Section A7.1.2. Rate and route of degradation in aquatic systems:
Annex Point IIIA-XII2.1 Dissipation in outdoor microcosm, study 1

3.3.8	Sampling	Prior to treatment, 1h ,4 h, 24 h, 48 h, 7 days, 28 days, 56 days, 112 days, 161 days after treatment. Additional sediment samples were taken at day 294, 385 and 441 after treatment.
3.3.9	Intermediates/ degradation products	Not identified
3.3.10	Nitrate/nitrite measurement	Not applicable
3.3.11	Controls	A third pond remand untreated and served as a control.
3.3.12	Statistics	Kinetic evaluation of the dissipation of HWG 1608 in the water phase by curve fitting to first order kinetics (Leicht and Grau, 1999).

4 RESULTS

4.1	**Degradation of test substance**	
4.1.1	Graph	Graphs are provided in the report and in table 7_1_2.2.
4.1.2	Degradation	The concentrations of tebuconazole in pond water measured as a function of time are summarised in table 7_1_2.3. The experimental values can be described by a decline curve which is in accordance with pseudo-first order kinetics. Omitting the initial two values from samples drawn 1 and 4 hours after application of the test substance, when complete mixing of the system had not yet occurred, but taking into account all remaining values, the DT50-values calculated by non-linear regression analysis were found to be 17.7 and 5.4 days, respectively. Taking into account all values, the DT50-values are 25.5 and 5.7 days (calculation according to W. Leicht and R. Grau, 1999, see table 7_1_2.2).
4.1.3	Other observations	-
4.1.4	Degradation of TS in abiotic control	No abiotic control
4.1.5	Degradation of reference substance	-
4.1.6	Intermediates/ degradation products	n.a.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	A pond study has been performed in [redacted] on a commercial trout and carp farm to investigate the distribution of tebuconazole (HWG 1608 EC250, 25 % a.s.) in water and sediment and the impact on water/sediment organisms. Three ponds were used: A control pond, a pond with 3 g tebuconazole (equal to 375 g a.s./ha) and a pond with about 10 g tebuconazole (equal to 1500 g a.s./ha). Water and sediment samples were analysed up to 161 days after application in the main report.

Section A7.1.2. Rate and route of degradation in aquatic systems:
Annex Point IIIA-XII2.1 Dissipation in outdoor microcosm, study 1

5.2	**Results and discussion**	From the concentration of tebuconazole in the water phase of the two ponds, dissipation half-lives of 25.5 and 5.7 days were calculated using 1st order kinetics (Leicht and Grau, 1999). This includes the adsorption to sediments as well as degradation.
5.3	**Conclusion**	Both studies support the observation that tebuconazole rapidly changes its distribution from the water phase to the sediment phase of a pond.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

EVALUATION BY COMPETENT AUTHORITIES

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 28 October, 2005

Materials and Methods [redacted]

Results and discussion [redacted]

Conclusion [redacted]

Reliability [redacted]

Acceptability [redacted]

Remarks [redacted]

Section A7.1.2. Rate and route of degradation in aquatic systems:
Annex Point IIIA-XII2.1 Dissipation in outdoor microcosm, study 1

	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 7_1_2.1 and 7_1_2.1a: Test System

Pond	Length [m]	Width [m]	Depth [cm]	Area [m^2]	Volume [m^3] *)
KT (=control)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
W1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
W4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

*) Note: Taking into account a ground area of 87.5 % of the water surface area.

Pond	pH	Organic C [%]	N [%]	P [%]	$CaCO_3$ [%]	Sand [%]	Silt [%]	Clay [%]
KT (=control)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
W1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
W4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table 7_1_2.2: Concentrations of tebuconazole as a function of time in two pond systems

[redacted]

Table 7_1_2.3: Recovery of tebuconazole in pond study ([redacted] 1989, [redacted])

	Pond 1				Pond 2			
	Depth	**Area**		**Volume***	**Depth**	**Area**		**Volume***
Pond size	0.79 m	76.2 m^2		56.3 m^3	0.80 m	61.2 m^2		46.0 m^3
Sampling after:	**Water (mean µg/l)**	**Sediment (mg/kg)**		**Total,% of appl. rad.**	**Water, (mean µg/l)**	**Sediment (mg/kg)**		**Total,% of appl. rad.**
		wet w	dry w			wet w	dry w	
1 h	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
1 d	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2 d	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
4 d	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
7 d	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
14 d	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
28 d	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
56 d	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
112 d	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
161 d	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
294 d		[redacted]	[redacted]			[redacted]	[redacted]	
385 d		[redacted]	[redacted]			[redacted]	[redacted]	
441 d		[redacted]	[redacted]			[redacted]	[redacted]	

*: Pond volume is calculated assuming ground area of the pond to be 87.5% of the water surface area, as stated in the study report.

Section 7.1.2.1.2 Annex Point IIIA 12.2	Anaerobic biodegradation	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [...]**	**Technically not feasible [ ] Scientifically unjustified [ ]** **Other justification [X].**	
Detailed justification:	A test on anaerobic biodegradation with regard to the sewage treatment plant is not required for actives used in wood preservatives.	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*10. 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		

Section A7.1.2.2.1 Aerobic Aquatic Degradation Study

Annex Point IIIA XII2.1

Official use only

1 REFERENCE

1.1	**Reference**	R. Fritz, 1987/1988, Degradational Behaviour of HWG 1608 (Folicur) in Rhine water. Bayer AG, Crop Protection Research, Institute for Metabolism Research, Report No. 3070, September 30th 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**	No, no guidelines available, methods developed in co-operation wt h the Dutch authorities, comparable to (later) EPA guidelines
2.2	**GLP**	[redacted]
2.3	**Deviations**	

3 MATERIALS AND METHODS

3.1	**Test material**	a) [Phenyl-UL-^{14}C] HWG 1608 (tebuconazole)s
3.1.1	Lot/Batch number	
3.1.2	Specification	Specific radioactivity: 3.12 MBq/mg, sample provided from [redacted]
3.1.3	Purity	[redacted] radiochemical purity
3.1.4	Further relevant properties	No problems related to abiotic stability or volatility are expected from the data available
3.1.5	Composition of Product	n.a.
3.1.6	TS inhibitory to micro-organisms	Not to be expected because of the favourable results of the respiration inhibition tests in soil and sewage sludge
3.1.7	Specific chemical analysis	Radio thin layer and HPLC analysis (reversed phase)
3.2	**Reference substance**	No
3.2.1	Initial concentration of reference substance	n.a.
3.3	**Testing procedure**	

Section A7.1.2.2.1 Aerobic Aquatic Degradation Study

Annex Point IIIA XII2.1

3.3.1	Inoculum / test species	Water from the river Rhine (km 706)
3.3.2	Test system	See table A7_1_2_2_1-1
3.3.3	Test conditions	See table A7_1_2_2_1-1
3.3.4	Method of preparation of test solution	The radiolabelled tebuconazole was dissolved in acetone and the radioactivity measured by liquid scintillation. A fixed of this stock solution was used to fortify the vessels.
3.3.5	Initial TS concentration	The amount of tebuconazole applied to the water sediment systems was 0.46 mg/l, which is related to the maximum application rate in agriculture (assumption: dosage is dissolved in a 10 cm deep water area).
3.3.6	Duration of test	up to 362 days
3.3.7	Analytical parameter	Radioactivity/UV Thin layer analysis: silica gel plates with different solvents Radioactivity/UV HPLC analysis: reversed phase (RP 18) Radioactivity measurement of volatile compounds: a) sorption on oil coated quartz wool plugs, extraction with ethyl acetate, which was measured by liquid scintillation. b) sorption on sodium carbonate and release of CO_2 (after acidification) in a scintillation cocktail. Radioactivity measurement of solid samples (e.g. centrifuged suspended particles): combustion and analysing radiolabelled CO_2
3.3.8	Sampling	0 (4 samples, only water parameters tested), 70 days, 173 days and 362 days. Duplicate samples at 362 days.
3.3.9	Intermediates/ degradation products	Not identified (sum up to 5 %), only CO_2 and tebuconazole were individually identified
3.3.10	Nitrate/nitrite measurement	n.a.
3.3.11	Controls	
3.3.12	Statistics	

4 RESULTS

4.1	**Degradation of test substance**	
4.1.1	Graph	-
4.1.2	Degradation	See table A7_1_2_2_1-2
4.1.3	Other observations	-
4.1.4	Degradation of TS in abiotic control	Not relevant, because no hydrolytic degradation can be expected from the data, light induced degradation was excluded by running the experiment in the dark.

Section A7.1.2.2.1 Aerobic Aquatic Degradation Study

Annex Point IIIA XII2.1

4.1.5	Degradation of reference substance	n.a.
4.1.6	Intermediates/ degradation products	Only intermediates < 3% found and where not identified. Only tebuconazole, CO_2 and bound residues were individually quantified

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The degradation behaviour of [phenyl-UL-^{14}C]tebuconazole was investigated by Fritz (1988a) in water taken from the river Rhine without sediment portion. The applied amount of tebuconazole was 0.46 mg/L. The incubation was conducted under exclusion of light and samples processed at days 70, 173 and 362. A material balance was established.
5.2	**Results and discussion**	After the period of 362 days 74.2 to 77.6% (average = 75.9%) of unchanged parent compound were still found in the system. Unidentified, predominantly polar metabolites of a magnitude of about 5% were found. The mineralization of tebuconazole to CO2 increased with ongoing time, amounting for 3.7% of the applied radioactivity after 70 days, about 7.8% after 174 days and 8.3 to 9.1% after 362 days. Mineralization rates in the same order of magnitude were determined from the studies in water/sediment systems.
5.3	**Conclusion**	The dissipation of tebuconazole in water systems is a slowly ongoing process. After about one year still 7 % of the applied radioactivity assigned to tebuconazole are found. Nevertheless some simulation experiments show that due to light induced reactions (indirect photolysis, e.g. via oxygen related radicals) an enhancement of the degradation of tebuconazole in surface water systems occur (**see annex**). The study is well documented and reported. A complete material balance was performed at all samplings by radioactive analysis. The parameters from the samplings show no major deviations from the zero samplings except an increase in pH.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Section A7.1.2.2.1 Aerobic Aquatic Degradation Study

Annex Point IIIA XII2.1

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*01 04 04*
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_1_2_2_1-1 Test system and Test conditions

Criteria	Details
Culturing apparatus	1 l Erlenmeyer glass vessels containing 500 ml Rhine water containing a tube to adsorb CO_2 and other volatile substances.
Number of culture flasks/concentration	10 for each water sediment system, and two blank systems
Aeration device	Not applied
Measuring equipment	Measurements of pH, the Redox potential and of the oxygen content of the water were performed from each sampling vessel and in addition from the four vessels at day zero
Redox potential	+ 117 - + 150 from day 70 to day 362 (day zero = + 100 - + 105)
Test temperature	22 ± 2 °C
pH	9.3 – 9.9 from day 70 to day 362 (day zero = 8.3)
Oxygen content (in % of maximum oxygen content: at 22°C: 8.73 mg O_2/l)	87 – 98 from day 70 to day 362 (day zero = 93-97)
microbial numbers/ ml water at day 362	1033 ± 153 / 1133 ± 115
Aeration of dilution water	No
Suspended solids concentration	not determined
Other relevant criteria	a) the test was conducted in the dark, b) the water phase was moved by a shaker (60 U/minute) to maintain oxygen uptake

Table A7_1_2_2_1-2 **Distribution of radioactivity [% of applied] in the Rhine water system after application of 0.46 mg/l [phenyl-UL-^{14}C]tebuconazole (Fritz, 1988)**

	Rhine water days incubation		
	70	173	362
Sum $^{14}CO_2$	[redacted]	[redacted]	[redacted]
Water (centrifuged without CO_2)	[redacted]	[redacted]	[redacted]
Tebuconazole	[redacted]	[redacted]	[redacted]
unidentified Metabolites	[redacted]	[redacted]	[redacted]
Particles from water	[redacted]	[redacted]	[redacted]
Tebuconazole	[redacted]	[redacted]	[redacted]
Sum Tebuconazole	[redacted]	[redacted]	[redacted]
Recovery	[redacted]	[redacted]	[redacted]

Annex (from the Environmental Toxicity/Fate Summary)

Research projects were initiated to investigate the degradation and metabolism of [phenyl-UL-^{14}C]- and [triazole-3,5-^{14}C] tebuconazole in natural water, considering realistic environmental conditions (Fritz and Brauner, 1990; Fritz, 1990 a+b).

In the first study (Fritz and Brauner, 1990) surface water containing environmentally relevant amounts of nitrate (50 mg/L) and humic acids (10-50 mg/L) was treated with tebuconazole (phenyl- and triazolyl-labelled) at a concentration of 0.375 mg/L. The glass aquaria were installed outdoors on a temperature controlled table (adjusted to 20 °C) under natural insolation and they were aerated continuously. After 58 days incubation (257 hours of sunshine) 26.5% of unchanged parent compound could still be determined in the water.

In case of natural water treated at a 5-fold higher rate but without addition of nitrate and humic acids, 30.2% of tebuconazole were found after 243 days (1160 hours of sunshine).

In a parallel running test, natural water (without "sensitizers") treated at a 20-fold higher rate with triazolyl-labelled tebuconazole was exposed to artificial light. At the end of the experiment, after 119 days only 12 % of unchanged tebuconazole were recovered from the surface water.

Main metabolites found in the water were the KFF 1224 and JA-231-2, which amounted 2.7 to 40.2% depending on the experimental conditions. Also triazole was found at higher concentrations from < 3% (field conditions) up to 18.3% (under artificial light), while the other identified metabolites occurred in smaller quantities only of < 2.6%. The low recovery rate (47.4%) in the experiment with the [phenyl-UL-^{14}C]tebuconazole can be explained basically by the fact of mineralisation to CO_2.

In the second experiment (Fritz, 1990a) surface water with and without addition of environmentally relevant amounts of nitrate was treated with [phenyl-UL-^{14}C]tebuconazole at a concentration of 0.375 mg/L and exposed to natural sun light in the field and during winter time incubated in the greenhouse.

The influence of the additional nitrate (50 mg/L) is demonstrated by the fact that only 7% tebuconazole were found after 53 days incubation compared to about 30% from the water without additional nitrate. The corresponding values from the 503 day samples were 0% and about 8%, respectively. It was shown that the degradation rate increased with higher concentrations of the active substance, i.e. after 75 days were found 37% parent compound in case of a 5-fold application rate and 76% in case of a 20-fold higher application rate.

The active ingredient was intensively metabolised, being 22 to 39% of the applied radioactivity transformed into CO_2 already after 54 days and 32 to 54% after 503 days.

In the last study (Fritz, 1990b) sterilized and natural water were treated each at the same rate of 0.375 mg/L tebuconazole (phenyl- and triazolyl-labelled) and incubated under artificial light for 53 days. In the test with sterilized water, 52 to 64% of unchanged parent compound were recovered after 15 to 18 days.

In the natural water experiment 56 to 60% tebuconazole were degraded after 28 days and 92 to 97% at the end of the experiment, after 53 days. After this period only 1% CO_2 had been formed in the natural water with the triazole-labelled tebuconazole compared to about 54% CO_2 liberated from the water treated with the phenyl-labelled compound.

As already found in the study of Fritz and Brauner (1990), KFE 1224 and JA-231-2 were the main metabolites besides triazole. The quantities found of KFE 1224 and JA-231-2 were up to 21 and 26.4%, respectively, while triazole reached the amount of 14% after 53 days.

References:

Fritz, R. and Brauner, A.; (1990)

Experiments on the environmentally relevant degradation of tebuconazole in water. Report No.: PF3594, Bayer AG, Germany; unpublished, January 15, 1990

Fritz, R.; (1990a)

Experiments on the degradation of tebuconazole in natural water at different rates of application and with the addition of "sensitises" with exposure to sunlight

Report No.: PF3595, Bayer AG, Germany; unpublished, January 15, 1990

Fritz, R.; (1990b)

Balance experiments on the degradation of tebuconazole in natural water with the exposure to artificial light. Report No.: PF3596, Bayer AG, Germany; unpublished

January 15, 1990

Section A7.1.2.2.1 Aerobic Aquatic Degradation Study – supplemental studies

Annex Point IIIA XII2.1 (R. Fritz, 1990a)

			Official use only
		1 REFERENCE	
1.1	**Reference**	R. Fritz, 1990a: Experiments on the Degradation of Tebuconazole in Natural Water at Different Rates of Application and with the Addition of "Sensitizers", with Exposure to Sunlight. Bayer AG, Crop Protection Research, Institute for Metabolism Research, Report No. 3595, January 15th 1990	
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**	No	
2.2	**GLP**	[redacted]	
2.3	**Deviations**		
		3 MATERIALS AND METHODS	
3.1	**Test material**	[Phenyl-UL-^{14}C] HWG 1608 (tebuconazole) and non-radioactive labelled HWG 1608 (tebuconazole)	
3.1.1	Lot/Batch number		
3.1.2	Specification	Specific radioactivity: [Phenyl-UL-^{14}C] HWG 1608 (tebuconazole): 4.2 MBq/mg, sample provided from [redacted]	
3.1.3	Purity	[redacted] radiochemical purity (both labels and non-labelled)	
3.1.4	Further relevant properties	No problems related to abiotic stability or volatility are expected from the data available	
3.1.5	Composition of Product	n.a.	
3.1.6	TS inhibitory to micro-organisms	Not to be expected because of the favourable results of the respiration inhibition tests in soil and sewage sludge	
3.1.7	Specific chemical analysis	Radio thin layer analysis	
3.2	**Reference substance**	HWG 1608 (tebuconazole), purity [redacted]	
3.2.1	Initial concentration of reference	n.a.	

Section A7.1.2.2.1 **Aerobic Aquatic Degradation Study – supplemental studies**

Annex Point IIIA XII2.1 (R. Fritz, 1990a)

	substance	
3.3	**Testing procedure**	
3.3.1	Inoculum / test species	Natural water from IJzendoorn (The Netherlands, euthrophic, drainage ditch in a fruit orchard), in case of four tests environmentally relevant amounts of humic acid (10 mg/L) and/or nitrate (50 mg/L) were added.
3.3.2	Test system	The experiments were carried out in flattened quartz glass vessels with a volume of about 430 mL. These were filled with 250 mL water each. The vessels were provided with a trap attachment for $^{14}CO_2$. The traps consisted of a glass socket into which 5 g soda lime were weighed and a quartz wool plug soaked with paraffin oil was introduced for absorption of organic volatile compounds. An injection needle inserted into the trap attachment, which ended in the water, allowed for sampling during the incubation period.
3.3.3	Test conditions	See table A7_1_2_2_1-8
3.3.4	Method of preparation of test solution	The radiolabelled tebuconazole was dissolved in acetone and the radioactivity measured by liquid scintillation counting. For experiments JA-218 non-radiolabelled test substance was added.
3.3.5	Initial TS concentration	The amount of tebuconazole applied to the water was 0.358 mg/L in the four tests JA-217, 1.85 mg/L in test JA-218-1, 3.721 mg/L in test JA-218-2 and 7.486 mg/L in test JA-218-3.
3.3.6	Duration of test	Up to 503 days (experiments JA-217) up to 483 days (experiments JA-218)
3.3.7	Analytical parameter	Radioactivity/UV thin layer analysis on silica gel plates Radioactivity measurement of liquid samples: liquid scintillation counting Radioactivity measurement of volatiles: volatiles trapped on oil-coated quartz wool were extracted with 100 mL ethyl acetate. Aliquots were taken for liquid scintillation counting. Radioactivity absorbed to soda lime was liberated by acidification into scintillation cocktail and was measured by liquid scintillation counting.
3.3.8	Sampling	After 53, 95, 153, 333, 423 and 503 days (experiments JA-217) after 33, 75, 133, 313, 403 and 483 days (experiments JA-218).
3.3.9	Intermediates/ degradation products	CO_2 was trapped. No identification of degradation products.
3.3.10	Nitrate/nitrite measurement	The natural water from IJzendoorn was measured before the experiments. Nitrate amounted to < 1 mg/L and nitrite to 0.05 mg/L.
3.3.11	Controls	n.a.
3.3.12	Statistics	n.a.
	4 RESULTS	
4.1	**Degradation of test substance**	

Section A7.1.2.2.1 **Aerobic Aquatic Degradation Study – supplemental studies**
Annex Point IIIA XII2.1 (R. Fritz, 1990a)

4.1.1	Graph	-
4.1.2	Degradation	The degradation of tebuconazole was enhanced by sensitizers and sunlight. After 53 days radioactive carbon dioxide ranged from 22.4 – 38.5% of applied radioactivity depending on the experimental conditions. After 503 days radioactive carbon dioxide ranged from 31.8 – 54.2% of applied radioactivity. Tables A7_1_2_2_1-9 and A7_1_2_2_1-10 show the amounts of tebuconazole after the different sampling times.
4.1.3	Other observations	Experiments JA-217-1 and JA-217-2 compared to JA-217-3 and JA-217-4 showed the influence of sensitizers and sunlight on the aerobic degradation of tebuconazole in natural water.
4.1.4	Degradation of TS in abiotic control	Not relevant, because no hydrolytic degradation can be expected from the data.
4.1.5	Degradation of reference substance	n.a.
4.1.6	Intermediates/ degradation products	After 53 days radioactive carbon dioxide ranged from 22.4 – 38.5% of applied radioactivity depending on the experimental conditions. After 503 days radioactive carbon dioxide ranged from 31.8 – 54.2% of applied radioactivity.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The degradation behaviour of [phenyl-UL-^{14}C] was investigated in natural water taken from IJzendoorn (the Netherlands) without sediment portion. Incubations were performed in flattened quartz glass vessels with a capacity of approx. 430 mL closed with a trap attachment for volatile organic compounds (to be absorbed in a quartz wool plug soaked with paraffinic oil) and carbon dioxide (to be absorbed by granulated soda lime). An injection needle inserted into the trap attachment ended in the water phase and allowed for sampling during the incubation. Four of the incubations were conducted at relevant test substance concentrations of 0.358 mg/L with and without addition of nitrate (50 mg/L) for up to 503 days. Three other incubations were conducted with addition of sensitizers for up to 483 days at elevated concentrations (1.850 – 7.486 mg/L). All incubations were performed in an open air zone under natural sunshine or in the greenhouse. Duration of sunshine was measured with a sunshine autograph and the irradiated heat units with a pyranometer.
5.2	**Results and discussion**	The degradation of tebuconazole was enhanced by sensitizers and sunlight. After 53 days radioactive carbon dioxide ranged from 22.4 – 38.5% of applied radioactivity depending on the experimental conditions. After 503 days radioactive carbon dioxide ranged from 31.8 – 54.2% of applied radioactivity. For test substance concentrations see table A7_1_2_2_1-9 and table A7_1_2_2_1-10.
5.3	**Conclusion**	The results indicate the importance of secondary photoreactions for the aerobic degradation of tebuconazole in water. While the degradation in water sediment systems and natural water under exclusion of light is a slow though continuously ongoing process, it occurs more rapidly under the influence of natural sunshine. After one year approximately 15% of

Section A7.1.2.2.1 **Aerobic Aquatic Degradation Study – supplemental studies**

Annex Point IIIA XII2.1 (R. Fritz, 1990a)

the starting concentration had been left. In an experiment with nitrate as a sensitizer this value decreased to 2%. According to the test results from experiments JA-218 the degradation rate decreases significantly at concentrations exceeding 1.850 mg/L.

5.3.1 Reliability [redacted]

5.3.2 Deficiencies [redacted]

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*April 2004*
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_1_2_2_1-8 Test system and Test conditions

Test No.	Volume of water	Amount of subst.	Appl. radio-activity	Concentration *)	Additives [mg/L]
JA-217-1	250 mL				
JA-217-2	250 mL				
JA-217-3	250 mL				
JA-217-4	250 mL				
JA-218-1	250 mL				
JA-218-2	250 mL				
JA-218-3	250 mL				

Notes: *)

**) N = sodium nitrate, H = humic acid.

Table A7_1_2_2_1-9: Degradation of tebuconazole in natural water under the influence of sunshine and nitrate after application of 0.358 mg/L [phenyl-UL-^{14}C]tebuconazole, data given in % of applied radioactivity (Fritz, 1990a)

Incubation time	JA-217-1/2 (without nitrate)	JA-217-1/2 (with nitrate)
0 days		
53 days		
95 days		
153 days		
333 days		
423 days		
503 days		

Table A7_1_2_2_1-10: Degradation of tebuconazole in natural water under the influence of sunshine, with addition of nitrate and humic acid after application of highly elevated concentrations of [phenyl-UL-^{14}C]tebuconazole, data given in % of applied radioactivity (Fritz, 1990a)

Incubation time	JA-218-1	JA-218-2	JA-218-3
0 days			
33 days			
75 days			
133 days			
313 days			
403 days			
583 days			

Section A7.1.2.2.1 Aerobic Aquatic Degradation Study – supplemental studies

Annex Point IIIA XII2.1 (R. Fritz, 1990b)

			Official use only
		1 REFERENCE	
1.1	**Reference**	R. Fritz, 1990b: Balance Experiments on the Degradation of Tebuconazole in Natural Water with Exposure to Artificial Light. Bayer AG, Crop Protection Research, Institute for Metabolism Research, Report No. 3595, January 15th 1990	
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**	No	
2.2	**GLP**	[redacted]	
2.3	**Deviations**		
		3 MATERIALS AND METHODS	
3.1	**Test material**	[Phenyl-UL-^{14}C] HWG 1608 (tebuconazole) [Triazole-3,5-^{14}C] HWG 1608 (tebuconazole)	
3.1.1	Lot/Batch number		
3.1.2	Specification	Specific radioactivity: [Phenyl-UL-^{14}C] HWG 1608 (tebuconazole): 3.1 MBq/mg, sample provided from Bayer AG, Isotopenlabor Elberfeld [Triazole-3,5-^{14}C] HWG 1608 (tebuconazole): 2.33 MBq/mg, sample provided from Bayer AG, Isotopenlabor Elberfeld	
3.1.3	Purity	[redacted] radiochemical purity (both labels and non-labelled)	
3.1.4	Further relevant properties	No problems related to abiotic stability or volatility are expected from the data available	
3.1.5	Composition of Product	n.a.	
3.1.6	TS inhibitory to micro-organisms	Not to be expected because of the favourable results of the respiration inhibition tests in soil and sewage sludge	
3.1.7	Specific chemical analysis	Radio thin layer chromatography and HPLC analysis (reversed phase)	
3.2	**Reference substance**	HWG 1608 (tebuconazole), purity [redacted]	
3.2.1	Initial concentration of reference	n.a.	

Section A7.1.2.2.1 **Aerobic Aquatic Degradation Study – supplemental studies**

Annex Point IIIA XII2.1 (R. Fritz, 1990b)

	substance	
3.3	**Testing procedure**	
3.3.1	Inoculum / test species	Natural water from IJzendoorn (The Netherlands, euthrophic, drainage ditch in a fruit orchard), sterilized and not sterilized.
3.3.2	Test system	The experiments were carried out in flattened quartz glass vessels with a volume of about 430 mL. These were filled with 250 mL water each. The vessels for experiment JA-219 were connected with a column of wash bottles. The CO_2-containing air being sucked through the vessel was passed through three bottles with ethyleneglycol, two bottles with barium hydroxide solution, one bottle with sulphuric acid and one bottle with caustic soda solution. The vessels for the sub-experiment JA-220 (sterile variant) were provided with a trap attachment for $^{14}CO_2$. The traps consisted of a glass socket into which 5 g soda lime were weighed and a quartz wool plug soaked with paraffin oil was introduced for adsorption of organic volatile compounds. Trap attachments for $^{14}CO_2$ were fixed to the vessels for experiments JA-221 and JA-222 and closed with a rubber stopper. An injection needle inserted into the trap attachment, which ended in the water, allowed for sampling during the incubation period. All incubations were carried out in a Suntest apparatus. The xenon lamp (1.1 kW) showed a similar spectral distribution as natural sunlight.
3.3.3	Test conditions	See table A7_1_2_2_1-11
3.3.4	Method of preparation of test solution	The radiolabelled tebuconazole was dissolved in acetone and the radioactivity measured by liquid scintillation counting.
3.3.5	Initial TS concentration	See table A7_1_2_2_1-11
3.3.6	Duration of test	Up to 26 days (experiments JA-219-1 and JA-219-2), up to 18 days (experiments JA-220-1 and JA-220-2), up to 53 days (experiments JA-221-1 and JA-222-1), up to 28 days (experiments JA-221-2 and JA-222-2).
3.3.7	Analytical parameter	Radioactivity/UV thin layer analysis on silica gel plates Radioactivity measurement of liquid samples: liquid scintillation counting Radioactivity absorbed to soda lime was liberated by acidification into scintillation cocktail and was measured by liquid scintillation counting. Radioactivity which were taken up with cellulose tissues were pressed into pills. For radioactivity determination, the samples were combusted in and oxidizer. Liberated $^{14}CO_2$ was transferred to a scintillation cocktail and was measured by liquid scintillation counting.
3.3.8	Sampling	After 15, 19 and 26 days (experiments JA-219-1 and JA-219-2), after 7 and 18 days (experiments JA-220-1 and JA-220-2), after 53 days (experiments JA-221-1 and JA-222-1), after 28 days (experiments JA-221-2 and JA-222-2).

Section A7.1.2.2.1 **Aerobic Aquatic Degradation Study – supplemental studies**
Annex Point IIIA XII2.1 (R. Fritz, 1990b)

3.3.9	Intermediates/ degradation products	$^{14}CO_2$ and volatiles were trapped. Quantification and identification of degradation products by radio-HPLC and TLC. Sample processing: Amounts of 100 and 200 µL of water samples were applied to thin-layer plates without pre-treatment, developed and measured by radiography-scanning. Experiment JA-219: Contents of the washing bottles serving as traps for volatile metabolites including carbon dioxide were replaced after 5, 19 and 26 days and the radioactivity was determined by LSC. Experiment JA-220: Air in the head-space of incubation vessels was swept into the trap attachment with a stream of nitrogen. Volume and radioactivity of water were determined. Sterility was checked by applying sample to a nutrient media. Experiment JA-221/JA-222: Air in the head-space and water phase treated in a similar way as in experiment JA 220. In order to enrich components, amounts of 50 mL from the water were drawn through solid phase extraction cartridges. The cartridges were eluted with methanol and the eluate concentrated by evaporation After having measured its volume and radioactivity it was investigated by means of TLC with radioactivity scanning.
3.3.10	Nitrate/nitrite measurement	The natural water from IJzendoorn was measured before the experiments. Nitrate amounted to < 1 mg/L and nitrite to 0.05 mg/L.
3.3.11	Controls	n.a.
3.3.12	Statistics	n.a.
		4 RESULTS
4.1	**Degradation of test substance**	
4.1.1	Graph	-
4.1.2	Degradation	Tables A7_1_2_2_1-12, A7_1_2_2_1-13, A7_1_2_2_1-14 and A7_1_2_2_1-15
4.1.3	Other observations	-
4.1.4	Degradation of TS in abiotic control	Not relevant, because no hydrolytic degradation can be expected from the data.
4.1.5	Degradation of reference substance	n.a.
4.1.6	Intermediates/ degradation products	See table A7_1_2_2_1-15.
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	The degradation behaviour of [phenyl-UL-^{14}C]- and [triazole-3,5-^{14}C]-tebuconazole was investigated in natural water taken from IJzendoorn (the Netherlands) without sediment portion. Incubations were performed in flattened quartz glass vessels with a capacity of approx. 430 mL closed with a trap attachment for volatile organic compounds (to be

Section A7.1.2.2.1 **Aerobic Aquatic Degradation Study – supplemental studies**

Annex Point IIIA XII2.1 (R. Fritz, 1990b)

absorbed in a quartz wool plug soaked with paraffin oil) and carbon dioxide (to be absorbed by granulated soda lime). An injection needle inserted into the trap attachment ended in the water phase and allowed for sampling during the incubation. Four of the incubations (JA-219-1, JA-219-2, JA-220-1 and JA-220-2) were conducted at relevant test substance concentrations of 0.348 – 0.512 mg/L with filter-sterilized and non-sterilized water for either 18 or 26 days. Four other incubations (JA-221-1, JA-221-2, JA-222-1, JA-222-2) were conducted to investigate the formation of metabolites. Test concentrations were in the range of 0.40 – 0.468 mg/L and the incubation time was either 28 or 53 days. All incubations were performed under artificial light.

5.2 Results and discussion

The first set of experiments (JA-219 and JA-220) showed that tebuconazole is degraded in sterilized and non-sterilized water (see tables A7_1_2_2_1-12 and A7_1_2_2_1-13). However, the faster degradation in non-sterilized water indicates that micro-organisms or their enzymes may also be involved in the degradation of tebuconazole besides the abiotic degradation process.

From the results of experiments JA-221 and JA-222 summarized in tables A7_1_2_2_1-14 and A7_1_2_2_1-15, between 56 and 60% of tebuconazole were degraded after 28 days, and between 92 and 97% at the end of the experiment, after 53 days. After that period only 1% of carbon dioxide had been released in the experiment with the triazole-labelled tebuconazole, compared to about 54% in the experiment with the phenyl-labelled compound. As already found in the study by Fritz and Brauner (1990), HWG1608-lactone and HWG1608-pentanoic acid were the main metabolites besides triazole. HWG1608-lactone and HWG1608-pentanoic acid amounted up to 21 and 26%, respectively, triazole up to 14% after 53 days.

5.3 Conclusion

The results of the experiments show that both, abiotic light-induced degradation and microbial degradation under the influence of light take part in the overall degradation of tebuconazole. The substance is thoroughly metabolized in natural water under the conditions chosen.

5.3.1 Reliability [redacted]

5.3.2 Deficiencies [redacted]

Section A7.1.2.2.1 Aerobic Aquatic Degradation Study

Annex Point IIIA XII2.1

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*April 2004*
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_1_2_2_1-11 Test system and Test conditions

Test No.	Volume of water	Amount of subst.	Label	Appl. radio-activity	Concentration *)	Test parameter
JA-219-1	250 mL					
JA-219-2	250 mL					
JA-220-1	250 mL					
JA-220-2	250 mL					
JA-221-1	250 mL					
JA-221-2	250 mL					
JA-222-1	250 mL					
JA-222-2	250 mL					

Notes: *) Orientated at an application rate of 375 g a.s./ha, considering a water depth of 10 cm, application rate corresponds to a concentration of 0.375 mg/L of a.s.

Table A7_1_2_2_1-12: Results from experiments JA-219 and JA-220: Biotic degradation and light induced degradation. - Comparison of sterile and non-sterile conditions. Distribution of radiocarbon and parent compound in water

Batch	JA-219-1		JA-219-2		JA-220-1		JA-220-2	
Label	[phenyl-U-^{14}C]-		[triazole-3,5-^{14}C]-		[phenyl-U-^{14}C]-		[triazole-3,5-^{14}C]-	
	radiocar-bon [%]	Tebucon-azole [%]	radiocar-bon [%]	Tebucon-azole [%]	radiocar-bon [%]	Tebucon-azole [%]	radiocar-bon [%]	Tebucon-azole [%]
Water	non-sterile	non-sterile	non-sterile	non-sterile	sterile	sterile	sterile	sterile
Incubation								
7 days								
15 days								
18 days								
19 days								
26 days								

Table A7_1_2_2_1-13: Results from experiments JA-219 and JA-220 - Biotic degradation and light induced degradation.
Distribution of radiocarbon in % of applied radioactivity 18 and 26 days after application

Batch	JA-219-1	JA-219-2	JA-220-1	JA-220-2
Label	[phenyl-U-^{14}C]-	[triazole-3,5-^{14}C]-	[phenyl-U-^{14}C]-	[triazole-3,5-^{14}C]-
Incubation period	26 days	26 days	18 days	18 days
Headspace				
$^{14}CO_2$				
Other volatiles				
Water				
Dissolved $^{14}CO_2$				
Remaining water phase				
Walls of vessel				
Recovery				

Table A7_1_2_2_1-14: Results from experiments JA-221 and JA-222 - Biotic degradation and light induced degradation
Distribution of radiocarbon in % of applied radioactivity 28 and 53 days after application

Batch	JA-221-2	JA-221-1	JA-222-1	JA-222-2
Label	[phenyl-U-^{14}C]-	[triazole-3,5-^{14}C]	[phenyl-U-^{14}C]	[triazole-3,5-^{14}C]
Incubation period	28 days	53 days	28 days	53 days
Headspace				
$^{14}CO_2$				
Other volatiles				
Water				
Dissolved $^{14}CO_2$				
Extract in methanol				
Remaining in water phase				
Recovery				

Table A7_1_2_2_1-15: Results from experiments JA-221 and JA-222 – Biotic degradation and light induced degradation.
Distribution of radiocarbon in % of applied radioactivity 28 and 53 days after application

Batch	JA-221-2		JA-221-1		JA-222-1		JA-222-2	
Label	[phenyl-U-^{14}C]		[phenyl-U-^{14}C]		[triazole-3,5-^{14}C]		[triazole-3,5-^{14}C]	
Incubation period	28 days		53 days		28 days		53 days	
% of applied radioactivity	methanol	water	methanol	water	methanol	water	methanol	water
Tebuconazole								
HWG1608-desbutyl								
HWG1608-1-hydroxy								
HWG1608-piperidinetriazole								
HWG1608-5-hydroxy								
HWG1608-lactone								
HWG1608-pentanoic acid								
1,2,4-triazole								
$^{14}CO_2$								
Unknown								
Loss due to processing								

n.d. = not detected , n.m. = not measured
*) Radioactivity of compounds resulting from cleavage of phenyl-ring was corrected by a factor of 6, only one sixth of the radioactivity from the statistically uniformly labelled [phenyl-U-^{14}C]-tebuconazole remained in the metabolite.

Section A7.1.2.2.1 Aerobic Aquatic Degradation Study – supplemental studies

Annex Point IIIA XII2.1 (R. Fritz and A. Brauner, 1990)

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		1 REFERENCE
1.1	**Reference**	R. Fritz and A. Brauner, 1990: Experiments on the Environmentally Relevant Degradation of Tebuconazole in water. Bayer AG, Crop Protection Research, Institute for Metabolism Research, Report No. 3594, January 15th 1990
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**	No, comparable to (later) EPA guidelines
2.2	**GLP**	[redacted]
2.3	**Deviations**	
		3 MATERIALS AND METHODS
3.1	**Test material**	[Phenyl-UL-^{14}C] HWG 1608 (tebuconazole) [Triazole-3,5-^{14}C] HWG 1608 (tebuconazole) and non-radioactive labelled HWG 1608 (tebuconazole)
3.1.1	Lot/Batch number	
3.1.2	Specification	Specific radioactivity: [Phenyl-UL-^{14}C] HWG 1608 (tebuconazole): 3.1 MBq/mg, sample provided from [redacted] [Triazole-3,5-^{14}C] HWG 1608 (tebuconazole): 2.33 MBq/mg, sample provided from [redacted]
3.1.3	Purity	[redacted] radiochemical purity (both labels and non-labelled)
3.1.4	Further relevant properties	No problems related to abiotic stability or volatility are expected from the data available
3.1.5	Composition of Product	n.a.
3.1.6	TS inhibitory to micro-organisms	Not to be expected because of the favourable results of the respiration inhibition tests in soil and sewage sludge
3.1.7	Specific chemical analysis	Radio thin layer and HPLC analysis (reversed phase)
3.2	**Reference substance**	HWG 1608 (tebuconazole), purity [redacted]

Section A7.1.2.2.1 Aerobic Aquatic Degradation Study – supplemental studies

Annex Point IIIA XII2.1 (R. Fritz and A. Brauner, 1990)

3.2.1	Initial concentration of reference substance	n.a.
3.3	**Testing procedure**	
3.3.1	Inoculum / test species	Natural water from IJzendoorn (The Netherlands, euthrophic, drainage ditch in a fruit orchard), in case of two tests environmentally relevant amounts of humic acid (10-50 mg/L) and nitrate (50 mg/L) were added, water from a recultivated gravel pit in Lienden (The Netherlands)
3.3.2	Test system	Glass aquaria with a capacity of about 10 and 40 L were used as incubation vessels which could be covered with a quartz glass plate. The water level in the 10 L aquaria was about 14-15 cm and that in the 40 L aquaria about 20-21 cm. The water surface being exposed to the sunshine was calculated to be 550 cm^2 and 1450 cm^2, respectively. During the entire incubation period, the aquaria were placed on a temperature-controlled table for samples in the open-air area. All aquaria were continuously aerated by means of a diaphragm pump with aeration stone.
3.3.3	Test conditions	See table A7_1_2_2_1-3
3.3.4	Method of preparation of test solution	The radiolabelled tebuconazole was dissolved in acetone and the radioactivity measured by liquid scintillation counting. Aliquots of the solution were pipetted into centrifuge tubes and mixed with non-radioactively labelled active substance.
3.3.5	Initial TS concentration	The amount of tebuconazole applied to the water was 0.375 mg/L in the two tests with [phenyl-UL-^{14}C] HWG 1608 (tebuconazole) and 1.86 and 1.85 mg/L in the two tests with [triazole-3,5-^{14}C] HWG 1608 (tebuconazole). In an additional overdose experiment for isolation of metabolites a 20fold excess of [triazole-3,5-^{14}C] HWG 1608 (tebuconazole) was used (7.36 mg/L).
3.3.6	Duration of test	58 days (two tests with [phenyl-UL-^{14}C] HWG 1608 (tebuconazole)) and 243 days (two tests with [triazole-3,5-^{14}C] HWG 1608 (tebuconazole))
3.3.7	Analytical parameter	Radioactivity/UV thin layer analysis: silica gel plates with different solvents Radioactivity/UV (DAD) HPLC analysis: reversed phase (RP 18 and RP 8) Radioactivity measurement of liquid samples: liquid scintillation counting Radioactivity measurement of solid samples: combustion and analysing radiolabelled CO_2 Identification by GC/MS after derivatization and NMR

Section A7.1.2.2.1 **Aerobic Aquatic Degradation Study – supplemental studies**
Annex Point IIIA XII2.1 (R. Fritz and A. Brauner, 1990)

3.3.8	Sampling	After 58 days sampling of the two test systems with [phenyl-UL-^{14}C] HWG 1608. After 147, 237 and 243 days (two tests with [triazole-3,5-^{14}C] HWG 1608 (tebuconazole)), after 243 days of incubation quantification of metabolites The overdose experiment was sampled after 119 and 132 days.
3.3.9	Intermediates/ degradation products	In tests with [phenyl-UL-^{14}C] HWG 1608 (tebuconazole): See table A7_1_2_2_1-6 In tests with [triazole-3,5-^{14}C] HWG 1608 (tebuconazole): see table A7_1_2_2_1-7
3.3.10	Nitrate/nitrite measurement	n.a.
3.3.11	Controls	n.a.
3.3.12	Statistics	n.a.

4 RESULTS

4.1	**Degradation of test substance**	
4.1.1	Graph	-
4.1.2	Degradation	See tables A7_1_2_2_1-6 and A7_1_2_2_1-7
4.1.3	Other observations	-
4.1.4	Degradation of TS in abiotic control	Not relevant, because no hydrolytic degradation can be expected from the data.
4.1.5	Degradation of reference substance	n.a.
4.1.6	Intermediates/ degradation products	See tables A7_1_2_2_1-6, A7_1_2_2_1-7

Section A7.1.2.2.1 **Aerobic Aquatic Degradation Study – supplemental studies**

Annex Point IIIA XII2.1 (R. Fritz and A. Brauner, 1990)

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The degradation behaviour of [phenyl-UL-^{14}C] and [triazole-3,5-^{14}C]tebuconazole was investigated in natural water taken from IJzendoorn and Lienden (both in the Netherlands) without sediment portion. Two of the incubations were conducted with addition of humic acid (10-50 mg/L) and nitrate (50 mg/L) for 58 days (applied amount of [phenyl-UL-^{14}C]tebuconazole was 0.38 mg/L). The other two incubations were conducted without addition of sensitizers for 243 days (applied amount of [triazole-3,5-^{14}C]tebuconazole was 1.86 mg/L). All incubations were performed outdoors on a temperature controlled table (adjusted to 20°C) under natural sunshine.

An additional experiment was designed for the production, isolation and identification of metabolites. Therefore, a 20fold higher concentration of 7.36 mg/L [triazole-3,5-^{14}C] HWG 1608 (tebuconazole) was applied to the water. In this case the test system was exposed to artificial light (Xenon lamp of 1.1 kW with a spectral distribution similar to that of natural sunlight) for 132 days.

5.2 Results and discussion

The degradation of tebuconazole in natural water under natural conditions was investigated.

See table A7_1_2_2_1-4 to table A7_1_2_2_1-7.

After a period of 58 days with addition of sensitizers a portion of 86.4% of the applied radioactivity was found in the water. Parent tebuconazole accounted for 26.5% of the applied radioactivity. Major metabolites are HWG 1608-pentanoic acid and HWG 1608-lactone. These two metabolites can easily be transformed to the other by hydrolysis and condensation. Other metabolites are HWG 1608-desbuthyl, HWG 1608-1-hydroxy, HWG 1608-piperidine-triazole and HWG 1608-5-hydroxy.

After a period of 243 days without addition of sensitizers 69.5% of the applied radioactivity was found in the water. Parent tebuconazole accounted for 30.2% of the applied radioactivity. The same metabolites as described above were detected. 1,2,4-Triazole was found at 3.0% of the applied radioactivity.

5.3 Conclusion

The degradation of tebuconazole in natural water systems under natural conditions is shown. Due to light induced reactions (indirect photolysis, e.g. via oxygen related radicals) an enhancement of the degradation of tebuconazole in surface water systems occur.

The study is well documented and reported.

5.3.1 Reliability [redacted]

5.3.2 Deficiencies [redacted]

Section A7.1.2.2.1 **Aerobic Aquatic Degradation Study – supplemental studies**

Annex Point IIIA XII2.1 (R. Fritz and A. Brauner, 1990)

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*April 2004*
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_1_2_2_1-3 Test system and Test conditions

Test No.	Volume of water	Origin of water	Filling height	Amount of subst.	Label	Appl. radio-activity	Concen-tration *)	Additives [mg/L]
JA-211	8 L	IJzend.	10–15cm					
JA-212	8 L	IJzend.	10–15cm					
JA-229	8 L	Lienden	10–15cm					
JA-230	30 L	Lienden	20–21cm					
JA-231/1	1 L	IJzend.	12.7 cm					
JA-231/2	1 L	IJzend.	12.7 cm					

Notes: *) Orientated at an application rate of 375 g a.s./ha, considering a water depth of 10 cm, application rate corresponds to a concentration of 0.375 mg/L of a.s.
**) N = sodium nitrate, H = humic acid.

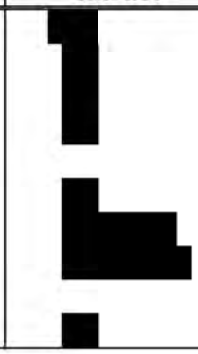
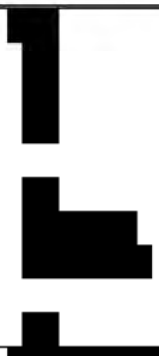
Table A7_1_2_2_1-4: Distribution of radioactivity in natural water after application of 0.38 mg/L [phenyl-UL-^{14}C]tebuconazole and 58 days of incubation under natural sunshine (Fritz and Brauner 1990)

	% of applied radioactivity
Extraction of water Methanol extract Water extract	
Recovery	

Table A7_1_2_2_1-5: Distribution of radioactivity in natural water after application of 1.86 mg/L [triazole-3,5-^{14}C]tebuconazole and 243 days of incubation under natural sunshine (Fritz and Brauner 1990)

	% of applied radioactivity
Extraction of water: Organic extract Water extract	
Extraction of algae Organic extract Water extract solid residues	
Silicone sealing	
Recovery	

Table A7_1_2_2_1-6: Distribution of active substance and degradation products in water in natural water after application of 0.38 mg/L [phenyl-UL-^{14}C]tebuconazole and 58 days of incubation under natural sunshine (in % of applied radioactivity) (Fritz and Brauner 1990)

Compound	Methanol extract	Water extract	sum
Tebuconazole HWG 1608-desbutyl (HWG 3877) HWG 1608-1-hydroxy (HWG 2061) HWG 1608-poperidine-triazole (JA-230-4) HWG 1608-5-hydroxy (JA-230-5) HWG 1608-lactone (KFE 1224) * HWG 1608-5-pentanoic acid (JA-231-2) * unknown			

n.d. = not detected

* These metabolites contain only 1 carbon atom from the uniformly labelled test substance. Therefore, due to statistical reasons only 1/6 of their amount is detectable by radioactivity measurements. This is taken into account by the numbers given in brackets.

Table A7_1_2_2_1-7: Distribution of active substance and degradation products in water in natural water after application of 1.86 mg/L [triazole-3,5-^{14}C]tebuconazole and 243 days of incubation under natural sunshine (in % of applied radioactivity) (Fritz and Brauner 1990)

Compound	Extraction of water		Extraction of algae		sum
	Organic extract	Water extract	Organic extract	Water extract	
Tebuconazole HWG 1608-desbutyl (HWG 3877) HWG 1608-1-hydroxy (HWG 2061) HWG 1608-poperidine-triazole (JA-230-4) HWG 1608-5-hydroxy (JA-230-5) HWG 1608-lactone (KFE 1224) HWG 1608-5-pentanoic acid (JA-231-2) 1,2,4-Triazole Unknown Insoluble residues					

n.d. = not detected

Section A7.1.2.2.2 Water/sediment degradation study

Annex Point IIIA XII2.1

Official use only

1 REFERENCE

1.1	**Reference**	R. Fritz, 1987/1988, Degradation of HWG 1608 (Folicur) in a model aquatic ecosystem, part 1, 2 and 3. Bayer AG, Crop Protection Research, Institute for Metabolism Research, Reports No. 2821 (5th July 1987), 2890 (7th October 1987), 3069 (7th October1988)
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**	No, no guidelines available, methods developed in co-operation with the Dutch authorities, comparable to (later) EPA guidelines
2.2	**GLP**	[redacted]
2.3	**Deviations**	

3 MATERIALS AND METHODS

3.1	**Test material**	a) [Phenyl-UL-^{14}C] HWG 1608 (tebuconazole) b) non-active standard substance (tebuconazole)
3.1.1	Lot/Batch number	
3.1.2	Specification	a) specific radioactivity was 3.12 MBq/mg, sample provided from [redacted]. b) see purity, sample provided by Dr. Krohn (Elberfeld)
3.1.3	Purity	a) [redacted] radiochemical purity b) [redacted] purity
3.1.4	Further relevant properties	No problems related to abiotic stability or volatility are expected from the data available
3.1.5	Composition of Product	n.a.
3.1.6	TS inhibitory to micro-organisms	Not to be expected because of the favourable results of the respiration inhibition tests in soil and sewage sludge
3.1.7	Specific chemical analysis	Radio thin layer and HPLC analysis (reversed phase)
3.2	**Reference substance**	No

Section A7.1.2.2.2 Water/sediment degradation study

Annex Point IIIA XII2.1

3.2.1	Initial concentration of reference substance	n.a.
3.3	**Testing procedure**	
3.3.1	Inoculum / test species	Two different aquatic micro ecosystems (500 ml volume) containing a sediment portion. The water/sediment samples were taken from a recultivated gravel pit (Lienden, NL) and from a drainage ditch in a fruit orchard (Ijzendoorn, NL). The characterisation of the sediments is shown in table A7_1_2_2_2-1.
3.3.2	Test system	see table A7_1_2_2_2-2
3.3.3	Test conditions	see table A7_1_2_2_2-2
3.3.4	Method of preparation of test solution	The radiolabelled tebuconazole was dissolved in acetone and the radioactivity measured by liquid scintillation. A volume of 113 µl of this stock solution was used to fortify the vessels. A mean of three such samplings was used to estimate the applied radioactivity (about 611 kBq per vessel).
3.3.5	Initial TS concentration	The amount of tebuconazole applied to the water sediment systems was 0.39 mg/l, which is related to the maximum application rate in agriculture (assumption: dosage is dissolved in a 10 cm deep water area).
3.3.6	Duration of test	up to 52 weeks
3.3.7	Analytical parameter	Radioactivity/UV Thin layer analysis: silica gel plates with different solvents Radioactivity/UV HPLC analysis: reversed phase (RP 18) Radioactivity measurement of volatile compounds: a) sorption on oil coated quartz wool plugs, extraction with ethyl acetate, which was measured by liquid scintillation. b) sorption on sodium carbonate and release of CO_2 (after acidification) in a scintillation cocktail. Radioactivity measurement of solid samples (e.g. sediment): pre-treatment by e.g. drying and milling, than combustion and analysing radiolabelled CO_2
3.3.8	Sampling	Duplicate sampling 1,4, 10 weeks (part 1), 29 weeks (part 2, only one sample), 52 weeks (part 3)
3.3.9	Intermediates/ degradation products	Not identified, only CO_2 and bound residues were found in relevant amounts
3.3.10	Nitrate/nitrite measurement	n.a.
3.3.11	Controls	Blank control (duplicate) to check the water system parameters
3.3.12	Statistics	

Section A7.1.2.2.2 Water/sediment degradation study

Annex Point IIIA XII2.1

		4 RESULTS
4.1	**Degradation of test substance**	
4.1.1	Graph	not supplied
4.1.2	Degradation	See tables A7_1_2_2_2-3 and A7_1_2_2_2-4
4.1.3	Other observations	-
4.1.4	Degradation of TS in abiotic control	Not relevant, because no hydrolytic degradation can be expected from the data, light induced degradation was excluded by running the experiment in the dark.
4.1.5	Degradation of reference substance	n.a.
4.1.6	Intermediates/ degradation products	Only intermediates < 3% found and where not identified. Only tebuconazole, CO_2 and bound residues were individually quantified
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	The degradation and metabolism behaviour of [phenyl-UL-^{14}C]tebuconazole in an aquatic micro ecosystem containing a sediment portion was investigated in two different water/sediment systems (Fritz, 1987a and b; 1988b). The water/sediment samples were taken from a recultivated gravel pit (Lienden, NL) and from a drainage ditch in a fruit orchard (Ijzendoorn, NL). A test system was used which was developed with the Dutch authorities. Material balances were performed using by radioactivity measurements of all test components.
5.2	**Results and discussion**	During the incubation period (52 weeks) approximately 80% of the applied radioactivity were adsorbed to the sediment of the system "Ijzendoorn", which showed a higher content of clay, silt and also organic carbon, compared to the sediment of the system "Lienden". Approximately 48% of the applied radioactivity were adsorbed to the sediment of the system "Lienden" during the incubation time. In the same time period 59% of the unchanged substance were recovered from the sediment of the system "IJzendoorn" and about 33% from the sediment of the system "Lienden". The amount of unchanged parent compound in the surface water decreased with ongoing time and reached after 52 weeks 8% in the water from "IJzendoorn" and about 23% in the water from "Lienden". Other, not further identified metabolites (non-volatile) were found at a maximum concentration of approximately 3%. Tebuconazole was mineralised to CO_2 in both water/sediment systems. At the end of the experiment 10% of the applied radioactivity was identified as CO_2 in the system "IJzendoorn", compared to approximately 21% in the system "Lienden".

Section A7.1.2.2.2 Water/sediment degradation study

Annex Point IIIA XII2.1

5.3	**Conclusion**	The dissipation of tebuconazole in both water/sediment systems is a slowly ongoing process. After one year still 56 to 67% of the applied radioactivity assigned to tebuconazole was found in the two systems. Nevertheless some simulation experiments show that due to light induced reactions (indirect photolysis, e.g. via oxygen related radicals) an enhancement of the degradation of tebuconazole in surface water systems occur (**see annex**). The study is well documented and reported. A complete material balance was performed at all samplings by radioactive analysis. The parameters from two blank water sediment systems show no deviations from the fortified systems.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Section A7.1.2.2.2 Water/sediment degradation study

Annex Point IIIA XII2.1

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	01 04 04
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_1_2_2_2-1 Properties of the Natural Water Sediment Systems

System	Sand [%]	Silt [%]	Clay [%]	N org. [%]	C org. [%]	pH	$CaCO_3$ [mg/kg]
IJzendoorn	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Lienden	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table A7_1_2_2_2-2 Test system and Test conditions

Criteria	Details
Culturing apparatus	Glass vessels containing 500 ml water and 10% (w/w) sediment (portions corresponding to 50 g dry weight), a system to adsorb CO_2 and other volatile substances.
Number of culture flasks/concentration	10 for each water sediment system, and two blank systems
Aeration device	Not applied
Measuring equipment	Measurements of pH and of the oxygen content of the water were performed from each sampling vessel and in addition from the two blank vessels.
Composition of medium	see table A7_1_2_2_2-1
Additional substrate	No
Pre-incubation of the test systems	yes, 6 days
Test temperature	22 ± 2 °C
pH	Lienden: 8.2 - 8.8 (blank 7.9-8.8) Ijzendoorn: 7.7 - 8.5 (blank (7.6-8.4)
Oxygen content (in % of maximum oxygen content: at 22°C: 8.73 mg O_2/l)	Lienden: 77 – 90 (blank 78 – 98) Ijzendoorn: 61-89(blank (75 – 91)
TOC content at the beginning of the study	Lienden: 5 mg/l, Ijzendoorn: 4 mg/l
Aeration of dilution water	No
Suspended solids concentration	not determined
Other relevant criteria	a) the test was conducted in the dark. b) the water phase was slowly stirred by a magnetic stirrer to maintain oxygen uptake

Table A7_1_2_2_2-3 Distribution of radioactivity [% of applied] in two water/sediment systems after application of 0.39 mg/l [phenyl-UL-^{14}C]tebuconazole (Fritz, 1988)

	Ijzendoorn weeks incubation					Lienden weeks incubation				
	1	4	10	29	52	1	4	10	29	52
surface water	■	■	■	■	■	■	■	■	■	■
sediment extractable	■	■	■	■	■	■	■	■	■	■
Sediment non extractable	■	■	■	■	■	■	■	■	■	■
sediment	■	■	■	■	■	■	■	■	■	■

Table A7_1_2_2_2-4 Distribution of tebuconazole and CO2 [% of applied] in two water/sediment systems after application of 0.39 mg/l [phenyl-UL-^{14}C]tebuconazole (Fritz, 1988)

	IJzendoorn weeks incubation					Lienden weeks incubation				
	1	4	10	29	52	1	4	10	29	52
CO_2	■	■	■	■	■	■	■	■	■	■
% tebuconazole in:										
surface water	■	■	■	■	■	■	■	■	■	■
sediment	■	■	■	■	■	■	■	■	■	■
water/sediment	■	■	■	■	■	■	■	■	■	■

Annex (from the Environmental Toxicity/Fate Summary)

Research projects were initiated to investigate the degradation and metabolism of [phenyl-UL-^{14}C]- and [triazole-3,5-^{14}C] tebuconazole in natural water, considering realistic environmental conditions (Fritz and Brauner, 1990; Fritz, 1990 a+b).

In the first study (Fritz and Brauner, 1990) surface water containing environmentally relevant amounts of nitrate (50 mg/L) and humic acids (10-50 mg/L) was treated with tebuconazole (phenyl- and triazolyl-labelled) at a concentration of 0.375 mg/L. The glass aquaria were installed outdoors on a temperature controlled table (adjusted to 20 °C) under natural insolation and they were aerated continuously. After 58 days incubation (257 hours of sunshine) 26.5% of unchanged parent compound could still be determined in the water.

In case of natural water treated at a 5-fold higher rate but without addition of nitrate and humic acids, 30.2% of tebuconazole were found after 243 days (1160 hours of sunshine).

In a parallel running test, natural water (without "sensitizers") treated at a 20-fold higher rate with triazolyl-labelled tebuconazole was exposed to artificial light. At the end of the experiment, after 119 days only 12 % of unchanged tebuconazole were recovered from the surface water.

Main metabolites found in the water were the KFE 1224 and JA-231-2, which amounted 2.7 to 40.2% depending on the experimental conditions. Also triazole was found at higher concentrations from < 3% (field conditions) up to 18.3% (under artificial light), while the other identified metabolites occured in smaler quantities only of < 2.6%. The low recovery rate (47.4%) in the experiment with the [phenyl-UL-^{14}C]tebuconazole can be explained basically by the fact of mineralisation to CO_2.

In the second experiment (Fritz, 1990a) surface water with and without addition of environmentally relevant amounts of nitrate was treated with [phenyl-UL-^{14}C]tebuconazole at a concentration of 0.375 mg/L and exposed to natural sun light in the field and during winter time incubated in the greenhouse.

The influence of the additional nitrate (50 mg/L) is demonstrated by the fact that only 7% tebuconazole were found after 53 days incubation compared to about 30% from the water without additional nitrate. The corresponding values from the 503 day samples were 0% and about 8%, respectively. It was shown that the degradation rate increased with higher concentrations of the active substance, i.e. after 75 days were found 37% parent compound in case of a 5-fold application rate and 76% in case of a 20-fold higher application rate.

The active ingredient was intensively metabolised, being 22 to 39% of the applied radioactivity transformed into CO_2 already after 54 days and 32 to 54% after 503 days.

In the last study (Fritz, 1990b) sterilized and natural water were treated each at the same rate of 0.375 mg/L tebuconazole (phenyl- and triazolyl-labelled) and incubated under artificial light for 53 days. In the test with sterilized water, 52 to 64% of unchanged parent compound were recovered after 15 to 18 days.

In the natural water experiment 56 to 60% tebuconazole were degraded after 28 days and 92 to 97% at the end of the experiment, after 53 days. After this period only 1% CO_2 had been formed in the natural water with the triazole-labelled tebuconazole compared to about 54% CO_2 liberated from the water treated with the phenyl-labelled compound.

As already found in the study of Fritz and Brauner (1990), KFE 1224 and JA-231-2 were the main metabolites besides triazole. The quantities found of KFE 1224 and JA-231-2 were up to 21 and 26.4%, respectively, while triazole reached the amount of 14% after 53 days.

References:

Fritz, R. and Brauner, A.; (1990)

Experiments on the environmentally relevant degradation of tebuconazole in water. Report No.: PF3594, Bayer AG, Germany; unpublished, January 15, 1990

Fritz, R.; (1990a)

Experiments on the degradation of tebuconazole in natural water at different rates of application and with the addition of "sensitises" with exposure to sunlight. Report No.: PF3595, Bayer AG, Germany; unpublished, January 15, 1990

Fritz, R.; (1990b)

Balance experiments on the degradation of tebuconazole in natural water with the exposure to artificial light. Report No.: PF3596, Bayer AG, Germany; unpublished, January 15, 1990

Section 7.1.4.1 Annex Point IIIA 12.2	Field study on accumulation in the sediment	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [...]**	**Technically not feasible [ ] Scientifically unjustified [ ]** **Other justification [X].**	
Detailed justification:	A specific field study on accumulation in sediment was not performed, because is not a data requirement. In addition sediment is not the compartment at risk according to the risk assessment. No guideline is available at the time being on such a field study. Nevertheless, information on sediment accumulation can be derived both from the laboratory water sediment study and from the pond studies. The latter can be regarded as near to a field study.	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	10. 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		

Section A7.2.1 and A7.2.2.4 Aerobic and anaerobic degradation in soil

Annex Point IIIA XII 1.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	Lee, S.G.H. & Hanna-Bay, L.A., 1987, The metabolism of ®FOLICUR in Soil, Mobay Corporation Agricultural Chemicals Division, Kansas City, Missouri, Report Number 94369, March 11, 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**	EPA Pesticide Assessment Guidelines 162-1 and 162-2	
2.2	**GLP**	[redacted]	
2.3	**Deviations**		
		3 MATERIALS AND METHODS	
3.1	**Test material**	Two radioactive labelled tebuconazole molecules were used: phenyl-UL-^{14}C and triazolc-3,5-^{14}C.	
3.1.1	Lot/Batch number		
3.1.2	Specification		
3.1.3	Purity	[redacted] for phenyl-UL-^{14}C and [redacted] for triazole-3,5-^{14}C.	
3.1.4	Further relevant properties		
3.1.5	Method of analysis	Soil was extracted with water, methanol/water (7:3) and methanol. Extracts were pooled radioassayed by LSC and analysed with HPLC and TLC. Analysing of bound residues: the soil was washed twice with 0.5 M NaOH centrifuged and the washed with water. To precipitate the humic acid fraction the supernatant was acidified with HCl to a pH of 1. The remaining supernatant included fulvic acid. The radioactivity remaining in soil was considered to be the humin fraction. The quantification of the humic acid, fulvic acid and humin fraction was done with LSC. Verification of microbial activity was accomplished by monitoring the evolved $^{14}CO_2$ from 50 g soil treated with 10 mg D-(1-^{14}C)glucose/kg soil. CO_2 trapping solutions were radioassayed by LSC.	
3.2	**Reference substance**	Non-labelled compounds available as standards: tebuconazole, HWG 2061, HWG 2251, HWG 2558 and HWG 2606 (see appendix 1)	

Section A7.2.1 and A7.2.2.4 Aerobic and anaerobic degradation in soil

Annex Point IIIA XII 1.1

3.2.1	Method of analysis for reference substance	TLC
3.3	**Soil types**	One soil type was used, see table A7_2_1-1
3.4	**Testing procedure**	
3.4.1	Test system	
3.4.1.1	Aerobic soil metabolism	Radioactive labelled tebuconazole (phenyl-UL-^{14}C) was dissolved in acetone and applied to 50 g soil screened to a particle size ≤ 2 mm, resulting in a concentration of 10 mg/kg. Then incubated in glass flasks with CO_2-trap under aerobic conditions in the dark at 23 ± 2 °C. Duplicate flasks were sampled at day 0, 7, 14, 28, 56, 84 and 112 and after 6 and 12 months. An study conducted in the same manner were carried out with triazole-3,5-^{14}C labelled tebuconazole, except that this study only were sampled at day 0, 30 and 58.
3.4.1.2	Anaerobic soil metabolism	Radioactive labelled tebuconazole (phenyl-UL-^{14}C) was dissolved in acetone and applied to 50 g soil screened to a particle size ≤ 2 mm, resulting in a concentration of 10 mg/kg. Then incubated in glass flasks under aerobic conditions in the dark at 23 ± 2 °C, after 30 days an anaerobic environment was introduced by flooding the soil with water. Duplicate flasks were sampled at time of flooding (day 0), 30 and 60.
3.4.2	Test solution and Test conditions	The radioactive labelled tebuconazole was dissolved in acetone.

4 RESULTS

4.1	**Aerobic soil metabolism**	See table A7_2_1-2
4.2	**Anaerobic soil metabolism**	See table A7_2_1-2

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	US EPA Guideline 162-1 and 162-2 was followed. An aerobic and an anaerobic degradation study were performed in the laboratory. In the aerobic study soil was treated with 10 mg phenyl-UL-^{14}C/kg soil or 10 mg triazole-3,5-^{14}C/kg soil and the incubated for 365 and 58 days respectively. In the anaerobic study soil was treated with 10 mg phenyl-UL-^{14}C/kg soil. The soil was incubated for 30 days under aerobic conditions and then flooded and incubated for 60 days under anaerobic conditions.

Section A7.2.1 and A7.2.2.4 Aerobic and anaerobic degradation in soil

Annex Point IIIA XII 1.1

5.2	**Results and discussion**	
5.2.1	DT50 values	Extrapolation of data indicated a half-life for primary degradation of phenyl-UL-^{14}C labelled tebuconazole of approximately 800 days. The study performed with triazole-3,5-^{14}C labelled tebuconazole lasted for 58 days, but the degradation was about the same rate as for triazole-3,5-^{14}C labelled tebuconazole. Under anaerobic conditions the degradation was slightly faster than under aerobic conditions.
5.2.2	Degradation products (% of a.s.)	During both studies no metabolites were identified. In the aerobic study with phenyl-UL-^{14}C labelled tebuconazole an unknown metabolite accounted for 2.6 and 2.1% of applied radioactivity after 6 and 12 months respectively. In the anaerobic study a similar unknown metabolite accounting for 2.2% of applied radioactivity was detected.
5.2.3	Bound residues	The bound residues were at a similar level (14.5-19.5) in the three studies after app. 60 days. For triazole-3,5-^{14}C labelled tebuconazole bound residues accounted for 14.5% of applied radioactivity after 58 days. For the phenyl-UL-^{14}C labelled tebuconazole 29.1% bound residues was found after 12 month. In the anaerobic study 19.5%bound residues was found after 60 days.
5.2.4	CO_2 formation	The CO_2 formation was 0.3% of applied radioactivity under aerobic conditions after 12 month. Under anaerobic conditions no CO_2 formation was detected.
5.3	**Conclusion**	Tebuconazole is not metabolised rapidly in soil, the half-life is greater than one year. Tebuconazole behaved similarly under aerobic and anaerobic conditions.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	

Section A7.2.1 Aerobic and anaerobic degradation in soil

Annex Point: IIIA XII 1.1

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	
	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	[redacted]

Table A7_2_1-1: Classification and physico-chemical properties of soils used

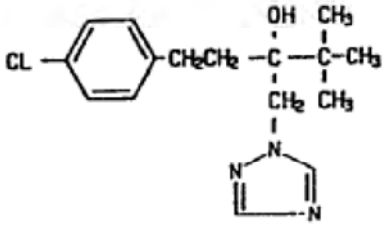
	Soil 1
Soil order	
Soil series	
Classification	Sandy loam
Location	Greenhouse soi from the Mobay Research Farm in Stanley, Kansas
Horizon	
Sand [%]	54.0
Silt [%]	37.0
Clay [%]	9.0
Organic carbon [%]	0.95
Carbonate as $CaCO_3$	
insoluble carbonates [%]	
pH (1:1 H_2O)	4.5 in 0.01 M $CaCl_2$
Cation exchange capacity (MEQ/100 g at pH 8.2)	16,0
Extractable cations (MEQ/100 g)	
Ca	
Mg	
Na	
K	
H	
Special chemical/mineralogical features	
Clay fraction mineralogy	

Table A7_2_1-2 Degradation in soil under standard laboratory conditions

	Aerobic conditions		Anaerobic conditions
	Phenyl-UL-^{14}C	triazole-3,5-^{14}C	Phenyl-UL-^{14}C
Dose (mg/kg soil)	10	10	10
Incubation (days)	365	58	60
Tebuconazole (%)	[redacted]	[redacted]	[redacted]
$^{14}CO_2$ (%)	[redacted]	[redacted]	[redacted]
Bound residues	[redacted]	[redacted]	[redacted]
Fulvic acid	[redacted]	[redacted]	[redacted]
Humic acid	[redacted]	[redacted]	[redacted]
Humin	[redacted]	[redacted]	[redacted]
Total recovered radioactivity (%)	[redacted]	[redacted]	[redacted]

[redacted]

Appendix 1: Non-labelled compounds available as standards.



FOLTCUR

[redacted]

Section A7.2.1 Aerobic degradation in soil – supplementary experiment

Annex Point IIIA XII 1.1

Official use only

1 REFERENCE

1.1	**Reference**	Fritz, R. & Brauner, A., 1989, Supplementary Experiment on the Degradation of Tebuconazole in Soil, Bayer AG, Crop Protection-Research, Leverkusen-Bayerwerk, Laboratory Project ID: M 125 0207-7.
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**	No
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

3.1	**Test material**	Two radioactive labelled tebuconazole molecules were used (phenyl-UL-^{14}C and triazole-3,5-^{14}C)
3.1.1	Lot/Batch number	
3.1.2	Specification	As given in section 2
3.1.3	Purity	
3.1.4	Further relevant properties	
3.1.5	Method of analysis	Soil was extracted with water, methanol/water, methanol, ethyl acetate and methanol/ammonia. Methods of analysis were LSC, TLC and HPLC
3.2	**Reference substance**	Yes
3.2.1	Method of analysis for reference substance	The identity of the substances was verified by NMR and MS-spectrometry
3.3	**Soil types**	see table A7_2_1-1

Section A7.2.1 Aerobic degradation in soil – supplementary experiment

Annex Point IIIA XII 1.1

3.4	**Testing procedure**	
3.4.1	Test system	Four different test were performed
3.4.1.1	Standard conditions	Radioactive labelled tebuconazole was dissolved in methanol. Moist soil (soil 1 and 2, table A7_2_1-1) was screened to a particle size ≤ 2 mm, the soil was treated with cattle manure (about 80 ml/kg soil). 100 g soil (relative to dry weight) and 100 µl test solution (phenyl-UL-^{14}C 0.96 µg/µl and triazole-3,5-^{14}C 1.12 µg/µl) was incubated in 300 ml Erlenmeyer flasks with CO_2-trap. That is a concentration of 0.96 mg/kg soil and 1.12 mg/kg soil respectively. The flasks were incubated under aerobic condition in the dark at 20 ± °C for 123, 299 and 433 days. One batch with phenyl-UL-^{14}C and triazole-3,5-^{14}C at each incubation time. Soil 2 was pre-treated 3 times with 10 mg tebuconazole/kg soil at an interval of about 4 weeks; the last application was made 10 days prior to the start of the study.
3.4.1.2	With and without vegetation	27 kg of Soil 1 was mixed with 2.2 l liquid manure. 10 batches (see table A7_2_1-2) were incubated in a greenhouse from November to March and in glass covered open-air grounds from April to October. Test solution was applied to glass beakers (3 l) filled with 1 kg quartz sand and on top of this 2.5 kg soil. Immediately after this grass was planted in the batches with vegetation.
3.4.1.3	Under the influence of artificial light	Soil 1 was screened to 5 mm; the soil was treated with cattle manure (about 80 ml/kg soil). The experiment was conducted in flattened quartz glass vessels; 65 ml in volume, the vessels were closed with a CO_2 trap. The bottom was covered with filter paper and an injection needle allowed a constant moistening. The active ingredient was added via a sub-sample of soil, either 0.65 mg phenyl-UL-^{14}C/kg soil or 0.8 mg triazole-3,5-^{14}C/kg soil. Batches were incubated at 17-18 °C in a Suntest apparatus. The first 9 days the Suntest lamp followed a day night rhythm hereafter there was a constant light exposure. One batch with each radioactive labelling was sampled at day 7, 26, 49 and 89.
3.4.1.4	Degradation in natural light	Soil 2 and 3 (se table 7_2_1-1) was taken fresh from the field. Radioactive tebuconazole (Triazole-3,5-^{14}C) was added to a concentration of 3 mg/kg soil for soil 2 and 5.5 mg/kg soil for soil 3. The treated soil were spread out in a thin layer on an aluminium foil (30x30 cm) and covered with a quartz glass cover. The soil was incubated in open-air grounds for 67/73 or 86 days. The soil was moistened sporadically by low-volume-spraying the surface. The surface temperature was adjusted to 20 ± 2 °C, weather data was recorded.
3.4.2	Test solution and Test conditions	The radioactive labelled tebuconazole was dissolved in methanol.
	4 RESULTS	
4.1	**Standard conditions**	See table A7_2_1-3
4.2	**With and without vegetation**	See table A7_2_1-4

Section A7.2.1 Aerobic degradation in soil – supplementary experiment

Annex Point IIIA XII 1.1

4.3	**Under the influence of artificial light**	See table A7_2_1-5
4.4	**Degradation in natural light**	See table A7_2_1-6

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Four different degradation studies were performed. Test 1: Batches of soil 1 and 2 was treated with 0.96 mg phenyl-UL-^{14}C/kg soil or 1.12 mg triazole-3,5-^{14}C/kg soil. Soil 2 was pre-treated with tebuconazole. Test 2: 5 batches with and 5 batches without vegetation was incubated in greenhouse during winter and in open-air during summertime, the total incubation period was 291-393 days. Dose, ^{14}C-label and application method was also varied. Test 3: Soil 1 with 0.65 mg phenyl-UL-^{14}C/kg soil or 0.8 mg triazole-3,5-^{14}C/kg soil was incubated in a Suntest lamp for 89 days. Test 4: Soil 2 and 3 were taken fresh from the field, triazole-3,5-^{14}C was added in a concentration of 3 and 5,5 mg/kg soil respectively. The batches were incubated in open-air grounds for 67/73 or 86 days.
5.2	**Results and discussion**	
5.2.1	DT50 values	DT50 values were not calculated. After 433 incubation days under standard conditions 29.6 to 69.3% of tebuconazole was left in the soil. In the test with and without vegetation 2.3 to 28.9% tebuconazole was left in the soil after around 300 days. For batches with vegetation it was 14-15% and for batches without vegetation 21-29%. The plants took up tebuconazole 0.8-5.1%. In artificial light 3.8-5.9% of tebuconazole was left after 89 days. After around 80 days of degradation in natural light 51.7-53% of tebuconazole was still in the soil. The great difference between the studies performed in artificial and natural light is perhaps due to the difference in applied concentration of tebuconazole that is 0.65-0.8 mg/kg soil in artificial light and 3.0-5.5 mg/kg soil in natural light. This indicates that the degradation of tebuconazole decreases with increasing concentration.
5.2.2	Degradation products (% of a.s.)	Triazole was the major metabolite formed. In the degradation with and without degradation 0.9-9.0% triazole was found at the end of the study. In the degradation in natural light 0.6-1.0% of triazole was found. Other metabolites found were SN 320-1, STJ 5706, KFE 1224, SN 3678-7/A+B, HWG 3877 and HWG 2685. Proposed metabolic pathway is shown in appendix 1. No metabolite was measured to more than 10% at any time during the four studies.
5.2.3	Bound residues	The percentage of bound residues varied a great deal in the four experiments, from 7.2 to 64.9%. The amount of bound residues was lowest in the degradation study in natural light (12.5-14.1%).

Section A7.2.1 Aerobic degradation in soil – supplementary experiment

Annex Point IIIA XII 1.1

5.2.4	CO_2 formation	CO_2 formation was measured in standard test and in test with artificial light. For the phenyl-UL-^{14}C labelled tebuconazole the CO_2 formation was generally higher (1.4-32.2%) than for triazole-3,5-^{14}C labelled tebuconazole (0.5-2.1%). This is probably because the phenyl ring is easier mineralised than the triazole ring.
5.3	**Conclusion**	In the present study it was tried to cover the environmental behaviour of tebuconazole. Under the given conditions, the active ingredient was thoroughly metabolized in the soil. Several intermediate products being important for plausible degradation pathway were identified.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	02 04 04
Materials and Methods	Applicants version is acceptable
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_2_1-1: Classification and physico-chemical properties of soils used

	Soil 1	Soil 2	Soil 3
Soil order			
Soil series			
Classification	Silty loam	Silt soil	Sandy loam
Location	Netherlands (Nisse, Zeeland)	Germany (Bayer experimental farm "Höfchen")	Germany
Horizon			
Sand [%]	22.1	20.5	75.9
Silt [%]	58.1	78.3	16.5
Clay [%]	19.8	1.2	7.6
Organic carbon [%]	0.8	2.6	2.2
Carbonate as $CaCO_3$			
insoluble carbonates [%]			
pH (1:1 H_2O)	6.0 in $CaCl_2$	5.4 in KCl	5.4 in $CaCl_2$
Cation exchange capacity (MEQ/100 g)	13.0	10.5	8.0
Extractable cations (MEQ/100 g)			
Ca			
Mg			
Na			
K			
H			
Special chemical/mineralogical features			
Clay fraction mineralogy			

Table A7_2_1-2: Testing system with and without vegetation

Batch	Phenyl-UL-^{14}C (mg)	triazole-3,5-^{14}C (mg)	Tebuconazole, non-radioactive (mg)	Total Dose (mg)	Vegetation	a.i. incorprorated in soil (I) or on soil surface (S)	Incubation time (days)
1	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
3	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
4	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
5	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
6		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
7		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
8		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
9		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
10		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table A7_2_1_2-3: Degradation in soil under standard laboratory conditions

	Phenyl-UL-^{14}C		triazole-3,5-^{14}C	
	Soil 1	Soil 2	Soil 1	Soil 2
Incubation (days)	433	433	433	433
$^{14}CO_2$ (%)	[redacted]	[redacted]	[redacted]	[redacted]
Other volatiles (%)	[redacted]	[redacted]	[redacted]	[redacted]
Total extracted (%)	[redacted]	[redacted]	[redacted]	[redacted]
Organic extract	[redacted]	[redacted]	[redacted]	[redacted]
Water extract	[redacted]	[redacted]	[redacted]	[redacted]
Alkali extract	[redacted]	[redacted]	[redacted]	[redacted]
Loss due to processing	[redacted]	[redacted]	[redacted]	[redacted]
Non extracted (%)	[redacted]	[redacted]	[redacted]	[redacted]
Total recovered radioactivity (%)	[redacted]	[redacted]	[redacted]	[redacted]
Tebuconazole (%)	[redacted]	[redacted]	[redacted]	[redacted]
SN 320-1, SN 3678-7/B, SN 3678-7/A	[redacted]	[redacted]	[redacted]	[redacted]
1,2,4 Triazole	[redacted]	[redacted]	[redacted]	[redacted]
Unknown	[redacted]	[redacted]	[redacted]	[redacted]

Table A7_2_1-4: **Results from degradation in soil with and without vegetation**

Batch	1	2	3	4	5	6	7	8	9	10
Incubation (days)	291	372	329	393	374	299	318	378	337	325
Soil: Extracted										
Non extracted										
Roots: Extracted										
Non extracted										
Grass: Extracted										
Non extracted										
Total										
Soil Extracts:										
Tebuconazole										
SN 320-1										
Triazole										
STJ 5706										
KFE 1224										
Unknown										
Loss due to process										
Tebuconazole extracted from plants										

Table A7_2_1-5: **Degradation under the influence of artificial light**

	phenyl-UL-^{14}C	triazole-3,5-^{14}C
Incubation (days)	89	89
$^{14}CO_2$ (%)		
Other volatiles (%)		
Total extracted (%)		
Organic extract (%)		
Water extract (%)		
Loss due to processing (%)		
Tebuconazole (%)		
Non extracted (%)		
Total recovered radioactivity (%)		

Table A7_2_1-6: **Degradation in natural light**

	Soil 2	Soil 3

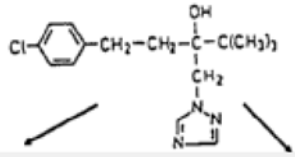
Incubation period (days)	86	67/73
Sun (hours)	[redacted]	[redacted]
Total found C_{14} (%)	[redacted]	[redacted]
Bound residues (%)	[redacted]	[redacted]
Tebuconazole (%)	[redacted]	[redacted]
Metabolite STJ5702 (%)	[redacted]	[redacted]
Metabolite KFE1224 (%)	[redacted]	[redacted]
Metabolite HWG3877 (%)	[redacted]	[redacted]
Metabolite HWG2685 (%)	[redacted]	[redacted]
Metabolite SN3678-7/A+B* (%)	[redacted]	[redacted]
Triazole (%)	[redacted]	[redacted]
Unknown (%)	[redacted]	[redacted]

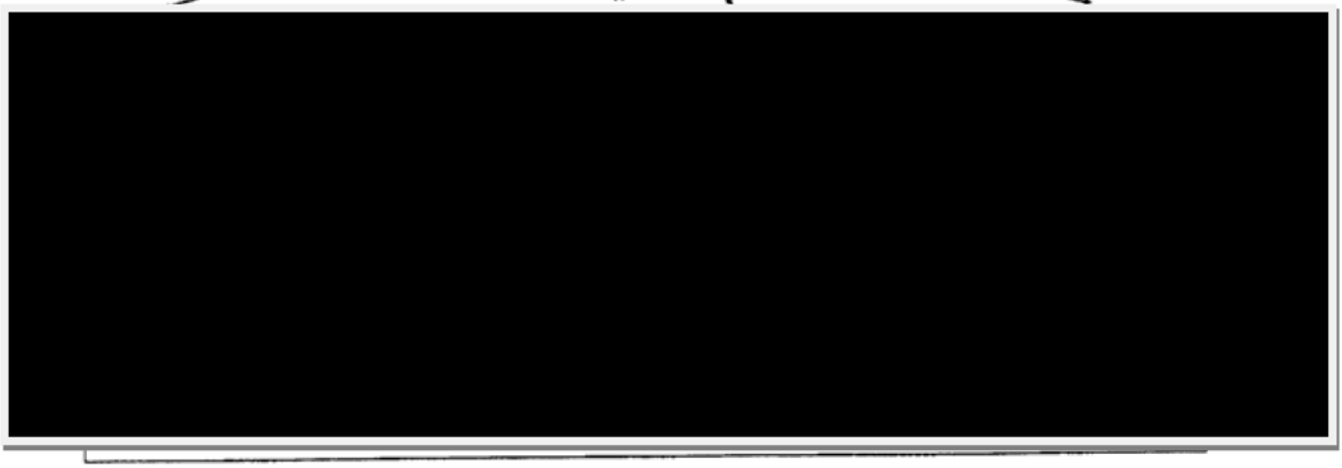
*Proposal based on mass spectrometry

Appendix 1:

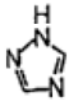
Proposed Metabolic Pathway of Tebuconazole in the Upper Soil Layer

Tebuconazole





Triazole



CO_2

*) Proposal based on MS- and NMR-Spectrometry

Section A7.2.2.1 Aerobic degradation in soil

Annex Point IIIA XII 1.1 (1,2,4-triazole)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Slangen, P.J., 2000, Degradation of 1,2,4-triazole in three soils under aerobic conditions, NOTOX, s-Hertogenbosch (The Netherlands), unpublished report No. MM 71	
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**	Commission Directive 95/36/EC Annex I, 7.1.1.2.1, EEC amending Council Directive 91/414/EEC, Annex II: Part A, 7.1.1 SETAC, Procedures for assessing the environmental fate and ecotoxicity of pesticides Part 1, 1.1 aerobic degradation	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
3.1	**Test material**	[3,5 ^{14}C]-1,2,4-triazole	
3.1.1	Lot/Batch number	Identification number 94923	
3.1.2	Specification		
3.1.3	Purity	Radiochemical purity [redacted] chemical purity [redacted]	
3.1.4	Further relevant properties	Specific radioactivity: 9.65 MBq/mg	
3.1.5	Method of analysis	Purity was measured by radio-TLC and radio-HPLC, chemical purity with GC-FID	
3.2	**Reference substance**	See table A7_2_2_1-2	
3.2.1	Method of analysis for reference substance	Certified by study sponsor, not specified in the report	
3.3	**Soil types**	See table A7_2_2_1-1	
3.4	**Testing procedure**		

Section A7.2.2.1 Aerobic degradation in soil

Annex Point IIIA XII 1.1 (1,2,4-triazole)

3.4.1	Test system	
3.4.1.1	Aerobic soil metabolism	For each type of soil 16 portions (14 for incubation with test substance, 2 for determination of biomass) of 100 g oven dry weight equivalent moist soil were weighed out in 1 L brown glass metabolism flasks, for equilibration at 20 °C ± 2 °C. Humidified air reduced in CO2 content was passed through the vessels. The flasks were kept at approx. 40 % of their water holding capacity by adding deionized water. At the end of an equilibration period of 7 days the soils were treated with 1 mL of the test solution. The soil was thoroughly mixed with a spatula. Mixing was repeated on day 1 and 2. The air leaving the metabolism flasks was passed through two traps (traps A and B) containing a solution of sodium hydroxide for trapping carbon dioxide followed by one trap containing 2-methoxy-ethanol for tapping volatiles (trap C). The moisture content of the soil was kept at approx. 40 % of the water holding capacity throughout the incubation period by checking moisture loss and adding water when necessary. After 0, 1, 3, 7, 14, 30, 61 and 120 days of incubation (in the case of soil Laacherhof AIII also after 83 days) a metabolism vessel with its traps was removed from the incubation system. Each sample was extracted three times: 1st step: Extraction by shaking with a mixture of 56 mL of methanol and 14 mL of water. 2nd step: Two times extraction by shaking with 70 mL of methanol. 3rd step: Extraction in a Soxhlet extraction apparatus with 250 mL of methanol for one hour. Extracts from shaking extraction were centrifuged. Each supernatant was separately weighed. Its radioactivity was determined in an aliqout by LSC. The combined shaking extracts were concentrated by evaporation (not to dryness). The Soxhlet extract was weighed and concentrated and its radioactivity determined by LSC. The composition of the extracts was determined by TLC combined with radiography scanning. The identity of metabolites and of 1,2,4-triazole was determined by co chromotography, with reference substances on selected samples. Residual radioactivity remaining after extraction in the soil was determined by combustion in an oxidizer followed by LSC of the trapped carbon dioxide. The sodium hydroxide solutions of the traps were weighed and their radioactivity determined in an aliquot by LSC. The identity of the radioactivity as ^{14}C-CO_2 was ensured by precipitation as barium carbonate in the solutions from the first trap of the samples from day 120. Volatiles others than carbon dioxide were estimated by determining the weight of the 2-methoxyethanol and measuring its radioactivity in an aliquot.
3.4.1.2	Anaerobic soil metabolism	Not applicable
3.4.2	Test solution and Test conditions	Radioactive labelled 1,2,4-triazole was dissolved in water (stock solution). The test solution was made by a second dilution step with water to a concentration of 6.11 µg/mL (59.0 kBq/mL) of 1,2,4-triazole.

Section A7.2.2.1 Aerobic degradation in soil

Annex Point IIIA XII 1.1 (1,2,4-triazole)

4 RESULTS

4.1	**Aerobic soil metabolism**	See table A7_2_2_1-3.
Anaerobic soil metabolism		Not applicable.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The aerobic degradation of radiolabelled 1,2,4-triazole was studied in a laboratory in three soils. The properties of the studied soils, Laacher Hof A III, Laacher Hof AXXa and BBA 2.2 are given in Table A7_2_2_1-1. The study was conducted for 120 days at 20 + 2 °C in the dark at a moisture content of approximately 40 % of the water holding capacity. Triazole was applied at a concentration of about 0.06 mg/kg dry soil which is equivalent to an application rate of triazole-releasing fungicides of 750 g/a.i./ha (reaching the soil for 50 %, incorporation in 5 cm of soil and assuming a soil bulk density of 1500 kg/m^3, a maximum metabolite formation of 50 % and a molar mass ratio of 1,2,4-triazole to parent of 0.25). Samplings were taken after 0, 1, 3, 7, 14, 30, 61 and 120 days of the incubation. The soil microbial biomass was determined before and at the end of the experiment. Radioactive CO_2, organic volatiles, extracted residues and unextracted residues were recorded.
5.2	**Results and discussion**	
5.2.1	DT50 values	See Table A7_2_2_1/-4
5.2.2	Degradation products (% of a.s.)	The extracts contained up to 7 % of the applied radioactivity as triazole acetic acid (TAA) (soil Laacherhof AXXa after 30 days) and 2.6 % as 1,2 dihydro-1,2,4 triazolone (soil Laacherhof A III, day 14). These metabolites declined afterwards and could not be detected any longer.
5.2.3	Bound residues	Maximum: 74.6% (soil Laacherhof AXXa after 61 days), 69.8% (soil BBA 2.2 after 30 days) 61.6% (soil Laacherhof A III after 30 days) see Table A7_2_2_1-3
5.2.4	CO_2 formation	Maximum: 19.6% (soil Laacherhof AXXa after 120 days), 1.6% (soil BBA 2.2 after 120 days) - 33.7% (soil Laacherhof AIII after 120 days), see Table A7_2_2_1-3
5.3	**Conclusion**	1,2,4-Triazole disappeared rapidly from the soil with a DT50 of 8 days.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	

Section A7.2.2.1 Aerobic degradation in soil

Annex Point IIIA XII 1.1

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_2_2_1-1: Classification and physico-chemical properties of soils used

Identity and provenience	Soil type (USDA)	Texture analysis [%]			Org.C [%]	Water-holding capacity	pH ($CaCl_2$)	Microbial biomass
		sand	silt	clay		[g/100 g]		[mgC/kg soil]
Laacherhof AXXa Germany	sandy loam	72.4	22.6	5.0	1.4	34.4	6.4	init.:334 end: 198
BBA2.2 Han-hofen, Germany	loamy sand	78.9	14.4	6.7	2.2	50.0	5.8	init.:294 end: 138
Laacherhof AIII Germany	silt loam	36.9	51.1	12.0	0.98	36.4	6.7	init.:252 end: 138

Table A7_2_2_1-2: Test substance and reference substances

Structural formula	Names used in in report	Purity	Specific radioactivity
	[3,5-^{14}C]1,2,4-triazole	radiochemical [redacted] chemical [redacted]	9.65 MBq/mg
	1,2,4-triazole	[redacted]	unlabelled
[redacted]	[redacted]	used for identification of metabolites	unlabelled
	[redacted]	used for identification of metabolites	unlabelled
	[redacted]	used for identification of metabolites	unlabelled

*) „ * "Indicating labelling position

**) Compound was named hydroxy-triazole in the report of. 1,2-dihydro-1,2,4-triazolone is its tautomer and the predominant form under most conditions.

Table A7_2_2_1-3 Mass balance of 1,2,4 triazole degradation in soil
(*values normalized to % of mean radioactivity recovered on day 0)*

	Carbon dioxide*) [%]			Extractable [%]			Non-extractable [%]			Recovery [%]		
Soil ->	AXXa	BBA 2.2	A III	AXXa	BBA 2.2	A III	AXXa	BBA 2.2	A III	AXXa	BBA 2.2	A III
Day 0				[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Day 0				[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Day 1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Day 3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Day 7	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Day 14	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Day 14	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Day 30	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Day 61	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Day 83			[redacted]			[redacted]			[redacted]			[redacted]
Day 120	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Day 120	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Note: *) Value including trace amounts of volatiles ≤ 0.01%.

Table A7_2_2_1/-4: Degradation half-lives of 1,2,4-triazole in three different soils under laboratory conditions

Soil	Soil type	Organic carbon	Model according ot best fit	DT50-values
Laacherhof AXXa	sandy loam	[redacted]	[redacted]	[redacted]
BBA 2.2	loamy sand	[redacted]	[redacted]	[redacted]
Laacherhof A III	silt loam	[redacted]	[redacted]	[redacted]
			mean	**8.0 days**

Section A7.2.2.2 Field soil dissipation

Annex Point IIIA XII 1.1 Monitoring studies of northern and southern European soils

Official use only

		1 REFERENCE
1.1	**Reference**	a) Sommer, H. (1997): Dissipation of tebuconazole in soils under field conditions (France, Italy). Bayer AG, now Bayer CropScience AG, unpublished report No. RA-2086/95. b) Schramel, O. (2001): Dissipation of tebuconazole (Folicur 250 EW) in soil under field conditions (France, Germany, Great Britain). Bayer AG, now Bayer CropScience AG, unpublished report No. RA-2095/00.
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) Guidelines for the official trial of crop protection products, part IV-4-1 Residence of crop protection products in soil, its degradation, transformation and metabolism, Germany 1986 b) Commission Directive 95/36/EC of l4 July l995 amending Council Directive 91/414/EEC; ECPA Guidance Document on Field Soil Dissipation Studies, D/97/NM/2047 of August l997; SETAC-Europe: Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides, March 1995
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]
		3 MATERIALS AND METHODS
3.1	**Test material**	Tebuconazole 250 WG* formulation *WG = water dispersible granules
3.1.1	Lot/Batch number	various product numbers
3.1.2	Specification	250 g pure active per kg formulation (specification for tebuconazole technical [redacted] % at that time)
3.1.3	Purity	250 g tebuconazole per kg formulation
3.1.4	Further relevant properties	Stability of the used formulations were proven

Section A7.2.2.2 Field soil dissipation

Annex Point IIIA XII 1.1 Monitoring studies of northern and southern European soils

3.1.5	Composition of product	Composition of product not given in report
3.1.6	TS inhibitory to micro-organisms	No, according to the known studies with soil micro-organisms
3.2	**Reference substance**	None
3.3	**Monitoring procedure**	
3.3.1	Soil properties	a) Two Sites in southern Europe: See Table 1, b) Four Sites in northern Europe: See Table 2
3.3.2	Test conditions	In the trials spray applications were done a) Sites in southern Europe: One application with 300 g a.s./ha b) Sites in northern Europe: One application with 400 g a.s./ha.
3.3.3	Application time	For details about the soil surface/crop: See Table 1 and Table 2, resp.
3.3.4	Duration of test	a) Sites in southern Europe: 1 year b) Sites in northern Europe: 2 years
3.3.5	Analytical parameter	The following analytical methods were used to analyse tebuconazole in the soil samples: a) H. Sommer: Method for gas chromatographic determination of tebuconazoIe in soil; Method 00120/001. Principle: Residues are extracted with a ethyl acetate/water mixture and cleaned up by column chromatography on silica gel. Quantitation is performed by gas chromatography (NPD) The limit of quantitation (LOQ) is 20 µg/kg. b) O. Schramel:Method for the determination of the residues of tebuconazole in soil and sediment by HPLC-MS/MS, Method 00708. Principle: Residues were extracted with a acetonitrile/water mixture. Supernatant resulting after centrifugation was directly measured by HPLC-MS-MS. The limit of quantitation (LOQ) is 5 µg/kg. The limit of detection (LOD) is 2 µg/kg.
3.3.6	Sampling	Samples were taken directly following application and up to nine intervals thereafter. The soil cores were taken using a pushing-sampling system down to a depth of 30 cm per sampling interval. Locations of sampling were statistically distributed over the plot to get representative samples. Due to an optimized sampling technique the scattering of data points could be reduced considerably.
3.3.7	Intermediates/ degradation products	Not identified
3.3.8	Controls	Yes; control samples were taken

Section A7.2.2.2 **Field soil dissipation**

Annex Point IIIA XII 1.1 Monitoring studies of northern and southern European soils

3.3.9	Statistics	The data were used for modelling calculations according to: -Guidance Document on Persistence in Soil, EU Document 9188/VI/97 rev. 8, July 2000 and - FOCUS 2000, FOCUS groundwater scenarios in the EU pesticide registration process. FOCUS groundwater Scenarios Workgroup In order to consider the different temperatures in the specific modelling scenarios, an average temperature for each dissipation trial was calculated from the temperature data of the individual time periods. This value was used to calculate a DT50-value normalized to 20 °C. However, this approach is far from optimum as the temperature undergoes long-term changes in the course of the trial. Therefore, temperature corrections of the rate constant should take into account the individual average temperature within each time period. This kind of calculation was performed in a re-evaluation of the original data, supplementing the field dissipation studies (Schad, 2001 and 2002*). The resulting DT50-values referenced to 20 °C from all trials conducted in northern and in southern Europe can be combined to a single mean which will be used for modelling the environmental concentrations after application of tebuconazole. *References for calculations: Schad, Th. (2001): Calculation of temperature referenced first order DT50 values of tebuconazole based on field dissipation studies conducted in Europe. Bayer AG, now Bayer CropScience AG, unpublished report No. MR-554/01 Schad, Th. (2002): Calculation of temperature referenced first order DT50 values of tebuconazole based on field dissipation studies conducted in southern Europe. Bayer AG, now Bayer CropScience AG, unpublished report No. MR-344/02
		4 RESULTS
4.1	**Soil concentrations**	
4.1.1	Half-lives in soil	The mean half-life value for the degradation of tebuconazole in southern European soils was 26 days (See Table 3), whereas a mean DT50 of 57 days was determined in northern Europe (See Table 4). The geometric mean of the DT50-values referenced to 20 C was calculated to be 29.4 d (See Table 5).
4.1.2	Accumulation	Not covered by the study
4.1.3	Other observations	
4.1.4	Controls	No

Section A7.2.2.2 Field soil dissipation

Annex Point IIIA XII 1.1 Monitoring studies of northern and southern European soils

4.1.5	Intermediates/ degradation products	Intermediates were not analysed. Due to the results of other studies the metabolite 1, 2, 4-Triazole is regarded a minor metabolite in soil (< 10%)

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Field trials were undertaken to characterise the dissipation of tebuconazole in southern (2 sites) and northern European (4 sites) soils. The tests were done according the following guidelines.

a) Southern Europe: Guidelines for the official trial of crop protection products, part IV-4-1 Residence of crop protection products in soil, its degradation, transformation and metabolism, Germany 1986

b) Northern Europe: Commission Directive 95/36/EC of l4 July l995 amending Council Directive 91/414/EEC;
ECPA Guidance Document on Field Soil Dissipation Studies, D/97/NM/2047 of August l997;
SETAC-Europe: Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides, March 1995

5.2 Results and discussion

The mean half-life value for the degradation of tebuconazole in southern European soils was 26 days, whereas a mean DT50 of 57 days was determined in northern Europe.

The geometric mean of the DT50-values referenced to 20 C was calculated to be 29.4 d. This value should be used for modelling calculations, as no reliable laboratory data are available for that purpose. According to Tebuconazole appeared to be persistent in soil under laboratory conditions (results of other tests), in contrast to the situation in the field where it proved to be moderately degradable.

5.3 Conclusion

The mean half-life value for the degradation of tebuconazole in southern European soils was 26 days, whereas a mean DT50 of 57 days was determined in northern Europe.

The geometric mean of the DT50-values referenced to 20 C was calculated to be 29.4 d.

5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Section A7.2.2.2 Field soil dissipation

Annex Point IIIA XII 1.1 Monitoring studies of northern and southern European soils

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date *June 2004*

Materials and Methods [redacted]

Results and discussion [redacted]

Conclusion [redacted]

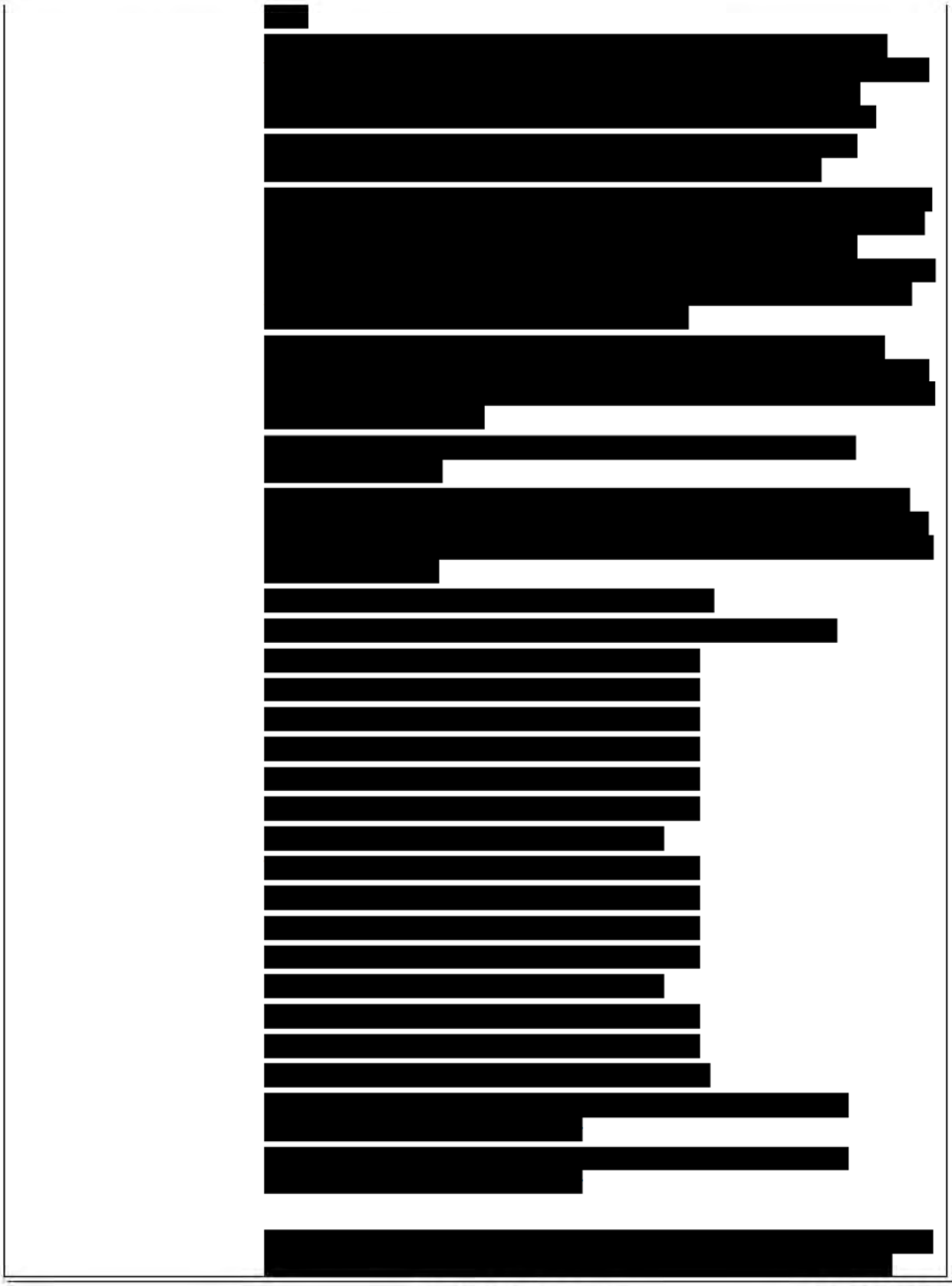
Reliability [redacted]

Acceptability [redacted]

Remarks [redacted]

Section A7.2.2.2 **Field soil dissipation**

Annex Point IIIA XII 1.1 Monitoring studies of northern and southern European soils



Section A7.2.2.2 Field soil dissipation

Annex Point IIIA XII 1.1 Monitoring studies of northern and southern European soils

[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 1: Characterisation of test sites in southern Europe (Sommer 1997) and application procedure:

Trial No.	Test site **Southern Europe**	Soil texture	Soil surface / crop	pH value KCl	org. C [%]	Application rate *) [g a.s./ha]	No. of applications
R 503 932	Pradelle di Nagarole Rocca, Italy	weak loamy sand	bare soil	[redacted]	[redacted]	[redacted]	[redacted]
R 503 940	St. Etienne du Gres, Southern France	loamy silt	bare soil	[redacted]	[redacted]	[redacted]	[redacted]

Note: *) applied as EW 250 formulation

Table 2: Characterisation of test sites in northern Europe (Schramel 2001) and application procedure:

	Test site	Soil texture	Soil surface / crop	pH value	org. C	Application rate *)	No. appli-cations
	Northern Europe		- 1st year - 2nd year	(KCl)	[%]	[g a.s./ha]	
R 2000 0448/6	Bury St. Edmunds, Suffolk (GB)	sandy clay loam	- spring barley - grass	[redacted]	[redacted]	[redacted]	[redacted]
R 2000 0449/4	Vatteville (La Village), northern France	silt sand	- spring barley - grass	[redacted]	[redacted]	[redacted]	[redacted]
R 2000 0550/4	Burscheid (Höfchen), Germany	silt loam	- spring barley - grass	[redacted]	[redacted]	[redacted]	[redacted]
R 2000 0551/2	Monheim (Laacherhof) Germany	sandy loam	- spring barley - grass	[redacted]	[redacted]	[redacted]	[redacted]

Note: *) applied as EW 250 formulation

Table 3: DT50 values calculated from concentration-time data points (Southern Europe)

Trial No.	Test site	No. Of samples	No of Data points	Correlation coefficient R^2	DT50*) [d]
R 503 932	Pradelle di Nagarole Rocca, Italy	[redacted]	[redacted]	[redacted]	[redacted]
R 503 940	St. Etienne du Gres, southern France	[redacted]	[redacted]	[redacted]	[redacted]
				geometric mean	**26**

Notes: *) Calculated according to non-linear first-order kinetics.

Table 4: DT50 values calculated from concentration-time data points (Northern Europe)

Trial No.	Location	No.of samples	No of Data points	DT50*) [d]	Correlation coefficient R^2
R 2000 0448/6	Bury St. Edmunds, (Suffolk),England	[redacted]	[redacted]	[redacted]	[redacted]
R 2000 0449/4	Vatteville (La Village), northern France	[redacted]	[redacted]	[redacted]	[redacted]
R 2000 0550/4	Burscheid (Höfchen), Germany	[redacted]	[redacted]	[redacted]	[redacted]
R 2000 0551/2	Monheim(Laacherhof) Germany	[redacted]	[redacted]	[redacted]	[redacted]
			geometric mean	**57**	

Notes: *) Calculated according to non-linear first-order kinetics.

Table 5: DT50-values referenced to 20 °C calculated from concentration-time–temperature data points

Trial No.	Test site	No.of sam-ples	No of data points	Average tempera-ture	DT50 20 °C [d]	Corre-lation coefficient R^2
	Southern Europe					
R 503 932	Pradelle di Nagarole Rocca, Italy	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
R 503 940	St. Etienne du Gres, southern France	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Northern Europe					
R 2000 0448/6	Bury St. Edmunds, (Suffolk),England	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
R 2000 0449/4	Vatteville (La Village), northern France	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
R 2000 0550/4	Burscheid (Höfchen), Germany	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
R 2000 0551/2	Monheim(Laacherhof) Germany	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
				geometric mean	**29.4**	

Notes: *) Soil temperature averaged over the relevant DT90 period.

**) Average soil temperature during study

Section A7.2.2.2 Field soil dissipation and accumulation

Annex Point IIIA XII 1.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	Allmendinger, 1997, Five year Long-Term Trial for the Determination of Residues of Folicur (250 EC, 250 EW), Institute for Metabolism Research and Residue Analysis, Report No. RA-2106/95, November 07, 1997. For study numbers related to the report see **table 1**.	
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**	No	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Tebuconazole (250 EC* formulation for the first applications, 250 EW** formulation for the rest of the applications) (* EC= emulsifiable concentrate, **EW = emulsion, oil in water)	
3.1.1	Lot/Batch number	various product numbers, see table 1	
3.1.2	Specification	250 g pure active per kg formulation (specification for tebuconazole technical [redacted]% at that time)	
3.1.3	Purity		
3.1.4	Further relevant properties	Stability of the used formulations were proven	
3.1.5	Composition of product	Composition 250 EC: [redacted] tebuconazole (active ingredient) [redacted] [redacted]) Composition 250 EW : [redacted] tebuconazole (active ingredient) [redacted]	

Section A7.2.2.2 Field soil dissipation and accumulation

Annex Point IIIA XII 1.1

[redacted]

3.1.6	TS inhibitory to micro-organisms	No according to the known studies with soil micro-organisms
3.2	**Reference substance**	No
3.3	**Monitoring procedure**	
3.3.1	Soil properties	see **table 2**
3.3.2	Method of preparation of test solution	Application of 1 litre of a EC 250 or EW 250 formulation per ha
3.3.2	Test conditions	For a compilation of climate and other conditions of the field trials see **table 3**
3.3.3	Initial TS concentration	Twice per year 1 l/ha EC /EW 250 was applied. This is equivalent to 250 g / ha tebuconazole for each application resulting in a theoretical concentration of tebuconazole in the upper 30 cm layer of the soil of 0.0558 mg a.i./kg soil dry weight under the assumption of a (dry) soil density of 1.5.
3.3.4	Duration of test	5 years (1991-1995)
3.3.5	Analytical parameter	For tebuconazole analysis, Bayer residue method 00269/M001 was used (Allmendinger 1992). Extraction and clean-up was performed on a RP-18 disposable column using a mini laboratory robot system. The limit of quantitation was 0.02 mg/kg based on soil dry weight. GC analysis was performed with N/P thermoionic detector or a mass selective detector.
3.3.6	Sampling	20 soil cores (50 x 5 cm) taken at each sampling time, 50% of the cores ware taken within row, another 50% between row. Holes were filled with untreated soil and marked to prevent later sampling from the same spot. At harvest straw was removed from the sample spots. The straw was later incorporated into the soil by ploughing. The samples were stored at –18 °C. Prior to analysis, soil cores were cut into 10 cm layers (0-10, 10-20, 20-30 and 30-40). The latter only in trials 505366 and 50374. For analysis samples of 50 g (related to soil dry weight) were used.
3.3.7	Intermediates/ degradation products	Not identified (see also point 4.1.6)
3.3.8	Controls	Soil cores from control soil areas were sampled and analyzed in the same way
3.3.9	Statistics	Not applied

Section A7.2.2.2 Field soil dissipation and accumulation

Annex Point IIIA XII 1.1

		4 RESULTS
4.1	**Soil concentrations**	
4.1.1	a.i. concentration in soil	see **table 4**
4.1.2	Accumulation	see **table 5**
4.1.3	Other observations	
4.1.4	Controls	No tebuconazole was found in the samples from the control area
4.1.5	Intermediates/ degradation products	Intermediates were not analyzed. Due to the results of other studies the metabolite 1, 2, 4-Triazole is regarded a minor metabolite in soil (< 10 %)
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	A study was conducted in the United states to determine the residue levels in soil and the behaviour following multiple applications of tebuconazole to winter wheat over 5 seasons. Folicur (as 250 EC or 250 EW) was applied seasonally in two spring applications to winter wheat at an application rate of 1 litre product / hectare. The trials started in 1991 at two test sites in England (Bury St. Edmunds, Suffolk and Wellesbourne, Warwick). Soil cores down to 50 cm were taken at harvest, in autumn and in early spring. Prior to analysis, they were cut into 10 cm layers. For tebuconazole analysis, Bayer residue method 00269/M001 was used. Extraction and clean-up was performed on a RP-18 disposable column using a mini laboratory robot system. Gas chromatographic analysis followed. The limit of quantitation was 0.02 mg/kg.
5.2	**Results and discussion**	After 5 years, tebuconazole was found mainly in the 0-10 cm layer. Incorporation by ploughing resulted in a transfer of a.i. into the 10-20 cm layer. In deeper layers tebuconazole was not observed. Typically highest residues were in the harvest samples, the shortest time after the preceding application. Tebuconazole declined moderately in soil with no tendency to accumulate. A plateau of 0.03 to 0.006 mg/kg (calculated for a 0-30 cm layer) is reached in the autumn samples. In the autumn samples of the fifth trail year, 90% of the total applied amount of tebuconazole have been degraded, whereas about 10% remained in the soil.
5.3	**Conclusion**	The study shows that in natural soils covered with vegetation, a duplicate application of tebuconazole ends up in a plateau with a tebuconazole concentration of about 0.05 mg/kg dry weight. The studies are well documented with respect to all parameters therefore the reliability of the study is regarded as high.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Section A7.2.2.2 Field soil dissipation and accumulation

Annex Point IIIA XII 1.1

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 ...
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 1: **Study numbers, applied formulations and locality / year of the study**

Study No	Formulation	Product No./ Batch resp. Fl. No	Study Content
[redacted]	250 EC	[redacted]	Suffolk 1991
[redacted]	250 EC	[redacted]	Suffolk 1992
[redacted]	250 EC	[redacted]	Suffolk 1992
[redacted]	250 EW	[redacted]	Suffolk 1993
[redacted]	250 EW	[redacted]	Suffolk 1994
[redacted]	250 EW	[redacted]	Suffolk 1995
[redacted]	250 EC	[redacted]	Warwick 1991
[redacted]	250 EC	[redacted]	Warwick 1992
[redacted]	250 EC	[redacted]	Warwick 1992
[redacted]	250 EW	[redacted]	Warwick1993
[redacted]	250 EW	[redacted]	Warwick 1994
[redacted]	250 EW	[redacted]	Warwick1995
		* Bayer Development No.	

Table 2: **Soil criteria**

Criteria	Details
Trial Location A	Elm Farm Development Station, IP 31 3SJ Bury St. Edmunds, Suffolk e.g. activated sludge
Trial Location B	Institute of Horticulture Research, CV 35 9EF Wellesbourne, Warwick
Soil A and B	Agricultural soil, cropped with winter wheat
Soil texture	A: 17.3% clay / 19.1% silt / 63.6% sand = sandy loam (USDA) B 15.1% clay / 14.2% clay / 70.7% sand = sandy loam (USDA)
Soil pH	A: 7.5 / B: 5.7
Soil Organic C content	A: 0.91 / B: 0.89
Soil history with respect to the application of other actives	some other pesticides were applied on the both the treated and the untreated plot

Table 3: Climate and other parameters monitored (detailed data are provided in the report)

Parameter	Frequency etc.
Mean soil temperature (at 10 cm) / Rainfall / Sunshine	for each location and year at least monthly
Pre-treatment	for each location and each year
Essential application data	including: dosage, type of formulation, date of application, wind speed
Application technique	Spraying, details on devices are given
Sampling and Packaging and storage of the samples	All samplings are documented in the report (including growth state of the crop)
Analytical method validation and recovery	done (mean recovery of fortified samples was 82-100 %)
Soil history with respect to the application of other actives	for each area and year

Table 4: Soil concentrations in the treated samples

A = Bury St. Edmunds, B = Wellesbourne *DALT: days after last treatment of the respective year

Study No.	Sample Material	Sample No.	DALT*	Sample Weight (g)	Results of Analysis (mg/kg) Single Values	Mean
101354	0-10	[redacted]	[redacted]	[redacted]	[redacted]	
1991 A		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
	10-20	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
	20-30	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	

Study No.	Sample Material	Sample No.	DALT*	Sample Weight (g)	Results of Analysis (mg/kg) Single Values	Mean
101559 1991 B	0-10	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
	10-20	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
	20-30	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
205362 1992 A	0-10	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
	10-20	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
	20-30	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
205370 1992 B	0-10	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
	10-20	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
	20-30	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	

Study No.	Sample Material	Sample No.	DALT*	Sample Weight (g)	Results of Analysis (mg/kg) Single Values	Mean
305367 1993 A	0-10	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	10-20	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	20-30	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
305375 1993 B	0-10	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	10-20	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	20-30	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
405361 1994 A	0-10	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	10-20	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	20-30	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Study No.	Sample Material	Sample No.	DALT*	Sample Weight (g)	Results of Analysis (mg/kg) Single Values	Mean
405370 1994 B	0-10	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
	10-20	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
	20-30	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
505366 1995 A	0-10	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
	10-20	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
	20-30	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
	30-40	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	

Study No.	Sample Material	Sample No.	DALT*	Sample Weight (g)	Results of Analysis (mg/kg) Single Values	Mean
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
505374 1995 B	0-10	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
	10-20	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
	20-30	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
	30-40	[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	
		[redacted]	[redacted]	[redacted]	[redacted]	

A = Bury St. Edmunds, B = Wellesbourne *DALT = days after last treatment of the respective year

Table 5: Residues in soil over several seasons (calculated for a 30 cm deep soil layer)

Season	Bury St. Edmunds autumn sample [mg/kg]*	Wellesbourne autumn sample [mg/kg]*
1991	[redacted]	[redacted]
1992	[redacted]	[redacted]
1993	[redacted]	[redacted]
1994	[redacted]	[redacted]
1995	[redacted]	[redacted]

* soil dry weight

Theoretical soil concentration of tebuconazole after 10 applications 250 g a.i./ha: 0.556 mg/kg

Section 7.2.2.4 Annex Point IIIA 12.1	Other soil degradation studies	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [...]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X].**	
Detailed justification:	There were other soil degradation studies on tebuconazole submitted which are referred e.g. in the IUCLID.	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*10. 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		

Section A7.2.3 (01) Adsorption / Desorption screening test

Annex Point IIIA XII 1.2

Official use only

1 REFERENCE

1.1	**Reference**	Fritz, R. (1988): Adsorption/Desorption of [R]Folicur (HWG 1608) on soils, Bayer AG, unpublished report No.: 2923
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-guideline § 163-1 of October 18, 1982
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

3.1	**Test material**	As given in section 2
3.1.1	Lot/Batch number	
3.1.2	Specification	As given in section 2
3.1.3	Purity	[redacted]
3.1.4	Further relevant properties	
3.1.5	Method of analysis	Analysis by standard liquid- (LS)-scintillation (liquid), combustion (soil), and TLC (thin-layer chromatographic (metabolites) method as described in section A4
3.2	**Degradation products**	Degradation products tested: Yes At any time during the test all degradation products account for < 4% of the a.s. added.
3.2.1	Method of analysis for degradation products	No degradation products were tested
3.3	**Reference substance**	No

Section A7.2.3 (01) Adsorption / Desorption screening test

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3.3.1	Method of analysis for reference substance	
3.4	**Soil types**	Available data are given in table A7_2_3-1
3.5	**Testing procedure**	
3.5.1	Test system	Adsorption and desorption of Folicur (HWG 1608) was measured using a batch equilibrium procedure (based on EPA guideline § 163-1) to determine the Kd and Koc values of [phenyl-U-^{14}C]HWG 1608 in four soils.
3.5.2	Test solution and Test conditions	The test substance HWG 1608 was tested in a concentration range of 1.6 to 16 mg/l
3.6	**Test performance**	
3.6.1	Preliminary test	According to the OECD guideline 106 Equilibration: as given in guideline
3.6.2	Screening test: Adsorption	According to the OECD guideline 106
3.6.3	Screening test: Desorption	Not according to the OECD guideline 106
3.6.4	HPLC-method	Not performed
3.6.5	Other test	Advanced test according to OECD 106
	4 RESULTS	
4.1	**Screening test**	The obtained solution is acceptable; the applicability of the method to the test substance HWG 1608 is given.
4.2	**Screening test: Adsorption**	Solid volume: 2 g (dry weight) Supernatant volume: 20 ml Degree of adsorption: varied between 28 and 67%, depending upon the investigated soil
4.3	**Screening test: Desorption**	Desorption tests showed that depending upon the investigated soil class between 44 and 78% of the adsorbed amount of parent compound were desorbed.

Section A7.2.3 (01) Adsorption / Desorption screening test

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4.4	**Calculations:**				
4.4.1	Ka , Kd	Soil type	Ka (mg/g)	Kd (mg/g)	
		Sandy loam soil (greenhouse soil)	12.69	18.77	
		Silt soil (Höfchen)	16.39	22.27	
		Sandy soil (BBA 2.1)	7.69	11.83	
		Sandy loam soil (Monheim I)	15.89	23.76	
4.4.2	Ka_{OC} , Kd_{OC}	Soil type	Ka_{oc} (mg/g)	Kd_{oc} (mg/g)	
		Sandy loam soil	906	1341	
		Silt soil	911	1237	
		Sandy soil	1025	1577	
		Sandy loam soil	1251	1871	
4.5	**Degradation product(s)**	No degradation product(s) occur in a significant amount (> 5% of a.s.)			

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test system is described in 3.5.1 (batch equilibrium procedure); the EPA guideline is given in 2.1. No relevant deviations from the guideline occurred.	X
5.2	**Results and discussion**	The test material-specific properties (e.g. solubility, stability, volatility, specific activity, radiochemical purity) are not expected to have any impact on results. The obtained results underline the known properties of the test substance HWG 1608 as found in the literature and prior testing. With regard to its low soil leaching behaviour, the results confirm the immobility of the test substance in soils.	X
5.2.1	Adsorbed a.s. [%]	The percentage adsorption of test substance varied between 20 and 67% of the applied a.i. depending on soil type and concentration.	
5.2.2	K_a	Between 7.69 and 16.39 mg/g	
5.2.3	K_d	Between 11.83 and 23.76 mg/g	
5.2.4	Ka_{oc}	Between 906 and 1251 mg/g	
5.2.5	Ka/Kd	0.7	

Section A7.2.3 (01) Adsorption / Desorption screening test

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5.2.6	Degradation products (% of a.s.)	All degradation products revealed are < 5%	
5.3	**Conclusion**	On the basis of these findings HWG 1608 should be classified as being of low mobility to immobile in soils. Folicur is partly reversibly adsorbed to the soil. The results of this study agree very well with those of leaching tests with packed columns.	X
5.3.1	Reliability	[redacted]	X
5.3.2	Deficiencies	[redacted]	X

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 A7.2.3 (01) Adsorption / Desorption screening test

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	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_2_3-1: Classification and physico-chemical properties of soils used as adsorbents

	Soil 1	Soil 2	Soil 3	Soil 4
Soil order				
Soil series				
Classification	Sandy loam soil	Silt soil	Sandy soil	Sandy loam soil
Location	Kansas	Burscheid (FRG)	Jockgrim (FRG)	Monheim (FRG)
Horizon			0 –30 cm	
Sand [%]	67	2	87.8	58.6
Silt [%]	27	89	8.7	28.1
Clay [%]	6	9	3.5	13.2
Organic carbon [%]	1.4	1.8	0.75	1.27
Carbonate as $CaCO_3$ [%]				
insoluble carbonates [%]				
pH (in 0.01 m $CaCl_2$)	5.2	5.3	5.6	5.2
Cation exchange capacity (MEQ/100 g)	22	10.5	4	7.5
Extractable cations (MEQ/100 g)				
Ca				
Mg				
Na				
K				
H				
Special chemical/mineralogical features				
Clay fraction mineralogy				

Table A7_2_3-2: Results of preliminary test

Test substance	Folicur
Sample purity	[redacted]
Weighed soil	1, 2, and 4 g
Volume of $CaCl_2$ solution	20 ml
Nominal concentration of a.s. final solution	16 mg/l
Analytical concentration final of a.s. solution	-
Concentration of the test solution (show calculation)	-
Details of the analytical method used:	
Method	Liquid – (LS)- scintillation measurements and combustion of the soil
Recovery rate	91 – 95%
Detection limit	-

Table A7_2_3-3: Results of screening test - adsorption

	Soil 1				Soil 2			
Concentration of test material [mg/l]	[redacted]							
After contact of 48 hours with soil [µg in 20 ml]	[redacted]							
Correction for blank with soil	[redacted]							
Correction for blank without soil	[redacted]							
Final corrected concentration [mg/l]	[redacted]							
Initial concentration of test solution [mg/l]	[redacted]							
Decrease in concentration [mg/l]	[redacted]							
Quantity adsorbed [µg]	[redacted]							
Quantity of soil [g of oven-dried equivalent]	[redacted]							
Quantity adsorbed [µg] per gram of soil	[redacted]							
Test material adsorbed [%]	[redacted]							
Temperature [°C]	[redacted]							
Volume of solution recovered after centrifugation [ml]	[redacted]							
Volume of solution not recovered [ml]	[redacted]							
Corresponding quantity of test substance [mg]	[redacted]							

Table A7_2_3-3: **Results of screening test – adsorption (continued)**

	Soil 3				Soil 4			
Concentration of test material [mg/l]								
After contact of 48 hours with soil [µg in 20 ml]								
Correction for blank with soil								
Correction for blank without soil								
Final corrected concentration [mg/l]								
Initial concentration of test solution [mg/l]								
Decrease in concentration [mg/l]								
Quantity adsorbed [µg]								
Quantity of soil [g of oven-dried equivalent]								
Quantity adsorbed [µg] per gram of soil								
Test material adsorbed [%]								
Temperature [°C]								
Volume of solution recovered after centrifugation [ml]								
Volume of solution not recovered [ml]								
Corresponding quantity of test substance [mg]								

Table A7_2_3-4: **Results of screening test - desorption**

	Soil 1				Soil 2			
	1.6	8	12	16	1.6	8	12	16
Temperature [°C]								
Concentration in combined washings [mg/l]								
Corresponding quantity of test material [mg]								
Quantity desorbed [µg]								
[%] of adsorbed test material, which is desorbed								
[%] of adsorbed test material, which is not desorbed								

Table A7_2_3-4: Results of screening test – desorption (continued)

	Soil 3				Soil 4			
Temperature [°C]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Concentration in combined washings [mg/l]								
Corresponding quantity of test material [mg]								
Quantity desorbed [µg]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[%] of adsorbed test material, which is desorbed	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[%] of adsorbed test material, which is not desorbed	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Section A7.2.3 (02) Adsorption / Desorption screening test

Annex Point IIA XII 1.2

Official use only

1 REFERENCE

1.1	**Reference**	Fritz, R. (1993): Adsorption/desorption of Tebuconazole on Lysimeter Soils Originating from "Borstel" and "Laacherhof" Bayer AG, unpublished report No.: 3875
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-guideline § 163-1 of October 18, 1982
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

3.1	**Test material**	As given in section 2
3.1.1	Lot/Batch number	
3.1.2	Specification	As given in section 2
3.1.3	Purity	[redacted]
3.1.4	Further relevant properties	
3.1.5	Method of analysis	Analysis by standard liquid- (LS)-scintillation (liquid), combustion (soil), and TLC (thin-layer chromatographic (metabolites) method as described in section A4
3.2	**Degradation products**	Degradation products tested: Yes No degradation product was found. The entire measured radioactivity could be assigned to unchanged parent compound.
3.2.1	Method of analysis for degradation products	No degradation products were tested
3.3	**Reference substance**	No

Section A7.2.3 (02) Adsorption / Desorption screening test

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3.3.1	Method of analysis for reference substance	
3.4	**Soil types**	Available data are given in table A7_2_3-1
3.5	**Testing procedure**	
3.5.1	Test system	Adsorption and desorption of tebuconazole was measured using a batch equilibrium procedure (based on EPA guideline § 163-1) to determine the Kd and Koc values of [triazole-3,5-^{14}C]tebuconazole in two soils. Portions of 4 g of soils were weighed into 43 ml. centrifuge tubes with screw cap, treated with 20 ml application solutions and shaken (25 rpm) for 48 hours. After the end of the shaking period, the samples were centrifuged for about 15 min (> 5000 g) and the aliquots of the clear supernatant were removed for LS-measurement.
3.5.2	Test solution and Test conditions	The test substance tebuconazole was tested in a concentration range of 1.91, 9.36, 13.97, and 18.01 mg/l. Soil/water ratio was 4 g soils (dry weight) and 20 ml 0.01 M $CaCl_2$ solution (1:5). Adsorption tested after 48 hours.
3.6	**Test performance**	
3.6.1	Preliminary test	Was not performed. Set up was based on previous adsorption/desorption tests, the equilibration time was assumed to be 48 hours.
3.6.2	Screening test: Adsorption	According to the OECD guideline 106
3.6.3	Screening test: Desorption	Performed. Not according to OECD guideline 106 since only one washing of the soil was performed. The soil was treated with 20 ml $CaCl_2$ solution and shaken for 48 hours. After centrifugation (15 min, > 5000 g), the radioactivity content of the clear supernatant was determined. The radioactivity of the soil was measured by combustion.
3.6.4	HPLC-method	Not performed
3.6.5	Other test	

4 RESULTS

4.1	**Screening test**	Not performed
4.2	**Screening test: Adsorption**	Summarize results in tabular form (see table A7_2_3-3) Degree of adsorption to soil "Borstel" range from 62% to 74% depending upon the tested concentrations of active ingredient. The proportion of active ingredient being adsorbed to soil "Laacherhof" range from 56% to 71%, depending upon the concentrations of active ingredient

Section A7.2.3 (02) Adsorption / Desorption screening test

Annex Point IIA XII 1.2

4.3 Screening test: Desorption

Summarize results in tabular form (see table A7_2_3-4). The desorption tests showed desorption rates of 21 – 39% as a function of the soil and the respective concentrations of active ingredient

4.4 Calculations:

4.4.1 Ka , Kd

Soil type	Ka (mg/g)	Kd (mg/g)
Sandy loam soil (Borstel)	12.69	16.80
Sandy loam soil (Laacherhof)	10.84	12.03

4.4.2 Ka_{OC} , Kd_{OC}

Soil type	Ka_{oc} (mg/g)	Kd_{oc} (mg/g)
Borstel	1057	1400
Laacherhof	803	891

4.5 Degradation product(s)

No degradation product(s) occur in a significant amount (> 5 % of a.s.)

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The test system is described in 3.5.1 (batch equilibrium procedure); the EPA guideline is given in 2.1. No relevant deviations from the guideline occurred. X

5.2 Results and discussion

The test material-specific properties (e.g. solubility, stability, volatility, specific activity, radiochemical purity) are not expected to have any impact on results. The obtained results underline the known properties of the test substance tebuconazole as found in the literature and prior testing. With regard to its low soil leaching behaviour, the results confirm the immobility of the test substance in soils. X

5.2.1 Adsorbed a.s. [%]

The percentage adsorption of test substance varied between 56 and 74% of the applied a.i. depending on soil type and concentration.

5.2.2 K_a

Between 10.84 and 12.69 mg/g

5.2.3 K_d

Between 12.03 and 16.80 mg/g

5.2.4 Ka_{oc}

Between 803 and 1057 mg/g

5.2.5 Ka/Kd

0.8 –0.9

Section A7.2.3 (02) Adsorption / Desorption screening test

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5.2.6	Degradation products (% of a.s.)	All degradation products revealed are < 5%	
5.3	**Conclusion**	On the basis of these findings tebuconazole should be classified as being of low mobility to immobile in soils.	X
5.3.1	Reliability	[redacted]	X
5.3.2	Deficiencies	[redacted]	X

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 ...
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_2_3-1: Classification and physico-chemical properties of soils used as adsorbents

	Soil 1	Soil 2
Soil order		
Soil series		
Classification	Sandy loam soil	Sandy loam soil
Location	Borstel, Hannover	Laacher Hof
Horizon	0 – 30 cm	0 – 30 cm
Sand [%]	68.3	72.4
Silt [%]	24.5	22.6
Clay [%]	7.2	5.0
Organic carbon [%]	1.2	1.35
Carbonate as $CaCO_3$ [%]		
insoluble carbonates [%]		
pH (in 0.01 m $CaCl_2$)	5.7	6.4
Cation exchange capacity (MEQ/100 g)	-	-
Extractable cations (MEQ/100 g)		
Ca		
Mg		
Na		
K		
H		
Special chemical/mineralogical features		
Clay fraction mineralogy		

Table A7_2_3-3: Results of screening test - adsorption

	Soil 1				Soil 2			
Concentration of test material [mg/l]								
After contact of 48 hours with soil [µg in 20 ml]								
Correction for blank with soil								
Correction for blank without soil								
Final corrected concentration [mg/l]								
Initial concentration of test solution [mg/l]								
Decrease in concentration [mg/l]								
Quantity adsorbed [µg]								
Quantity of soil [g of oven-dried equivalent]								
Quantity adsorbed [µg] per gram of soil								
Test material adsorbed [%]								
Temperature [°C]								
Volume of solution recovered after centrifugation [ml]								
Volume of solution not recovered [ml]								
Corresponding quantity of test substance [mg]								

Table A7_2_3-4: Results of screening test - desorption

	Soil 1				Soil 2			
Temperature [°C]								
Concentration in combined washings [mg/l]								
Corresponding quantity of test material [mg]								
Quantity desorbed [µg]								
[%] of adsorbed test material, which is desorbed								
[%] of adsorbed test material, which is not desorbed								

Section A7.2.3 Adsorption and desorption of 1,2,4-triazole in soil

Annex Point IIIA XII 1.2

Official use only

		1 REFERENCE
1.1	**Reference**	Hawkins, D.R. (1988): Soil adsorption and desorption of 1,2,4-triazole, Rohm and Haas (USA, unpublished report No. 34S-88-27
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-guideline § 163-1 of October 18, 1982
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]
		3 MATERIALS AND METHODS
3.1	**Test material**	[3,5-^{14}C]-1,2,4-triazole
3.1.1	Lot/Batch number	Lot No. [redacted]
3.1.2	Specification	
3.1.3	Purity	[redacted] (w/w) by TLC mean of [redacted] % by HPLC
3.1.4	Further relevant properties	specific radioactivity 182.4 mCi/ g (≡ 6.75 MBq/ g)
3.1.5	Method of analysis	Radio-TLC, radio-HPLC (determination of purity)
3.2	**Degradation products**	
3.2.1	Method of analysis for degradation products	Not applicable
3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	Not applicable
3.4	**Soil types**	Available data are given in table A7_2_3-1

Section A7.2.3 Adsorption and desorption of 1,2,4-triazole in soil

Annex Point IIIA XII 1.2

3.5 Testing procedure

3.5.1 Test system

Adsorption and desorption of 1,2,4-triazole was measured using a batch equilibrium procedure (based on EPA guideline § 163-1) to determine the Kd and Koc values in five soils.

Identity and provenience (sieved to < 2 mm)	**Soil type** (USDA)	**Soil weight** [g]	**Vol. of test solution** [mL]	**Ratio** (solution : soil)
Alpaugh	silty clay	2	10.0	5:1
Hollister	clay loam	2	8.0	4:1
Lakeland	sand	4	8.0	2:1
Lawrenceville	silty clay loam	2	8.0	4:1
Pachappa	sandy loam	2	6.0	3:1

3.5.2 Test solution and Test conditions

Stock solution with a nominal concentration of 10 mg/L of test substance in water.

Solutions with a nominal concentration of 0.1, 0.05, 0.01 and 0.005 mg/L were prepared by diluting the stock solution with a $CaCl_2$-solution, c($CaCl_2$) = 0.01 mol/L. The exact concentration of each of the solutions was determined by liquid scintillation counting (LSC) to be 0.086, 0.043, 0.0085 and 0.0043 mg/l.

Tests were performed at a temperature of 25 ± 1°C

3.6 Test performance

3.6.1 Preliminary test

Not performed

3.6.2 Screening test: Adsorption

Triplicate measurements for each soil and for each concentration level were prepared. The suspension of soil in water was shaken for 95 hours. After termination of the shaking period the suspension was centrifuged, the supernatant decanted into a graduated cylinder and its volume recorded. Aliquots of the clear supernatant were measured by liquid scintillation measurement. From the triplicate set of samples one soil sample was air dried and its radioactivity measured by combustion in order to check the recovery.

3.6.3 Screening test: Desorption

Two of the soil samples were used for measuring the desorption equilibrium. After the supernatant had been removed fresh $CaCl_2$-solution, c($CaCl_2$) = 0.01 Mol/L was added using the same volume as had been used for the adsorption step. The mixture was shaken for 46 hours and then treated in the same way as described above. The total process of desorption was then repeated. After fresh $CaCl_2$-solution had been added it was shaken for 24 hours, centrifuged, the supernatant

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		removed and its radioactivity measured in an aliquot. The soil sample was air dried and its radioactivity measured by combustion.
3.6.4	Methods	LSC, combustion and radioassay
3.6.5	Other test	Stability of test compound in test system determined by HPLC

4 RESULTS

4.1	**Screening test**	The recoveries from the stability test amounted to 102 ± 7 % of the expected value (average of all tested supernatants).
4.2	**Screening test: Adsorption**	The adsorption coefficients Ka ranging from 0.234 mL/g to 0.833 mL/g corresponded to Koc–values between 43 mL/g and 202 mL/g, with a mean value of 112 mL/g and a standard deviation of 58. The exceptionally high value obtained for the soil Lakeland sand is discarded as an outlier due to the low organic carbon content of the soil. The corresponding value is 89 mL/g, with a Freundlich coefficient of 0.91.
4.3	**Screening test: Desorption**	The Kd values for desorption were much higher than those for adsorption and ranged from 0.61-2130 mL/g indicating that some of the triazole may be irreversibly bound to the soils resulting in a lower mobility than predicted by the adsorption coefficients. Particularily, the values from 2nd desorption step are not valid. The concentrations of 1,2,4 triazole in the soils were lower than the results calculated from combustion analysis of the soil.

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4.4 Calculations:

4.4.1 Ka , Kd

Soil type	Ka (mg/g)	Kd, 1st desorption (mg/g)
Alpaugh, silty clay	0.833	2.130
Hollister, clay loam	0.748	1.143
Lakeland, sand	0.234	0.610
Lawrenceville, silty clay loam	0.722	0.816
Pachappa, sandy loam	0.720	1.065

4.4.2 Ka_{OC} , Kd_{OC}

Soil type	Ka_{oc} (mg/g)	Kd_{oc}, 1st desorption (mg/g)
Alpaugh, silty clay	120	306
Hollister, clay loam	43	66
Lakeland, sand	202	526
Lawrenceville, silty clay loam	104	117
Pachappa, sandy loam	89	131

4.5 Degradation product(s)

Not analysed, the stability of the test compound was measured to be 102.4 %.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The test system is described in 3.5.1 (batch equilibrium procedure); the EPA guideline is given in 2.1. No relevant deviations from the guideline occurred.

5.2 Results and discussion

The adsorption coefficients Ka ranging from 0.234 mL/g to 0.833 mL/g corresponded to Koc–values between 43 mL/g and 202 mL/g, with a mean value of 112 mL/g and a standard deviation of 58. If the exceptionally high value obtained for the soil Lakeland sand (202 mL/g) is discarded due to the low organic carbon content of the soil, the corresponding value is 89 mL/g, with a Freundlich coefficient of 0.91.

5.2.1 Adsorbed a.s. [%]

5.2.2 K_a From 0.234 mL/g to 0.833 mL/g

5.2.3 K_d From 0.61 mL/g and 2130 mL/g

5.2.4 Ka_{oc} From 43 mL/g and 120 mL/g (mean 89 mL/g)

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5.2.5	Ka/Kd	Not determined due to the diverging results in desoprtion indicating that some of the triazole may be irreversibly bound to the soils resulting in a lower mobility than predicted by the adsorption coefficients.
5.2.6	Degradation products (% of a.s.)	Not analysed, the stability of the test compound was measured to be 102.4 %.
5.3	**Conclusion**	On the basis of these findings 1,2,4-triazole should be classified as being of intermediate mobility in soils. The high desorption coefficients indicate that part of the 1,2,4-triazole may be bound to the soil irreversibly and therefore result in a lower mobility than predicted by the adsorption coefficients.
5.3.1	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*
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_2_3-1: Classification and physico-chemical properties of soils used as adsorbents

	Alpaugh	Hollister	Lakeland	Lawrenceville	Pachappa
Soil order	1	2	3	4	5
Classification (USDA)	Silty clay	Clay loam	sand	Silty clay loam	Sandy loam
Sand [%]	11	26	91	9	62
Silt [%]	44	46	0	62	21
Clay [%]	45	28	9	29	17
Organic carbon [%] *	0.70	1.74	0.12	0.70	0.81
Carbonate as $CaCO_3$ [%]	n.a.	n.a.	n.a.	n.a.	n.a.
insoluble carbonates [%]	n.a.	n.a.	n.a.	n.a.	n.a.
pH (in 0.01 m $CaCl_2$)	8.8	6.9	4.8	7.0	6.9
Cation exchange capacity (MEQ/100 g)	30.5	16.9	1.2	6.6	11.1
Extractable cations (MEQ/100 g)	n.a.	n.a.	n.a.	n.a.	n.a.

* calculated from data given in the report considering a factor of 1/1.724 to convert %OM in %OC

Section A7.2.3.2 Aged residues soil leaching study

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Official use only

1 REFERENCE

1.1	**Reference**	Smyser, B.P. & Lenz, C.A., 1987, Leaching of Aged Residues of ®FOLICUR-^{14}C, Mobay Corporation Agricultural Chemicals Division Research and Development Department, Kansas City, Missouri, Report Number 94801, August 10, 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**	
2.2	**GLP**	[redacted]
2.3	**Deviations**	

3 MATERIALS AND METHODS

3.1	**Test material**	Radioactive tebuconazole (UL-^{14}C-Chlorophenyl) was used.
3.1.1	Lot/Batch number	Vial [redacted] synthesized by Morgan and Koch
3.1.2	Specification	As given in section 2
3.1.3	Purity	[redacted]
3.1.4	Further relevant properties	
3.1.5	Method of analysis	The leachate was collected and assayed for radioactivity by LSC. Each soil segment was assayed for radioactivity by oxidation to $^{14}CO_2$ and LSC. Soil samples were extracted with methanol/water (30% water) and methanol. Extracts were pooled and analysed by TLC, MS and HPLC.
3.3	**Reference substance**	Yes
3.3.1	Method of analysis for reference substance	TLC
3.4	**Soil types**	Five soil types were used, see table A7_2_3_2-1

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3.5	**Testing procedure**	
3.5.1	Test system	Sandy loam was incubated under aerobic conditions for 30 and 90 days with 8.8 and 10.4 mg UL-^{14}C-Chlorophenyl/kg soil respectively. The soil was adjusted to a moisture content of 75% 1/3 bar. The treated soil was placed in amber glass jars with a connected trap to retain any volatile components. Following the ageing process the soil was divided into 40g sub samples and stored frozen until the soil columns were prepared. Sub samples of the aged soil were then transferred to glass soil columns (5.4 cm in diameter and 44.5 cm tall) containing five different types of soil. Duplicate columns of each soil type at each ageing interval were prepared. The columns were then leached for two days with 1100 ml 0.01 M calcium chloride solution equivalent to 500 mm rainfall. After leaching the soil column were divided 6 cm segments.
3.5.2	Test solution and Test conditions	The radioactive labelled tebuconazole was dissolved in ethyl acetate.
	4 RESULTS	
4.1		See table A7_2_3_2-2
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Sandy loam was incubated for 30 and 90 days with app. 10mg tebuconazole/kg. Sub samples of the aged soil were then transferred to soil columns containing five different types of soil. The columns were then leached over 2 day's period with app. 500mm rainfall.
5.2	**Results and discussion**	No radioactivity was lost due to volatilization. Less than 1% of radioactivity was found in the eluate. The total recovered radioactivity ranged between 84.7-128.5%. Most of the applied radioactivity stayed in the aged soil layer or in the 0-6 cm segment. The combined aged soil layer and 0-6 cm segment contained a minimum of 71% of applied radioactivity. Silty clay was the soil with most radioactivity found below the 0-6 cm segment, with a maximum of 14.2%. Most radioactivity extracted was identified as tebuconazole (78.6-87.7%), bound residues accounted for 9.5-16-5%. Generally there was no difference between the 30 day and the 90 day aged soil.
5.3	**Conclusion**	Less than 1% of the aged residues leached through soil columns. This demonstrates that tebuconazole and its aged residues are relatively immobile and have little potential to contaminate ground water.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	