta vulgaris.* When applied to foliage (post-emergence) no (single application rate) or only weak (triple application rate) phytotoxicity in comparison to the pre-emergence test occurred.
5.2.1	LC_{20}	-
5.2.2	LC_{50}	-
5.2.3	LC_{80}	-
5.3	**Conclusion**	In the pre-emergence test some phytotoxic effects were observed between the single and the triple maximum spray application rate. Taking into account relevant phytotoxic effects (> 25 %), ca. 45 % of all species showed effects of 30 – 95 % around the single maximal application rate (250 – 500 g a.s./ha). At the triple application rate (1,000 g a.s./ha), ca. 55 % of all species showed effects of 50 – 95 %. When applied directly to foliage (post-emergence), no phytotoxicity was observed around the maximum application rate (250 – 500 g a.s./ha), and only weak phytotoxicity at the triple rate of tebuconazole (27 % of all species showed effects of 30 – 60 %).
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

Remarks	[redacted]
	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*

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_5_1_3-1: Test plants

	Family	Species	Common name	Source (seed/plants)
Dicotyledonae	Malvaceae	*Abutilon theophrasti*	Common amaranth	
	Amaranthaceae	*Amaranthus retroflexus*	Indian mallow	
	Chenopodiaceae	*Beta vulgaris*	Sugarbeet	
	Rubiaceae	*Galium aparine*	Cleavers	
	Cruciferaceae	*Sinapis arvensis*	Wilde mustard	
Monocotyledonae	Gramineae	*Zea mays*	Corn, maize	
	Gramineae	*Alopecurus myosuroides*	Black twitch	
	Gramineae	*Avena fatua*	Wild oat	
	Gramineae	*Xanthium spp.*	Cocklebur	
	Gramineae	*Echinochloa crus-galli*	Cockspur	
	Gramineae	*Setaria viridis*	Green bristle grass	

Table A7_5_1_3-2: Test system

Criteria	Details
Test type	Greenhouse of Crop Protection Research
Container type	Greenhouse pots of 420 cm^2 surface (pot T59)
Seed germination potential	The soil allowed good germination
Identification of the plant species	
Number of replicates	Typically 10 seeds of each of the 11 species were placed.
Numbers of plants per replicate per dose	Typically 10 seeds of each of the 11 species were placed.
Date of planting	Study was performed in April/May 1999
Plant density	-
Date of test substance application	Plants were grown in the greenhouse for about 14 days prior to application of the test material. For the pre-emergence 10 seeds of each of the 11 species were placed within 24 hours prior to application of the test substance.
High of plants at application	-
Date of phytotoxicity rating or harvest	The final evaluation concerning phytotoxic effects for the pre-emergence test was done 21 days after treatment and for the foliar-applied test 17 days after treatment.
Dates of analysis	-

Table A7_5_1_3-3: Test conditions

Criteria	Details
Test type	Spray treatments are applied in an automatic spray chamber for screening tests. The spray chamber was adjusted as follows: pressure 3 bar, height of spray boom: 45 cm, nozzle type: 8003E
Method of application	The test material was applied as a laboratory formulation with a spray volume of 1,000 L/ha. The spray chamber was adjusted as follows: Water application rate to the target area 1,000 L/ha; the material was applied in single applications of 125, 250, 500 and 1,000 g a.s./ha. The application rates were up to 2.7 times higher than a maximal use rate in the fields of 375 g a.s./ha. Applications were made separately to the soil surface or on plants.
Application levels	See above
Dose rates	See above
Substrate characteristics	Soil Type (DIN): sandy loam Organic matter: 2.5-3% The soil allowed good germination
Watering of the plants	Growing plants were irrigated as needed
Temperature	The test plants were kept at 22 °C/15 °C in a day/night rhythm
Thermoperiod	See above
Light regime	Duration of illumination was 14 hours to 10 hours in a day/night rhythm (8000 Lux)
Relative humidity	50%
Wind volatility	-
Observation periods and duration of test	The final evaluation for the pre-emergence test was done 21 days after treatment and for the foliar-applied test 17 days after treatment.
Pest control	-
Any other treatments and procedures	-

Table A7_5_1_3-4: Findings: Visual damage observed at the completion of the pre-emergence test

	Results [% effect] at different application rates			
Species	125 g a.s./ha	250 g a.s./ha	500 g a.s./ha	1,000 g a.s./ha
Zea mays	[redacted]	[redacted]	[redacted]	[redacted]
Alopecurus myosuroides	[redacted]	[redacted]	[redacted]	[redacted]
Avena fatua	[redacted]	[redacted]	[redacted]	[redacted]
Echinochloa crus-galli	[redacted]	[redacted]	[redacted]	[redacted]
Setaria viridis	[redacted]	[redacted]	[redacted]	[redacted]
Beta vulgaris	[redacted]	[redacted]	[redacted]	[redacted]
Abutilon theophrasti	[redacted]	[redacted]	[redacted]	[redacted]
Amaranthus retroflexus	[redacted]	[redacted]	[redacted]	[redacted]
Galium aparine	[redacted]	[redacted]	[redacted]	[redacted]
Sinapis arvensis	[redacted]	[redacted]	[redacted]	[redacted]
Xanthium spp.	[redacted]	[redacted]	[redacted]	[redacted]

Table A7_5_1_3-5: Findings: Visual damage observed after the completion of the foliar-applied test.

	Results [% effect] at different application rates			
Species	125 g a.s./ha	250 g a.s./ha	500 g a.s./ha	1,000 g a.s./ha
Zea mays	[redacted]	[redacted]	[redacted]	[redacted]
Alopecurus myosuroides	[redacted]	[redacted]	[redacted]	[redacted]
Avena fatua	[redacted]	[redacted]	[redacted]	[redacted]
Echinochloa crus-galli	[redacted]	[redacted]	[redacted]	[redacted]
Setaria viridis	[redacted]	[redacted]	[redacted]	[redacted]
Beta vulgaris	[redacted]	[redacted]	[redacted]	[redacted]
Abutilon theophrasti	[redacted]	[redacted]	[redacted]	[redacted]
Amaranthus retroflexus	[redacted]	[redacted]	[redacted]	[redacted]
Galium aparine	[redacted]	[redacted]	[redacted]	[redacted]
Sinapis arvensis	[redacted]	[redacted]	[redacted]	[redacted]
Xanthium spp.	[redacted]	[redacted]	[redacted]	[redacted]

Table A7_5_1_3-6: Validity criteria for terrestrial plant toxicity according to EPA OPPTS 850.4150 (vegetative vigor test)

	Fulfilled	Not fulfilled
Adverse effect > 25% on one or more plant species (EPA)	X	

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

Official use only

		1 REFERENCE
1.1	**Reference**	Meisner, P., 2001, Herbicidal screening data for tebuconazole EW 250, Bayer Crop Science AG; Report No. MPE NTP 23/01 (unpublished), 2001-06-11
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes Procedures as recommended by OECD for non-herbicidal crop protection products.
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]
		3 METHODS
3.1	**Test material**	Tebuconazole (Folicur) EW 250
3.1.1	Lot/Batch number	Batch No. [redacted]
3.1.2	Specification	
3.1.3	Purity	[redacted] g a.s./L
3.1.4	Composition of Product	[redacted] g a.s./L
3.1.5	Further relevant properties	-
3.1.6	Method of analysis	Not performed
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Tebuconazole (Folicur) EW 250, containing [redacted] g a.s./L was applied as a formulation with a water application rate of 1000 L/ha.
3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	-

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

3.4	**Testing procedure**	
3.4.1	Dilution water	-
3.4.2	Test plants	see table A7_5_1_3-1
3.4.3	Test system	see table A7_5_1_3-2
3.4.4	Test conditions	see table A7_5_1_3-3
3.4.5	Test duration	10 seeds of each of the species were sown 24 hours prior to application of the test substance. The final evaluation concerning phytotoxic effects was done 21 days after treatment.
3.4.6	Test parameter	Phytotoxic effects
3.4.7	Sampling	The final evaluation concerning phytotoxic effects was done 21 days after treatment.
3.4.8	Method of analysis of the plant material	Not performed
3.4.9	Quality control	-
3.4.10	Statistics	Evaluation of phytotoxicity was done by visual observation using a rating scale of 0 – 100%
	4 RESULTS	
4.1	**Results test substance**	
4.1.1	Applied initial concentration	Water application rate to the target area 1,000 L/ha; The test material was applied in single applications of 15, 30, 60, 125 and 250 g a.s./ha to the soil surface in which plants were subsequently grown.
4.1.2	Phytotoxicity rating	In the **pre-emergence-test** *Abutilon theophrasti* and *Sinapis alba* showed relevant phytotoxic effects (≥ 40 %) in the highest tested application rate of 250 g a.s./ha.
4.1.3	Plant height	Not described
4.1.4	Plant dry weights	Not described
4.1.5	Root dry weights	Not described
4.1.6	Root length	Not described
4.1.7	Number of dead plants	Not described
4.1.8	Effect data	Findings (% effect at the different application rates) observed at the completion of the pre-emergence test are given in table A7_5_1_3-4. In the **pre-emergence-test** *Abutilon theophrasti* and *Sinapis alba* showed relevant phytotoxic effects (≥ 40 %) in the highest tested application rate of 250 g a.s./ha.

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

4.1.9	Concentration / response curve	Not given in report
4.1.10	Other effects	-
4.2	**Results of controls**	
4.2.1	Number/ percentage of plants showing adverse effects	Not described
4.2.2	Nature of adverse effects	Not described
4.3	**Test with reference substance**	Not performed
4.3.1	Concentrations	-
4.3.2	Results	-

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The study was performed according to procedures recommended by OECD for non-herbicidal crop protection products. Tebuconazole (Folicur) EW 250, containing [redacted] g a.s./L was applied as a formulation with a water application rate of 1000 L/ha. The test material was applied in single applications of 15, 30, 60, 125 and 250 g a.s./ha to the soil surface in which plants were subsequently grown. No significant deviation from the guideline.
5.2	**Results and discussion**	In the **pre-emergence-test** *Abutilon theophrasti* and *Sinapis alba* showed relevant phytotoxic effects (≥ 40 %) in the highest tested application rate of 250 g a.s./ha.
5.2.1	LC_{20}	-
5.2.2	LC_{50}	-
5.2.3	LC_{80}	-
5.3	**Conclusion**	In the **pre-emergence-test** *Abutilon theophrasti* and *Sinapis alba* showed relevant phytotoxic effects (≥ 40 %) in the highest tested application rate of 250 g a.s./ha.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*June 2004*
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

	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_1_3-1: Test plants

Test species					
Plant family	**WSSA / WSSJ Code**	**Species**	**Plant family**	**WSSA / WSSJ Code**	**Species**
Dicotyledonae			**Monocotyledonae**		
Malvaceae	ABUTH	*Abutilon theophrasti*	Gramineae	ALOMY	*Alopecurus myosuroides*
Amaranthaceae	AMARE	*Amaranthus retroflexus*	Gramineae	AVEFA	*Avena fatua*
Chenopodiaceae	BEAVA	*Beta vulgaris*	Gramineae	ECHCG	*Echinochloa crus-galli*
Rubiaceae	GALAP	*Galium aparine*	Gramineae	SETVI	*Setaria viridis*
Convulvulaceae	IPHOE	*Ipomoea herderacea.*	Gramineae	ZEAMX	*Zea mays*
Cruciferae	BRSNW	*Brassica napus*			
Cruciferae	SINAL	*Sinapis alba*			

Table A7_5_1_3-2: Test system

Criteria	Details
Test type	Greenhouse
Container type	Greenhouse pots of 420 cm^2 surface (pot T59)
Seed germination potential	The soil allowed good germination
Identification of the plant species	
Number of replicates	Typically 10 seeds of each of the species were planted together into soil.
Numbers of plants per replicate per dose	Typically 10 seeds of each of the species were planted together into soil.
Date of planting	Screening data generated in February 2001
Plant density	-
Date of test substance application	10 seeds of each of the species were sown 24 hours prior to application of the test substance.
High of plants at application	-
Date of phytotoxicity rating or harvest	The final evaluation concerning phytotoxic effects was done 21 days after treatment.
Dates of analysis	-

Table A7_5_1_3-3: Test conditions

Criteria	Details
Test type	Spray treatments are applied in an automatic spray chamber for primary screening tests. The spray chamber was adjusted as follows: pressure 3 bar, height of spray boom: 45 cm, nozzle type: 8003E
Method of application	Tebuconazole (Folicur) EW 250, containing [redacted] g a.s./L was applied as a formulation with a water application rate of 1000 L/ha. The test material was applied in single applications of 15, 30, 60, 125 and 250 g a.s./ha to the soil surface in which plants were subsequently grown.
Application levels	See above
Dose rates	See above
Substrate characteristics	Soil Type (DIN): sandy loam Organic matter: 2.5-3% The soil allowed good germination
Watering of the plants	Growing plants were watered as needed
Temperature	The test plants were kept at 22 °C/15 °C in a day/night rhythm
Thermoperiod	See above
Light regime	Duration of illumination was 14 hours to 10 hours in a day/night rhythm (8000 Lux)
Relative humidity	50%
Wind volatility	-
Observation periods and duration of test	The final evaluation was done 21 days after treatment
Pest control	-
Any other treatments and procedures	-

Table A7_5_1_3-4: Findings

Tebuconazole (Folicur) EW 250 pre-emergence test Results [% effect] at different application rates					
Species	15 g a.s./ha	30 g a.s./ha	60 g a.s./ha	125 g a.s./ha	250 g a.s./ha
Zea mays	▮	▮	▮	▮	▮
Beta vulgaris	▮	▮	▮	■	■
Aleopecurus myosuroides	▮	▮	▮	▮	■
Avena fatua	▮	▮	▮	▮	▮
Echinochloa crus-galli	▮	▮	▮	▮	■
Setaria viridis	▮	▮	▮	▮	▮
Abutilon theophrasti	▮	▮	▮	■	■
Amaranthus retroflexus	▮	▮	▮	▮	■
Galium aparine	▮	▮	▮	▮	▮
Ipomoea herderacea.	▮	▮	▮	▮	■
Brassica napus	▮	▮	▮	▮	■
Sinapis alba	▮	▮	▮	■	■

Table A7_5_1_3-5: Validity criteria for terrestrial plant toxicity according to EPA OPPTS 850.4150 (vegetative vigor test)

	Fulfilled	**Not fulfilled**
Adverse effect > 25% on one or more plant species (EPA)	**X**	

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

Official use only

		1 REFERENCE
1.1	**Reference**	Meisner, P., 2001, Herbicidal screening data for tebuconazole EW 250, Bayer Crop Science AG; Report No. MPE NTP 25/01 (unpublished), 2001-08-22
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes Procedures as recommended by OECD for non-herbicidal crop protection products.
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]
		3 METHODS
3.1	**Test material**	Tebuconazole (Folicur) EW 250
3.1.1	Lot/Batch number	Batch No. [redacted]
3.1.2	Specification	
3.1.3	Purity	[redacted] g a.s./L
3.1.4	Composition of Product	[redacted] g a.s./L
3.1.5	Further relevant properties	-
3.1.6	Method of analysis	Not performed
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Tebuconazole (Folicur) EW 250, containing [redacted] g a.s./L was applied as a formulation with a water application rate of 1000 L/ha.
3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	-

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

3.4	**Testing procedure**	
3.4.1	Dilution water	-
3.4.2	Test plants	see table A7_5_1_3-1
3.4.3	Test system	see table A7_5_1_3-2
3.4.4	Test conditions	see table A7_5_1_3-3
3.4.5	Test duration	Plants were grown in the greenhouse for about 14 days prior to application of the test substance. The final evaluation concerning phytotoxic effects was done 21 days after treatment initiation.
3.4.6	Test parameter	Phytotoxic effects
3.4.7	Sampling	The final evaluation concerning phytotoxic effects was done 21 days after treatment initiation.
3.4.8	Method of analysis of the plant material	Not performed
3.4.9	Quality control	-
3.4.10	Statistics	Evaluation of phytotoxicity was done by visual observation using a rating scale of 0 – 100%
	4 RESULTS	
4.1	**Results test substance**	
4.1.1	Applied initial concentration	Water application rate to the target area 1,000 L/ha; The test material was applied in single applications of 125, 250, 500 and 750 g a.s./ha to the foliage of emerged plants.
4.1.2	Phytotoxicity rating	In the **post-emergence** test all tested plant species showed no relevant phytotoxic effects (i.e.≥40%) up to an application rate of 500 g a.s./ha.
4.1.3	Plant height	Not described
4.1.4	Plant dry weights	Not described
4.1.5	Root dry weights	Not described
4.1.6	Root length	Not described
4.1.7	Number of dead plants	Not described
4.1.8	Effect data	Findings (% effect at the different application rates) observed at the completion of the post-emergence test are given in table A7_5_1_3-4. In the **post-emergence** test all tested plant species showed no relevant phytotoxic effects up to an application rate of 500 g a.s./ha.
4.1.9	Concentration / response curve	Not given in report

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

4.1.10	Other effects	-
4.2	**Results of controls**	
4.2.1	Number/ percentage of plants showing adverse effects	Not described
4.2.2	Nature of adverse effects	Not described
4.3	**Test with reference substance**	Not performed
4.3.1	Concentrations	-
4.3.2	Results	-

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The study was performed according to procedures recommended by OECD for non-herbicidal crop protection products. Tebuconazole (Folicur) EW 250, containing [redacted] g a.s./L was applied as a formulation with a water application rate of 1000 L/ha. The test material was applied in single applications of 125, 250, 500 and 750 g a.s./ha to the foliage of emerged plants. No significant deviation from the guideline.
5.2	**Results and discussion**	In the **post-emergence** test all tested plant species showed no relevant phytotoxic effects up to an application rate of 500 g a.s./ha.
5.2.1	LC_{20}	-
5.2.2	LC_{50}	-
5.2.3	LC_{80}	-
5.3	**Conclusion**	In the **post-emergence** test all tested plant species showed no relevant phytotoxic effects up to an application rate of 500 g a.s./ha.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	*June 2004*
Materials and Methods	[redacted]
Results and discussion	[redacted]

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	[redacted]

	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_1_3-1: Test plants

Test species					
Plant family	WSSA / WSSJ Code	Species	Plant family	WSSA / WSSJ Code	Species
Dicotyledonae			**Monocotyledonae**		
Malvaceae	ABUTH	*Abutilon theophrasti*	Gramineae	ALOMY	*Alopecurus myosuroides*
Amaranthaceae	AMARE	*Amaranthus retroflexus*	Gramineae	AVEFA	*Avena fatua*
Chenopodiaceae	BEAVA	*Beta vulgaris*	Gramineae	ECHCG	*Echinochloa crus-galli*
Rubiaceae	GALAP	*Galium aparine*	Gramineae	SETVI	*Setaria viridis*
Convulvulaceae	IPHOE	*Ipomoea herderacea.*	Gramineae	ZEAMX	*Zea mays*
Cruciferae	BRSNW	*Brassica napus*			
Cruciferae	SINAL	*Sinapis alba*			

Table A7_5_1_3-2: Test system

Criteria	**Details**
Test type	Greenhouse
Container type	Greenhouse pots of 420 cm^2 surface (pot T59)
Seed germination potential	The soil allowed good germination
Identification of the plant species	
Number of replicates	Typically 10 seeds of each of the plant species were planted together into soil.
Numbers of plants per replicate per dose	Typically 10 seeds of each of the plant species were planted together into soil.
Date of planting	Screening data generated in July 2001
Plant density	-
Date of test substance application	Plants were grown in the greenhouse for about 14 days prior to application of the test substance.
High of plants at application	-
Date of phytotoxicity rating or harvest	The final evaluation concerning phytotoxic effects was done 21 days after treatment initiation.
Dates of analysis	-

Table A7_5_1_3-3: Test conditions

Criteria	Details
Test type	Spray treatments are applied in an automatic spray chamber for primary screening tests. The spray chamber was adjusted as follows: pressure 3 bar, height of spray boom: 45 cm, nozzle type: 8003E
Method of application	Tebuconazole (Folicur) EW 250, containing [redacted] g a.s./L was applied as a formulation with a water application rate of 1000 L/ha. The test material was applied in single applications of 125, 250, 500 and 750 g a.s./ha to the foliage of emerged plants.
Application levels	See above
Dose rates	See above
Substrate characteristics	Soil Type (DIN): sandy loam Organic matter: 2.5-3% The soil allowed good germination
Watering of the plants	Growing plants were watered as needed
Temperature	The test plants were kept at 22 °C/15 °C in a day/night rhythm
Thermoperiod	See above
Light regime	Duration of illumination was 14 hours to 10 hours in a day/night rhythm (8000 Lux)
Relative humidity	50%
Wind volatility	-
Observation periods and duration of test	The final evaluation was done 21 days after treatment initiation
Pest control	-
Any other treatments and procedures	-

Table A7_5_1_3-4: Findings

Tebuconazole (Folicur) EW 250 post-emergence test Results [% effect] at different application rates				
Species	125 g a.s./ha	250 g a.s./ha	500 g a.s./ha	750 g a.s./ha
Zea mays	▮	▮	▮	▮
Beta vulgaris	▮	▮	■	■
Aleopecurus myosuroides	▮	▮	▮	■
Avena fatua	▮	▮	▮	▮
Echinochloa crus-galli	▮	▮	▮	▮
Setaria viridis	▮	▮	▮	■
Abutilon theophrasti	▮	▮	▮	▮
Amaranthus retroflexus	▮	▮	■	■
Galium aparine	▮	▮	▮	■
Ipomoea herderacea.	▮	▮	▮	▮
Brassica napus	▮	▮	▮	■
Sinapsis alba	▮	▮	■	■

Table A7_5_1_3-5: Validity criteria for terrestrial plant toxicity according to EPA OPPTS 850.4150 (vegetative vigor test)

	Fulfilled	**Not fulfilled**
Adverse effect > 25% on one or more plant species (EPA)	**X**	

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

Official use only

		1 REFERENCE
1.1	**Reference**	Leimkuehler W.M.; Lenz, C.A.; Valadez, S.K.; Moore, K.S., 1992, Radioactive Residues of [Phenyl-UL-^{14}C]-tebuconazole in rotational crops. Miles Inc., Agric. Div., now Bayer CropScience LP; Report No. 100126.
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes EPA Guidelines 165-1, Rotational Crops - Confined
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]
		3 METHODS
3.1	**Test material**	Tebuconazole WG 22.5 (^{14}C-Tebucoanzole)
3.1.1	Lot/Batch number	Vial [redacted]
3.1.2	Specification	
3.1.3	Purity	Radiochemical purity: [redacted]
3.1.4	Composition of Product	
3.1.5	Further relevant properties	
3.1.6	Method of analysis	TLC
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	None
3.3	**Reference substance**	None
3.3.1	Method of analysis for reference substance	

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

3.4	**Testing procedure**	
3.4.1	Dilution water	see table A7_5_1_3-2
3.4.2	Test plants	see table A7_5_1_3-3
3.4.3	Test system	see table A7_5_1_3-4
3.4.4	Test conditions	see table A7_5_1_3-5
3.4.5	Test duration	
3.4.6	Test parameter	(a) Determination of organosoluble radioactivity (b) Distribution of metabolites
3.4.7	Sampling	Give details on sampling intervals and sample storage before analysis See table A7_5_1_3-4
3.4.8	Method of analysis of the plant material	TLC, HPLC, GLC-MS
3.4.9	Quality control	In part (at the time the study was started, GLP was not required)
3.4.10	Statistics	None
	4 RESULTS	
4.1	**Results test substance**	
4.1.1	Applied initial concentration	560 g ai/ha
4.1.2	Phytotoxicity rating	Not described
4.1.3	Plant height	Not described
4.1.4	Plant dry weights	Not described
4.1.5	Root dry weights	Not described
4.1.6	Root length	Not described
4.1.7	Number of dead plants	Not described
4.1.8	Effect data	Not described
4.1.9	Concentration / response curve	
4.1.10	Other effects	
4.2	**Results of controls**	
4.2.1	Number/ percentage of plants showing adverse effects	Not described

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

4.2.2	Nature of adverse effects	Not described
4.3	**Test with reference substance**	Not performed
4.3.1	Concentrations	
4.3.2	Results	

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	EPA 165-1 Rotational crops – confined No deviations from this guideline
5.2	**Results and discussion**	See table A7_5_1_3-6 till A7_5_1_3-10 After application of [phenyl-UL-^{14}C]tebuconazole, only low residues were detected in rotational crops. Residue of tebuconazole-derived radioactivity was greatest in wheat straw. The major organo-soluble residue in all crops was unchanged parent compound. The water-soluble radioactivity in wheat straw consisted of a group of polar compounds associated with the matrix and did not resemble tebuconazole in nature.
5.2.1	LC_{20}	Not described
5.2.2	LC_{50}	Not described
5.2.3	LC_{80}	Not described
5.3	**Conclusion**	
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	September 2004
Materials and Methods	[redacted]
Results and discussion	[redacted]

Section 7.5.1.3 Terrestrial plant toxicity

Annex Point IIIA XIII 3.4

Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	

	COMMENTS FROM ... *(specify)*
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A7_5_1_3-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	Yes, formulated as WG 22.5
Radiochemical labelling	^{14}C-Tebuconazole labelled in the phenyl ring (25.97 mCi/mmol, Vial C-358).
Radiochemical purity	[redacted]
Preparation of dosing solution	From Vial C-358, 3.05 ml of ethanol containing 13.9 mg of [^{14}C]Tebuconazole per ml were removed and transferred to a 250 ml small-mouthed flint bottle. This was evaporated to 0.5 ml under a gentle stream of nitrogen. To this was added 223.7 mg of a 22.5% dry flowable Tebucoanzole formulation, tech. Purity [redacted] 146.8 mg of a 22.5 dry flowable formulation blank and 80 ml distilled water. The bottle was tightly capped, shaken vigorously, and sonicated five minutes to disperse the contents.
Final activity	12 mCi/mmol
Final purity	[redacted]

Table A7_5_1_3-2: Dilution water

Criteria	Details
Source	
Alkalinity / Salinity	
Hardness	
pH	
Oxygen content	
Conductance	
Holding water different from dilution water	

Table A7_5_1_3-3: Test plants

	Family	Species	Common name	Source (seed/plant)
Dicotyledonae			Beet	
			Kale	
Monocotyledonae		*Triticum valgare*	Wheat	

Table A7_5_1_3-4: Test system

Criteria	Details
Test type	Greenhouse
Container type	Galvanised tub (surface area 1.85 m^2)
Seed germination potential	
Identification of the plant species	
Number of replicates	
Numbers of plants per replicate per dose	
Date of planting	
Plant density	
Date of test substance application	1987-06-07
High of plants at application	No plants
Date of phytotoxicity rating or harvest	Wheat Forage harvest: 1987-08-27 Kale harvest: 1987-08-11 Beet tops harvest: 1987-10-21 Beet roots harvest: 1987-10-21 Wheat straw harvest: 1987-10-21 Wheat heads harvest: 1987-10-21 Wheat Forage harvest: 1987-12-15 Kale harvest: 1987-12-15 Beet tops harvest: 1988-02-18 Beet roots harvest: 1988-02-18 Wheat straw harvest: 1988-02-18 Wheat heads harvest: 1988-02-18 Wheat Forage harvest: 1988-05-02 Kale harvest: 1988-05-17 Beet tops harvest: 1988-07-18 Beet roots harvest: 1988-07-18 Wheat straw harvest: 1988-06-21 Wheat heads harvest: 1988-06-21
Dates of analysis	

Table A7_5_1_3-5: Test conditions

Criteria	Details
Test type	Terrestrial plants, EPA 165-1
Method of application	Sprayed onto soil and carefully incorporated
Application levels	1
Dose rates	560 g ai/ha
Substrate characteristics	Sandy loam soil
Watering of the plants	Crops were watered on a 'as needed' basis
Temperature	Normal greenhouse growing conditions
Thermoperiod	Normal greenhouse growing conditions

Criteria	Details
Light regime	Normal greenhouse growing conditions and when necessary supplemental lighting to yield the equivalent of 12 – 14 hour day.
Relative humidity	Normal greenhouse growing conditions
Wind volatility	None
Observation periods and duration of test	
Pest control	
Any other treatments and procedures	

Table A7_5_1_3-6: Total radioactive residue (TRR) in soil at each planting interval

Interval	Tebuconazole Equivalents [mg/kg]
Day 0 (soil treatment)	0.343
30 days	0.240
136 days	0.200
273 days	0.178

Table A7_5_1_3-7: Distribution of radioactive residues in soil in extractable and bound fractions

Interval (at planting)	Methanol-extractable	Bound	Total	Tebuconazole [%]
30	85.9	14.1	100.0	> 95[1]
136	47.1	52.9	100.0	
273	43.7	56.3	100.0	

[1] Analysed by TLC, no individual values given in the report

Table A7_5_1_3-8: Total radioactive residue (TRR) in rotational crops after soil treatment

	Tebuconazole Equivalents [mg/kg]		
	30 day re-plant	136 day re-plant	273 day re-plant
Wheat forage	[redacted]	[redacted]	[redacted]
Wheat grain	[redacted]	[redacted]	[redacted]
Wheat straw	[redacted]	[redacted]	[redacted]
Wheat chaff	[redacted]	[redacted]	[redacted]
Kale	[redacted]	[redacted]	[redacted]
Beet tops	[redacted]	[redacted]	[redacted]
Beet roots	[redacted]	[redacted]	[redacted]

Table A7_5_1_3-10: Quantitative distribution of metabolites in rotational crops (values are given in % of the total recovered radioactivity at harvest) after application of [phenyl-UL-^{14}C]tebuconazole

Crop	Re-plant (days)	Substance / Fraction									Total
		a.s.	*M03*	Org.[1]	U1	U2	Diff.[2]	Aqu.[3]	Refl.[4]	Bound	
Wheat, forage	30										
	136										
	273										
Wheat, grain	30										
	136										
	273										
Wheat, chaff	30										
	136										
	273										
Wheat, straw	30										
	136										
	273										
Beet, top	30										
	136										
	273										
Beet, root	30										
	136										
	273										
Kale	30										
	136										
	273										

[1] Organic extracts not analysed by HPLC.

[2] Diffuse radioactivity not in discrete fractions.

[3] Aqueous extracts not analysed.

[4] Released after refluxing with 1N HCl.

[5] Not analysed due to low level of radioactivity in organic extracts.

n. d.: not detected; U1, U2 are unknown metabolites

Section A7.5.1.2 Earthworm, reproduction toxicity test
Annex Point IIIA XIII 3.2

Official use only

		1 REFERENCE
1.1	**Reference**	Bätscher, R. Influence of low concentrations of tebuconazole (tech.) on reproduction of earthworms (*Eisenia fetida*), Bayer AG, RCC Study No. 729112, July05, 1999
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes Draft International Standards ISO/DIS 11268-2 "Soil quality-Effects of pollutants on earthworms (*Eisenia fetida*) – Part 2: Method for the determination of effects on reproduction, 1996 Also BBA (Germany) Guidelines Part VI, 2-2, 1994
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]
		3 METHOD
3.1	**Test material**	Tebuconazole (technical)
3.1.1	Lot/Batch number	Batch number [redacted]
3.1.2	Specification	[redacted]
3.1.3	Purity	[redacted] of active substance
3.1.4	Composition of Product	n.a.
3.1.5	Further relevant properties	Sufficient stability in soil, no losses due to volatilisation are expected
3.1.6	Method of analysis	Test with nominal concentrations
3.2	**Reference substance**	Yes (Benomyl)
3.2.1	Method of analysis for reference substance	Nominal concentrations

Section A7.5.1.2 Earthworm, reproduction toxicity test
Annex Point IIIA XIII 3.2

3.3	**Testing procedure**	
3.3.1	Preparation of the test substance	16 mg of the test substance was given into purified water and solved by mixing and ultrasonically treatment. This application solution was further diluted to the application concentrations from 0.1 until 3.2 mg/kg dry soil.
3.3.2	Application of the test substance	For the higher application rates of 10, 32 and 100 mg/kg a suitable amount of the test substance was mixed with 10 g of fine quartz sand for about 30 minutes.
3.3.3	Test organisms	see table A7_5_1_2-1
3.3.4	Test system	see table A7_5_1_2-2
3.3.5	Test conditions	see table A7_5_1_2-3
3.3.6	Test duration	4 weeks exposure + 4 weeks for determining the grow up of offspring
3.3.7	Test parameter	Mortality , weight alteration and reproduction
3.3.8	Examination	Visual examination
3.3.9	Monitoring of test substance concentration	No
3.3.10	Statistics	Changes in mean body weight of the surviving adult earthworms after the four weeks incubation period were compared to the control, and were statistically evaluated by means of a multiple Dunnett-test (Ref. 1 and 2 in the report) after a one-way analysis of variance (ANOVA).
		4 RESULTS
4.1	**Filter paper test**	Not performed
4.2	**Soil test**	
4.2.1	Initial concentrations of test substance	See table A 7_5_1_2-2
4.2.2	Effect data (Reproduction)	See table A 7_5_1_2-4
4.2.3	Concentration / effect curve	Determining the EC50 from a statistical dose effect analysis is given on page 26 in the report
4.2.4	Other effects	no
4.3	**Results of controls**	
4.3.1	Mortality	No significant mortalities (< 10% at lower concentrations) both in the tests samples and in the controls
4.3.2	Number/ percentage of earthworms showing adverse effects	No significant adverse effects were observed

Section A7.5.1.2 Earthworm, reproduction toxicity test
Annex Point IIIA XIII 3.2

4.4	**Test with reference substance**	Performed with benomyl
4.4.1	Concentrations	2.5 and 10 mg a.i. per kg dry soil
4.4.2	Results	The above mentioned study was performed with the same composition of the artificial soil as in this study (i.e. 5% Sphagnum peat, deviation from the guidelines). At the reference item concentration of 5 mg/kg dry soil the reproduction rate was reduced to 58% of the value in the control. The adult worms of the treatment group of 20 mg/kg showed a increased mortality rate (12.5%), a loss in mean body wet weight by 25% during the incubation period, and a completely inhibition of the reproduction.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Tebuconazole was exposed to adult earthworm *Eisenia fetida* (7 months old, 4x10 animals per concentration) for 4 weeks in an artificial soil to test item concentrations (nominal) of 0.10, 0.32, 1.0, 3.2, 10, 32, and 100 mg per kilogram dry soil, the cocoons and juvenile earthworms remained in the artificial soil for additional 4 weeks. After the additional 4 weeks the number of offspring was determined. The test was done according ISO and BBA Guidelines.
5.2	**Results and discussion**	The objective of this study was to assess the toxic effect of Tebuconazole (tech.) on survival, growth, and reproduction of the earthworm *Eisenia fetida* during an exposure period of eight weeks. The reproduction rate was determined by counting the number of offspring hatched from the cocoons. Effects were only seen on the reproduction rate (see 5.2.1 –5.2.3 and also table A 7_5_1_2-4)
5.2.1	NOEC (reproduction)	10 mg a.i. / kg dry weight substrate (LOEC = 32 mg/kg dry weight substrate)
5.2.2	$ECC_{50\ reproduction}$	55 mg/kg a.i./ kg dry weight substrate
5.2.3	NOEC (body wet weight /mortality)	100 mg a.i./ kg dry weight substrate (LOEC = >100)
5.3	**Conclusion**	The study shows a dose response relationship for the number of offspring in the three highest tested concentrations. From these curve the EC 50 of 55 mg/kg was derived. The controls fulfilled the validity criteria according to mortality. The reference control showed toxic effect as expected. Therefore the study can be regarded as valid without restrictions.
5.3.1	Other Conclusions	no
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	[redacted]

Section A7.5.1.2 Earthworm, reproduction toxicity test
Annex Point IIIA XIII 3.2

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*02 04 04*
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	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_1_2-1: Test organisms

Criteria	Details
Species/strain	*Eisenia fetida*
Source of the initial stock	Breeding station KRAUT & RUEBEN, Doris Haber, Zeilstr. 40 64367 Mühltal-Frankenhausen, Germany
Culturing techniques	The earthworms were held for one week in the laboratories of RCC. During holding they were fed with horse manure and potatoes.
Age/weight	The adult worms used in the test were 7 month old (± 2 weeks). The body weight at the start of the study ranged from 300- 499 mg per worm.
Pre-treatment	On the day prior to the start of the study, they were removed from the breeding substrate for acclimatisation and kept in the test substrate (without test substance) under the test conditions until the start of the study.

Table A7_5_1_1-2: Test system

Criteria	Details
Artificial soil test substrate	The test substrate consists of a) 73.7% sand with a particle size of 0.06 – 0.2 mm, b) 20% kaolin with a main (45 %) particle size < 0.2 µm, c) 5% sphagnum peat. This is a deviation from the Guideline which requires 10%. 5% were chosen to prevent too much detoxification by sorption. d) 0.3% calcium carbonate.
Size, volume and material of test container	Glass dishes with a diameter of 14 cm and a height of 7 cm were used as test vessels. The test vessels were covered with glass lids to prevent worms from escaping, but were sufficiently loose fitting to allow air exchange.
Amount of artificial soil (kg) / container	The 650 g wet soil (corresponding to 500 g dry soil) was filled into each test vessel resulting in a soil layer of approximately 5-6 cm in the test containers.
Test performed in closed vessels due to significant volatility of test substrate	No

Table A7_5_1_1-2: Test system (continued)

Criteria	Details
Test mixture	The test concentrations of nominal ≤ 3.2 mg/kg were prepared as follows: An aqueous application solution was prepared by mixing 16.03 mg test item homogeneously into 1000 ml purified water. The solution was treated ultrasonically for 15 minutes and stirred at room temperature for 10 minutes. This application solution was further diluted to obtain the application solutions of the three lowest test concentrations. Then 100ml aliquots of these intensively stirred application solutions were incorporated into the artificial soil of each replicate by intense mixing in a HOBART mixer to make sure, that the test item is distributed homogeneously in the test substrate. Thereafter, 38 ml purified water was mixed into the test substrate of each replicate. The water content in the test substrate was around 30% corresponding to about 57% of the total water holding capacity (WHC). No aqueous application solution could be prepared for the dosage of the three highest test concentrations of 10, 32, and 100 mg/kg dry soil. Therefore, the desired amounts for each replicate were mixed with 10 g of fine quartz sand for about 30 minutes by means of a roller mixer (amounts of the test item per replicate (rounded values): 5 mg, 16 mg, and 50-51 mg, respectively). The artificial soil was prepared by adding 138 ml of purified water to the weighed constituents. Then the mixture of sand and test item was incorporated directly into the artificial soil by intense mixing in a HOBART mixer.
Nominal levels of test concentrations	0.10,0.32,1.0,3.2,10,32, 100 mg/kg dry artificial soil
Number of replicates/concentration	4
Number of earthworms/test concentration	10
Number of earthworms/container	10

Table A7_5_1_2-3: Test conditions

Criteria	Details
Test temperature	20 °C (up to 23 °C The test temperature (room temperature) was continuously recorded by a temperature recorder.
Moisture content	The water content in the test substrate was around 30% corresponding to about 57% of the total water holding capacity (WHC).
pH	The pH was between 6.0 and 6.2 during the test period
Adjustment of pH	Yes
Light intensity / photoperiod	16-hour light to 8-hour darkness photoperiod (light intensity at light period between approximately 400-550 Lux Constant light (400 – 800 Lux)
Feeding	At the start of the test approximately 2.5 g of air-dried cow manure were evenly distributed over the surface of the artificial soil in each test container as food. The adult earthworms were fed once weekly during the test period in surplus with approximately 5-6 g food per vessel. The cow manure was moistened with purified water by spraying. In case of low food consumption, the amount of food was reduced approximately. The offspring were fed only once at the start of the second four weeks exposure period by mixing approximately 5 g cow manure into the soil
Relevant degradation products	Not to be expected during the test period

Table A7_5_1_2-4: **Results on reprotoxicity (table 4, page 24 from the report)**

RCC PROJECT 729112 REPORT Page 24
TEBUCONAZOLE (TECH.)

Table 4: Reproduction of the earthworms

Test concentration (mg/kg)	Vessel No.	Juvenile worms per test vessel Mean ± SD	Reproduction rate (per surviving adult) Mean ± SD	% of control	Statistical evaluation*
control	1	[redacted]			
	2				
	3				
	4				
0.1	1				
	2				
	3				
	4				
0.32	1				
	2				
	3				
	4				
1.0	1				
	2				
	3				
	4				
3.2	1				
	2				
	3				
	4				
10	1				
	2				
	3				
	4				
32	1				
	2				
	3				
	4				
100	1				
	2				
	3				
	4				

Statistical comparison of the mean number of juvenile worms per test vessel,
Results of a Dunnett-test, one-sided (smaller), $\alpha = 0.05$:
n.s.: mean value not significantly smaller than the control
s.: mean value significantly smaller than the control

Section 7.5.2.2 Annex Point IIIA 13.3	Long-term test with terrestrial plants	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [...]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	A specific long term test on terrestrial plants is not available at the time being. An agreed guideline is still missing. Nevertheless, the use of tebuconazole in the plant protection area during about 20 years indicates that tebuconazole will not cause long term plant damages at the applied concentrations. Under the controlled conditions of the 5 year field accumulation study (Allmendinger 1997) a twofold application of 250 g per hectare was applied per year. This results in a measured soil concentration of 0.056 mg a.i./kg dry weight soil (normalised to 30 cm depth). Because tebuconazole was mainly found in the 0-10 cm layer this value can be recalculated to about **0.150 mg a.i./ kg wet weight soil**. This concentration can be regarded as a NOEC with regard to this field study with winter wheat. Higher soil concentrations were reached in the greenhouse rotational crop studies (e.g. Leimkuehler et al. 1992). There the soil is treated with a single application twofold of the normal application. The measured concentration in a layer of the 6 inches (about 15 cm) was 0.343 ppm (soil dry weight). This corresponds to **0.455 mg a.i./kg wet weight soil.** The crops cultivated in three planting and harvest cycles over 378 days were wheat, kale and beet. No plant damages were reported. In addition several other NOECs from long term and reproductive tests on 8 terrestrial organisms are available which were used to derive a statistical HC5 approach for a PNEC derivation for the soil compartment. Taking also into account that in a refined risk assessment for the soil compartment a risk is not indicated, it is justified to use other information for a long term terrestrial risk assessment.	
Undertaking of intended data submission [ ]	–	

Section 7.5.2.2 Annex Point IIIA 13.3	Long-term test with terrestrial plants
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Date of action 14. April 2007*
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.5.3.1.1 Acute oral toxicity on birds

Annex Point IIIA XIII 1.1

Official use only

		1 REFERENCE
1.1	**Reference**	[redacted] (1987): HWG 1608 technical – Acute LD_{50} to bobwhite quail. [redacted], Report No. 828, March 31, 1987.
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes Study performed according to US-EPA, FIFRA Guideline, Section 163, 71-1 (1984) as well as those of the US-EPA Toxic Substances Control Act (TSCA) and the ASTM Standard Practice (Draft 6) "Standard Practice for Conducting Acute Oral LD_{50} Tests with Avian Species".
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]
		3 MATERIALS AND METHODS
3.1	**Test material**	Tebuconazole
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section 2 of dossier
3.1.3	Purity	[redacted]
3.1.4	Composition of Product	-
3.1.5	Further relevant properties	
3.1.6	Method of analysis	Methods not mentioned, results of feed analysis conducted by [redacted] (Study No. 86-015-02). Analysis of protein, moisture, fat, ash, crude fiber, carbohydrates, calories, several heavy metals, several aflatoxins, several organophosphates/organochlorine insecticides and PCB.
3.2	**Administration of the test substance**	. See table A7_5_3_1_1-1

Section A7.5.3.1.1 Acute oral toxicity on birds

Annex Point IIIA XIII 1.1

3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	-
3.4	**Testing procedure**	
3.4.1	Test organisms	See table A7_5_3_1_1-2
3.4.2	Test system	See table A7_5_3_1_1-3
3.4.3	Diet	See table A7_5_3_1_1-3
3.4.4	Test conditions	See table A7_5_3_1_1-4
3.4.5	Test duration	21 days
3.4.6	Test parameter	Mortality, toxic signs, body weight changes, feed consumption, necropsy examinations
3.4.7	Examination/ Observation	See table A7_5_3_1_1-3
3.4.8	Statistics	Body weight and feed consumption: The control group mean data was compared using t-test with $P \leq 0.05$ (Sokal, R.R. & F.J. Rohlf (1969): Biometry. Freeman & Co, San Fransisco, USA) and all treatment groups data were subjected to analysis of variance (ANOVA) with $P \leq 0.05$ (Sokal, R.R. & F.J. Rohlf (1969)). If ANOVA indicated significant differences, the mean of treated group was compared to the control group using the Williams test (Williams, D.A.: A test for differences between treatment means when several dose levels are compared with a zero dose control. Biometrics, 27, 103-117. Williams, D.A.: The comparison of several dose levels with a zero dose control. Biometrics, 28, 519-531). When a parameter mean was significantly different from the controls, that treatment was considered a toxicant effect. All statistical analysis was conducted using software supplied by SAS Institute Inc., Cary, North Carolina, USA.
		4 RESULTS
4.1	**Limit test / Range finding test**	Limit test was performed
4.1.1	Concentrations	See data given below
4.1.2	Number/ percentage of animals showing adverse effects	See data given below
4.1.3	Nature of adverse	See data given below

Section A7.5.3.1.1 Acute oral toxicity on birds

Annex Point IIIA XIII 1.1

	effects	
4.2	**Results test substance**	
4.2.1	Applied concentrations	0, 155, 260, 432, 720, 1,200 or 2,000 mg a.i./kg bw.
4.2.2	Effect data (Mortality)	Mortalities were observed in both the 1200 and the 2000 mg/kg dose groups.
4.2.3	Body weight	See table A7_5_3_1_1-6
4.2.4	Feed consumption	See table A7_5_3_1_1-6
4.2.5	Concentration / response curve	Not applicable
4.2.6	Other effects	Overt clinical signs of toxicity were noted only in those groups where mortalities occurred and included wing drop and hyperactivity. Transient decreases in body weight were observed at doses ≥ 720 mg a.i./kg bw. There were no sex-related differences in toxicity. Lesions noted in post-mortem examination of birds which died during the study suggest gastro-intestinal tract irritation.
4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	No mortalities or any adverse effects were observed in control animals
4.3.2	Nature of adverse effects	
4.4	**Test with reference substance**	Not performed
4.4.1	Concentrations	-
4.4.2	Results	-

Section A7.5.3.1.1 Acute oral toxicity on birds

Annex Point IIIA XIII 1.1

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	An avian single dose LD_{50} limit test was conducted to estimate the toxicity of Preventol A4-S to Bobwhite quail (*Colinus virginianus*). The test complies with US-EPA FIFRA Guideline, Section 163.71-1 (1984) as well as those of the US-EPA Toxic Substances Control Act (TSCA) and the ASTM Standard Practice (Draft 6) "Standard Practice for Conducting Acute Oral LD_{50} Tests with Avian Species". Each of six dose groups with 5 males and 5 females; a further group of 10 birds, 5 per sex, was similarly dosed with corn oil only and maintained as concomitant control. Following dosing all groups were held for a 21-day observation period.
5.2	**Results and discussion**	Mortalities were observed in both, the 1200 and the 2000 mg/kg dose groups. Overt clinical signs of toxicity were noted only in those groups where mortalities occurred and included wing drop and hyperactivity. Transient decreases in body weight were observed at doses ≥ 720 mg a.i./kg bw. There were no sex-related differences in toxicity. Lesions noted in post-mortem examination of birds which died during the study suggest gastro-intestinal tract irritation.
5.2.1	LD_{50}	= 1988 mg test substance/kg
5.2.2	NOEL	= 432 mg test substance/kg bw
5.3	**Conclusion**	The mortality rate in the control was below 10%. Therefore the validity criteria for avian acute oral toxicity test according to EPA OPPTS 850.2100 are fulfilled.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Section A7.5.3.1.1 Acute oral toxicity on birds

Annex Point IIIA XIII 1.1

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	June 2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
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_3_1_1-1: Method of administration of the test substance

Carrier/Vehicle	Details
Water	No
Organic carrier	Yes; corn oil
concentration of the carrier [% v/v]	Total solution volume: 50 ml
Other vehicle	No
Function of the carrier / vehicle	Solvent for test substance

Table A7_5_3_1_1-2: Test animals

Criteria	Details
Species/Strain	Bobwhite quail (*Colinus virginianus*)
Source	[redacted]
Age (in weeks), sex and initial body weight (bw)	Age: adult animals, 17 weeks old; Sex: males and females; Mean body weights: 205 ± 11 g (control group), 204 ± 12 to 212 ± 14 g (dose groups)
Breeding population	no data
Amount of food	Food and water were available *ad libitum*, prior to and throughout the study with the exception of the 20 hours immediately prior to dosing, during which the birds were fasted.
Age at time of first dosing	Age: adult animals, 17 weeks old
Health condition / medication	No prophylactic medication.

Table A7_5_3_1_1-3: Test system

Criteria	Details
Test location	Indoor, in galvanised steel brooders
Holding pens	galvanized steel brooders (91 x 71 x 23 cm), pelletized wood was used as cage bedding und cages were not changed during the course of the study
Number of animals	70 (35 males and 35 females)
Number of animals per pen [cm²/bird]	5 birds of a single sex (1260 cm²/bird)
Number of animals per dose	One control groups, each with 5 males + 5 females, Six dose groups, each with 5 males + 5 females
Pre-treatment / acclimatisation	Birds were examined upon receipt and daily throughout the 21 day laboratory acclimation period Food (Agway Gamebird Ration) and water were available *ad libitum*, prior to and throughout the study with the exception of the 20 hours immediately prior to dosing, during which the birds were fasted.
Diet during test	Food (Agway Gamebird Ration) and water were available *ad libitum* throughout the study.
Dosage levels (of test substance)	Single application at dose levels 0, 155, 260, 432, 720, 1,200 or 2,000 mg a.i./kg bw.
Replicate/dosage level	Each dose group with 5 males and 5 females; gang housed in two separate breeders
Feed dosing method	Orally by gavage
Dosing volume per application	Total solution volume: 50 ml; The test solutions were administered at a rate equal to 1% of the bird body weight.
Frequency, duration and method of animal monitoring after dosing	Observations for mortality and toxic signs were made daily for 21 days post-dosing; feed consumption for each group was recorded daily. At the end of the study, all surviving birds were sacrificed by CO_2 asphyxiation. Necropsy examinations were conducted on all surviving birds.
Time and intervals of body weight determination	Body weights were recorded on day 0, day 8, day 15 and day 21

Table A7_5_3_1_1-4: Test conditions (housing)

Criteria	Details
Test temperature	21.1 ± 2.2 °C.
Shielding of the animals	No data
Ventilation	No data
Relative huminity	40-60%
Photoperiod and lighting	8/16 hour light/dark cycle

Table A7_5_3_1_1-5 : Mortality data after test termination

Test substance dosage level, nominal [mg/kg bw]	Mortality after test termination (21 days)					
	Total number per dose level			Percentage per dose level		
	Males	Females	Total	Males	Females	Total
0 (control)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
155	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
260	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
432	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
720	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
1200	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2000	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table A7_5_3_1_1-6: Average body weights (g) and mean daily feed consumption (mean ± S.D.)

Test substance dosage level, nominal [mg/kg bw]	Body weight (g)				Mean daily feed consumption (g/bird/day)
	Initiation	Day 8	Day 15	Day 21	Day 5 to 12
0 (control)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
155	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
260	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
432	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
720	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
1200	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2000	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

*: Statistically significant difference (P<0.05) using Williams test

Table A7_5_3_1_1-7: Validity criteria for avian acute oral toxicity test according to EPA OPPTS 850.2100

	Fulfilled	Not fulfilled
Mortality of control animals <10%	yes	

Section A7.5.3.1.2 Short-term toxicity on birds

Annex Point IIIA XIII 1.2

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (1988): HWG 1608 (FOLICUR™) Subacute dietary LC 50 to bobwhite quail. [redacted]. Report No. 1023, June 17, 1988.	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes US-EPA, FIFRA Guideline 71-2; ASTM Standard E857-81	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Tebuconazole	
3.1.1	Lot/Batch number	Batch No.: [redacted]	
3.1.2	Specification	As given in section 2 of dossier	
3.1.3	Purity	[redacted]	
3.1.4	Composition of Product	-	
3.1.5	Further relevant properties	-	
3.1.6	Method of analysis in the diet	Liquid Chromatography with UV-VIS Detection.	
3.2	**Administration of the test substance**	Mixed in food. See table A7_5_3_1_2-1	
3.3	**Reference substance**	No	
3.3.1	Method of analysis for reference substance	-	
3.4	**Testing procedure**		
3.4.1	Test organisms	See table A7_5_3_1_2-2	

Section A7.5.3.1.2 Short-term toxicity on birds

Annex Point IIIA XIII 1.2

3.4.2	Test system	See table A7_5_3_1_2-3
3.4.3	Diet	See table A7_5_3_1_2-3
3.4.4	Test conditions	For details, see table A7_5_3_1_2-4
3.4.5	Test duration	12 days: 5 treatment days and 7-day observation period
3.4.6	Test parameter	Mortality, toxic signs, body weight changes, feed consumption, necropsy examinations
3.4.7	Examination/ Observation	See table A7_5_3_1_2-3
3.4.8	Statistics	Body weight and feed consumption: t-test with $P \leq 0.05$, Bartlett's test, standard one way analysis of variance, Dunett's test and William's test, Kruskal-Wallis test and Dunn's summed rank test. When a treatment mean was significantly different from the control means, that treatment was considered a toxicant effect level. All statistical analysis were conducted using software supplied by SAS Institute Inc., Cary, North Carolina, USA.
		4 RESULTS
4.1	**Limit test / Range finding test**	Not performed
4.1.1	Concentrations	-
4.1.2	Number/ percentage of animals showing adverse effects	-
4.1.3	Nature of adverse effects	-
4.2	**Results test substance**	
4.2.1	Applied concentrations	Animals were exposed to measured dietary concentrations (measured value of day 0): 325, 606, 1,250, 2,500 and 5,202 mg a.s./kg feed
4.2.2	Effect data (Mortality)	Compound-related mortalities occurred at 2,500 and 5,202 mg a.s./kg feed (40%; 30%). The LC_{50} was determined to be > 5,000 mg a.s./kg feed. The No-observed-effect concentration (NOEC) was < 325 mg a.s./kg feed and the Lowest-observed-effect concentration (LOEC) was 606 mg a.s./kg feed.
4.2.3	Body weight	Decreased body weight gains occurred in all levels tested during the 5-day period. Weight gains returned to control levels during the observation period indicating recovery.

Section A7.5.3.1.2 Short-term toxicity on birds

Annex Point IIIA XIII 1.2

4.2.4	Feed consumption	Feed consumption was reduced only at the 2,500 and 5,202 dietary levels.
4.2.5	Concentration / response curve	Not given in the report
4.2.6	Other effects	The only clinical sign of intoxication observed was wing drop, however, since this observation was limited to the 2,500 mg a.s./kg feed group and there were also signs of cage-mate aggression (bloody feet) the wing drop was considered incidental. There was one bird in the 325 mg a.s./kg feed group which showed signs of loss of equilibrium and later was found dead. This was also attributed to cage-mate aggression. Post mortem examinations showed no compound-related lesions.
4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	No mortality and no adverse effects were noted for the two control groups (20 birds).
4.3.2	Nature of adverse effects	-
4.4	**Test with reference substance**	Not performed
4.4.1	Concentrations	-
4.4.2	Results	-

Section A7.5.3.1.2 Short-term toxicity on birds

Annex Point IIIA XIII 1.2

		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	A subacute avian dietary toxicity test was conducted in accordance with FIFRA Guideline 71-2; ASTM Standard E857-81 in order to estimate the toxicity of tebuconazole to Bobwhite quail (*Colinus virginianus*). Young bobwhite quails (13 days old) were exposed for 5 days to measured dietary concentrations (measured value of day 0) of 325, 606, 1,250, 2,500 and 5,202 mg a.s./kg feed (10 animals per concentration), then given control feed for a 7-day observation period. Two additional non-treated groups of 10 birds each were maintained as concomitant controls. The study shows no significant deviations from the guideline.
5.2	**Results and discussion**	The LC_{50} was determined to be > 5,000 mg a.s./kg feed. The No-observed-effect concentration (NOEC) was < 325 mg a.s./kg feed and the Lowest-observed-effect concentration (LOEC) was 606 mg a.s./kg feed. Compound-related mortalities occurred at 2,500 and 5,202 mg a.s./kg feed (40%; 30%), decreased body weight gains occurred in all levels tested during the 5-day period. Feed consumption was reduced only at the 2,500 and 5,202 dietary levels. Weight gains returned to control levels during the observation period indicating recovery. The only clinical sign of intoxication observed was wing drop, however, since this observation was limited to the 2,500 mg a.s./kg feed group and there were also signs of cage-mate aggression (bloody feet) the wing drop was considered incidental. There was one bird in the 325 mg a.s./kg feed group which showed signs of loss of equilibrium and later was found dead. This was also attributed to cage-mate aggression. Post mortem examinations showed no compound-related lesions.
5.2.1	LC_{50}	> 5,000 mg a.s./kg feed
5.2.2	NOEC	< 325 mg a.s./kg feed
5.3	**Conclusion**	Validity criteria are given in table A7_5_3_1_2-6 The LC_{50} was determined to be > 5,000 mg a.s./kg feed. Based on the mean measured concentrations in feed on day 0 and 6 (average: 5,199 mg a.s./kg feed), a LC_{50} expressed as a daily dietary dose (DDD) of > 703 mg a.s./kg bw/day was calculated.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Section A7.5.3.1.2 Short-term toxicity on birds

Annex Point IIIA XIII 1.2

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	June 2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
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_3_1_2-1: Method of administration of the test substance

Carrier/Vehicle	Details
Water	No
Organic carrier	Yes, corn oil and acetone
Concentration of the carrier [% v/v]	Diet preparation: Appropriate amounts of tebuconazole, corn oil and acetone were combined in a 250 ml Erlenmeyer flask and added to the feed while mixing in a Hobart mixer.
Other vehicle	Yes, feed (Teklad JQ15 Bobwhite quail starter)
Function of the carrier / vehicle	Facilitation of uptake

Table A7_5_3_1_2-2: Test animals

Criteria	Details
Species/Strain	Bobwhite quail (*Colinus virginianus*)
Source	[redacted]
Age (in weeks), sex and initial body weight (bw)	Eggs were obtained from the quail farm and hatched at [redacted] facility; Test animals: Sex was unknown; Body weights at age of 13 days: 23-32 g
Breeding population	-
Amount of food	Food and water were available ad libitum, prior to and throughout the 12-day acclimation period.
Age at time of first dosing	Age: 13 days, body weights 23-32 g
Health condition / medication	No prophylactic medication.

Table A7_5_3_1_2-3: Test system

Criteria	Details
Test location	Indoor, in steel brooders
Holding pens	Galvanized steel brooders (91 x 71 x 23 cm); pelletized wood was used as cage bedding und was changed once during the study.
Number of animals	70 (unknown sex)
Number of animals per pen [cm²/bird]	10 birds of unknown sex (646 cm²/bird)
Number of animals per dose	10 animals per concentration Two control groups, each with 10 birds of unkown sex, Five dose groups, each with 10 birds of unkown sex

Criteria	Details
Pre-treatment / acclimatisation	Acclimatisation period:12 days. Less than 5% mortality was noted during the three days prior to test initiation and all unsuitable birds (injured, deformed etc.) were eliminated from inclusion in the test. Food (Teklad JQ15 Bobwhite quail starter) and water were available ad libitum.
Diet during test	Food (Teklad JQ15 Bobwhite quail starter)
Dosage levels (of test substance)	Animals were exposed to measured dietary concentrations (measured value of day 0): 325, 606, 1,250, 2,500 and 5,202 mg a.s./kg feed
Replicate/dosage level	One group of ten birds per dose level
Feed dosing method	Orally by feed
Dosing volume per application	Animals were exposed to measured dietary concentrations (measured value of day 0): 325, 606, 1,250, 2,500 and 5,202 mg a.s./kg feed respectively for a period of 5 days
Frequency, duration and method of animal monitoring after dosing	After 5 treatment days, birds were given control feed for 7 days (observation period). Observations for mortality and toxic signs were made twice daily except on weekends when only one observation per day was made; feed consumption for each group was recorded daily. At the end of the study, all surviving birds were sacrificed by CO_2 asphyxiation. Necropsy examinations were conducted on all birds at study termination, as well as on all birds that died during the course of the study.
Time and intervals of body weight determination	Body weights were recorded on day 0, 5 and 12

Table A7_5_3_1_2-4: Test conditions (housing)

Criteria	Details
Test temperature	Temperature gradient to ambient temperature (approximately 22.2 °C)
Shielding of the animals	No data
Ventilation	No data
Relative huminity	45 – 70%
Photoperiod and lighting	16/8 hour light/dark cycle

Table A7_5_3_1_2-5 a: Mortality data after test termination

Test substance dosage level [mg/kg bw]	Mortality after test termination (12 days)									
	Total number per dose level					Percentage per dose level				
	Pen 1	Pen 2	Pen 3	Pen 4	Pen 5	Pen 1	Pen 2	Pen 3	Pen 4	Pen 5
0 (control)	[redacted]									
325	[redacted]									
606	[redacted]									
1250	[redacted]									
2500	[redacted]									
5202	[redacted]									

Table A7_5_3_1_2-5 b: Body weights (g) and growth (mean ± S.D.)

Test substance dosage level [mg/kg bw]	Body weight (g)			Growth (g)	
	Initiation	Day 5	Day 12	Day 0 to 5	Day 5 to 12
0 (control)	[redacted]				
325	[redacted]				
606	[redacted]				
1250	[redacted]				
2500	[redacted]				
5202	[redacted]				

*: Statistically significant difference (P<0.05) using Williams test

Table A7_5_3_1_2-6: Validity criteria for short-term avian toxicity test according to OECD Guideline 205

	fulfilled	Not fulfilled
Mortality of control animals < 10%	X	
Test substance concentration > 80% of nominal concentration throughout the dosing period	X	
Lowest treatment level causing no compound-related mortality or other observable toxic effects	X	

Section 7.5.3.1.3 Annex Point IIIA 13.3	Bird toxicity: effects on reproduction	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	Give date of action: 14. September 2004	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted:*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		