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128997

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Subject: Terbuconazole New Chemical Standard

To: Susan Lewis
Product Manager 21
Registration Division (H7505C)

Hank Jacoby 9/18/90

From: Hank Jacoby, Chief
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

and

Henry Nelson
Acting Section Head, Review Section 3
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

H Nelson 9/12/90

Attached is the EFGWB science chapter for Terbuconazole. The chapter takes into account *proposed* uses as a seed treatment on wheat, barley, and peanuts, and as a treatment for grapes, and existing uses on lawns, turf, and grass grown for seed.

ENVIRONMENTAL FATE ASSESSMENT

Based on fairly extensive data, terbuconazole is persistent and relatively immobile. It is resistant to hydrolysis, aqueous photodegradation, and soil metabolism, but slowly photodegraded on soil. Unaged terbuconazole shows little mobility (K_d s of adsorption ranged from 7 - 16 in laboratory studies on a variety of soils). Aged material was still largely parent compound, and showed little tendency to move beyond the upper 6 cm of the soil column in laboratory studies. An unsatisfactory field dissipation study with bare-ground application indicated some movement in areas of sand soil in Florida. Uptake into plants may be a significant means of dissipation. There is accumulation of the triazolyl moiety into all confined crops tested (small grain, leafy vegetable, and root crops planted 30, 120, and 273 days after treatment). Chlorophenyl-labelled material was not tested. Field data also showed accumulation in some crop materials. Accumulation into fish also occurs with rapid depuration (BCFs of 25, 229, and 99 for edible tissue, non-edible tissue, and whole fish respectively).

There are several areas of concern which have been noted. Since the compound is persistent, some *phytotoxicity* to subsequent non-target crops planted on treated soil could occur. EFGWB defers to Ecological Effects Branch on this issue. Based on the current use on turf and seed grass, and the proposed uses on grapes and for seed treatment, under most conditions terbuconazole is considered unlikely to reach *ground water*. However, like most chemicals, it does have the potential to contaminate ground water in extremely vulnerable areas (high water table, sandy soil with low organic matter). Because of its tendency to remain adsorbed to soil, terbuconazole may move off-target into adjacent *surface water* during a storm event that produces soil erosion.

GROUND WATER ASSESSMENT

It should be noted, in considering the following environmental fate characteristics, that terbuconazole is a relatively low-dosage pesticide, used at a seasonal limit of 1.35 lb a.i. [1.35 ppm for a 3" soil layer]/A for turf and seed grass. 0.9 lb a.i. [0.9 ppm]/A is proposed for use on grapes. Proposed seed treatments are ca. 0.03 lb/100 lb seed, and expected planting rates are 35 - 150 lb of seed/A. Therefore a maximum of 0.045 lb a.i./A would result from use of treated seed.

According to available information, terbuconazole is highly stable to environmental degradation, both chemical and biological, with half-lives up to several years.

It is relatively immobile (K_d ads 7 - 16) in batch equilibrium studies on unaged compound.

After 30 days aging, the radiolabelled material is still more than 80% parent terbuconazole. In column leaching studies on "aged" compound, 35 - 60% eluted out of the treated layer into the first 6 cm of the column, and as much as 15% eluted into the second 6 cm. Mobility is greatest in soils of low organic content.

Based on these criteria, terbuconazole has little potential to reach ground water, except possibly in the most vulnerable areas, in soils which are high in sand and have little organic matter. Once there, however, it could persist for a considerable length of time.

SURFACE WATER ASSESSMENT

Terbuconazole is stable to most environmental degradative processes and is relatively immobile. Based on these data, in a runoff event, terbuconazole would probably remain adsorbed to suspended soil particles, and the compound could move into adjacent bodies of surface water. Since it would be likely to stay associated with the sediment, it would be resistant to the known routes of dissipation. Although not investigated in existing data, sensitized photolysis is a potential route for environmental dissipation. Even if it is rapid, it would probably not be much of a factor under these conditions. Therefore, terbuconazole in sediment could persist long enough to affect resident biota, particularly bottom feeders.

DATA BASE ASSESSMENT

The following data are REQUIRED:

Terrestrial field dissipation studies:

A turf field dissipation study must be done to support that use.

A vineyard study must be done to support the proposed use on grapes.

The following data requirements are PARTIALLY FULFILLED:

Aerobic soil metabolism: characterization of the unidentified degradates in *Lee and Hanna-Bey*, MRID # 407009-50 could fulfill this requirement. Otherwise a new study will be necessary.

Anaerobic soil metabolism: a requirement of the proposed use on grapes. Characterization of the unidentified degradates in *Lee and Hanna-Bey*, MRID

407009-50 could fulfill this requirement. Otherwise a new study will be necessary.

Confined rotational crop accumulation: a requirement of the *proposed* use on grapes. MRID # 407009-64 is partially acceptable, but is missing crucial information which the applicant should supply if available [details in the DER]. The study did establish that accumulation occurred. In such cases, either a field study or tolerance setting through Dietary Exposure Branch is required.

Field rotational crop accumulation: a requirement of the *proposed* use on grapes. MRID # 409959-23 partially satisfies the requirement, but is missing crucial information, detailed in the DER. The applicant must supply the missing information or perform a new study to remedy the deficiencies. As an alternative, the applicant may choose to support tolerance setting through the Dietary Exposure Branch.

Laboratory studies of pesticide accumulation in fish: characterization of unidentified degradates in the reviewed study (*Suprenant*, MRID # 409959-05; *Mulford*, MRID # 409959-06; *Howard*, MRID # 409959-07) could make it acceptable for fulfilling the data requirement. Otherwise a new study will be necessary.

The following data requirements are **FULFILLED**:

Hydrolysis: Based on an acceptable study (*Coffman and Sietsema*, MRID# 407009-57), no additional data are required at this time.

Photodegradation in water: Based on an acceptable study (*Coody*, MRID# 407009-58), no additional data are required at this time.

Photodegradation on soil: Based on an acceptable study (*Coody*, MRID # 407009-58), no additional data are required at this time.

Leaching/adsorption/desorption: Three studies were reviewed.

- 1) One study (*Fritz*, MRID # 409959-22) fulfills the data requirement on the mobility (batch equilibrium) of unaged terbuconazole in silt, sand, and two sandy loam soils.
- 2) Another study (*Smyser and Lenz*, MRID # 407009-60) fulfills the data requirement on the mobility (column leaching) of aged terbuconazole in sand, sandy loam soil, silt loam, and silty clay loam soils.
- 3) The third study (*Kavanaugh and Obrist*, MRID # 407009-61) is unacceptable for several reasons detailed in the DER.

Other data requirements are **DEFERRED OR DO NOT APPLY** to presently registered uses.

TABLE A
 GENERIC DATA REQUIREMENTS FOR CHEMICAL: TERBUCONAZOLE

Data Requirement	Composition/1	Use Pattern /2	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partial)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA 3(c)(2)(B)?	
<u>158.290 Environmental Fate</u>						
<u>DEGRADATION STUDIES-- LAB:</u>						
161-1	hydrolysis	TGAI, PAIRA	A*, B, H	YES	407009-57	NO
<u>PHOTODEGRADATION:</u>						
161-2	in Water		A*, B, H	YES	407009-58	NO
161-3	on Soil		A*, B, H	YES	407009-58	NO
161-4	in Air		A*, B, H	NO		RESERVED/4
<u>METABOLISM STUDIES-- LAB:</u>						
162-1	Aerobic Soil		A*, B, H	PARTIAL	407009-50	YES/5
162-2	Anaerobic Soil		A*	PARTIAL	407009-50	YES/5
162-3	Anaerobic Aquatic		N.A.			NO
162-4	Aerobic Aquatic		N.A.			NO
<u>MOBILITY STUDIES:</u>						
163-1	Leaching and Adsorption/Desorption		A*, B, H	YES	407009-60	NO
163-2	Volatility (Lab)		B, H	NO		RESERVED/4
163-3	Volatility (Field)		B, H	NO		RESERVED/6
<u>DISSIPATION STUDIES -- FIELD:</u>						
164-1	Soil		A*, B, H	PARTIAL	407009-62 407009-63	YES/8,9
164-2	Aquatic (Sediment)		N.A.			NO
164-3	Forestry		N.A.			NO
164-4	Combination and Tank Mixes		N.A.			NO
164-5	Soil, Long-Term		N.A.			NO

TABLE A
 GENERIC DATA REQUIREMENTS FOR CHEMICAL: TERBUCONAZOLE

Data Requirement	Composition	Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partial)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA 3(c)(2)(B)?
ACCUMULATION STUDIES:					
165-1	Rotational Crops (Confined)	A*	PARTIAL	407009-64	YES/5
165-2	Rotational Crops (Field)	A*	PARTIAL	407009-50	RESERVED/10
165-3	Irrigated Crops	N.A.	NO		
165-4	In Fish	A*, B	PARTIAL	409959-05 409959-06 409959-07	YES/5
165-5	In Aquatic Non-Target Organisms	N.A.			NO
158.440 Spray Drift					
201-1	Drift Field Evaluation	A*, B			YES
202-1	Drift Size Spectrum	A*, B			YES

FOOTNOTES

- * The A use, on grapes, is proposed, and has not been approved yet.
- 1/ Composition: TGAI = Technical Grade of the Active Ingredient; PAIRA = Pure Active Ingredient, Radiolabelled; IEP : Typical End Use Product
- 2/ The use patterns are coded as follows: A = Terrestrial Food Crop; B = Terrestrial Non- Food; C = Aquatic, Food Crop; D = Aquatic Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor; J = Indirect Discharge Aquatic Use
- 3/ Data must be submitted no later than _____.
- 4/ This requirement may be imposed if toxicological concerns so indicate.
- 5/ Some degradates must be identified.
- 6/ Current use patterns do not require these data.
- 7/ This requirement would be imposed based on toxicological concerns and only if a laboratory study indicated potential for significant volatility.
- 8/ The analytical method employed was unsatisfactory due to extremely variable recoveries. Reanalysis of samples may allow acceptance of the existing study.
- 9/ For turf use, a turf field dissipation study is required. A vineyard dissipation study will be required to support the proposed use on grapes.
- 10/ As an alternative to performing field studies, the registrant may elect to petition for tolerances on rotational crops.

TERBUCONAZOLE

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3.1 - 3.19	3) Soil Metabolism -- aerobic and anaerobic -- (Lee and Hanna-Bey, MRID # 407009-59)
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INTRODUCTION

Terbuconazole is a broad spectrum systemic fungicide developed for use on terrestrial nonfood (grasses grown for seed) and domestic outdoor (lawns and turf) use sites. Application is to the plant foliage; good coverage and wetting of the foliage is necessary for maximum effectiveness. Terbuconazole is formulated as a 1.2 lb/gallon EC, and marketed under the trade names Folicur 1.2 EC (for use on terrestrial nonfood sites) and Lynx 1.2 (for use on turf). According to the Folicur and Lynx label directions, terbuconazole is applied at 0.112 to 0.225 lb ai/A/application to terrestrial nonfood sites and at 0.6 to 2.4 lb ai/A to domestic outdoor sites, respectively. Multiple applications per season are permitted; the Folicur label states a 0.45 lb ai/A seasonal maximum for terrestrial nonfood sites, there is no maximum application stated on the Lynx label for domestic outdoor sites. Application is made using ground equipment, including solid set irrigation systems.

DATA EVALUATION RECORD

STUDY 1

CHEM 128997
161-1

Terbuconazole

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 40700957

Coffman, M.W. and W.K. Sietsema. 1984. Hydrolysis study of BAY HWG 1608 in sterile aqueous buffered solution. Mobay Project ID Report No. 88726. Unpublished study performed and submitted by Mobay Corporation, Kansas City, MO.

DIRECT REVIEW TIME = 4

REVIEWED BY: J. Harlin

TITLE: Staff Scientist

EDITED BY: K. Patten

TITLE: Task Leader

APPROVED BY: W. Spangler

TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD

TEL: 468-2500

APPROVED BY: B. Conerly

TITLE: Chemist

ORG: EFGWB/EFED/OPP

TEL: 557-5456

SIGNATURE: *E.B. Conerly* 8/6/90

CONCLUSIONS:

Degradation - Hydrolysis

1. This study is acceptable and completely fulfills EPA Data Requirements for Registering Pesticides by providing information on the hydrolysis of phenyl-labeled [¹⁴C]terbuconazole at pH 5, 7, and 9.
2. Terbuconazole did not hydrolyze in sterile aqueous buffered solutions (pH 5, 7, and 9) at 25 C over a 28 day period.

METHODOLOGY:

Phenyl-labeled [^{14}C]terbuconazole (radiochemical purity >99%, specific activity 18.5 mCi/mMol, Mobay Corp.), dissolved in acetonitrile, was added at 18 ppm (final concentration of acetonitrile = 1%) to individual Teflon bottles containing sterile 0.1 M aqueous phosphate buffered solutions (40 mL) adjusted to pH 5, 7, and 9; fourteen bottles were treated for each pH solution. Aliquots of each solution were analyzed by LSC immediately after treatment to establish the application rate. The bottles were capped, and the solutions were incubated in the dark at 25 ± 1 C. Duplicate bottles of each pH solution were removed for analysis at 0, 1, 4, 7, 14, 21, and 28 days posttreatment. The pH of the solutions was monitored throughout the study.

Duplicate aliquots from each solution were analyzed for total radioactivity using LSC and for specific compounds using reverse phase HPLC with UV absorbance (222 nm) and radioactivity detection. When the study had been completed, all remaining solutions of a given pH were combined regardless of sampling date. Aliquots (50 mL) from each of three composites were extracted twice with chloroform. The extracts were dried on a rotary evaporator, redissolved in methanol, and analyzed by MS. The method detection limit was 0.005 ppm.

DATA SUMMARY:

Phenyl-labeled [^{14}C]terbuconazole (radiochemical purity >99%), at 18 ppm, was stable in aqueous phosphate-buffered solutions (pH 5, 7, and 9) that were incubated at 25 ± 1 C in the dark for 28 days. During the study, material balances ranged from 97.3 to 106.9% of the applied.

COMMENTS:

1. The water solubility of terbuconazole was reported to be 25 ppm.
2. During the study, the pH of the solutions ranged from 5.05-5.20, 6.90-7.15, and 8.90-9.10.
3. Recovery efficiencies from fortified samples were not reported for the HPLC analysis. LSC efficiency was 84.1%.

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Pages 10 through 11 are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
 - Description of the product manufacturing process.
 - Description of quality control procedures.
 - Identity of the source of product ingredients.
 - Sales or other commercial/financial information.
 - A draft product label.
 - The product confidential statement of formula.
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 - FIFRA registration data.
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

STUDY AUTHOR(S)'S RESULTS AND/OR CONCLUSIONS

RESULTS AND DISCUSSION

Aliquots taken from each sample immediately after fortification were used to determine initial concentrations on which the material balance was based. Aliquots taken at the individual sampling intervals were used to determine the final concentration. These data are shown in Table I. Radioactivity counting data are shown in Appendix I. Final concentrations were in general slightly higher than the initial concentrations. However, the variation was always less than 7%. These data indicate that there was no volatility of BAY HWG 1608 during the course of the experiment.

The pH of each sample was measured at the sampling interval (see Table II). Final pH values were always within 0.2 pH units of the expected value, indicating that no significant change in pH of the samples took place during the experiment.

Analysis of each sample by HPLC showed BAY HWG 1608 to be stable at pH 5, 7, and 9 with no decomposition through 28 days. See Figures 1 and 2 for representative chromatograms of a 0-day sample and a 28-day sample, respectively.

Mass spectrometric analysis of extracts of each buffer composite confirmed the BAY HWG 1608 structure in each of those buffer solutions. Figure 3 shows the mass spectra of synthetic BAY HWG 1608 and of BAY HWG 1608 isolated from the pH 5 buffer. Mass spectra of BAY HWG 1608 isolated from pH 7 and 9 buffers were identical.

CONCLUSIONS

This investigation shows that BAY HWG 1608 is stable in pH 5, 7, and 9 sterile, aqueous phosphate buffers when stored in the dark at 25°C. No degradation was observed over a 28 day period. Material balance ranged from 97.3% to 106.9%, indicating no volatilization took place.

DATA EVALUATION RECORD

STUDY 2

CHEM 128997	Terbuconazole	161-2, 161-3
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FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 40700958
 Coody, P.N. 1987. Photodecomposition of Folicur in soil and water. Laboratory Project ID Report No. 94901. Unpublished study performed and submitted by Mobay Corporation, Kansas City, MO.

DIRECT REVIEW TIME = 6

REVIEWED BY: J. Harlin	TITLE: Staff Scientist	
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EDITED BY: K. Patten	TITLE: Task Leader	
----------------------	--------------------	--

APPROVED BY: W. Spangler	TITLE: Project Manager	
--------------------------	------------------------	--

ORG: Dynamac Corporation
 Rockville, MD
 TEL: 468-2500

APPROVED BY: B. Conerly
 TITLE: Chemist
 ORG: EFGWB/EFED/OPP
 TEL: 557-5456

SIGNATURE: *E.B. Conerly* 8/6/90

CONCLUSIONS:

Degradation - Photodegradation in Water

1. This study is acceptable and completely fulfills EPA Data Requirements for Registering Pesticides by providing information on the photodegradation of chlorophenyl-labeled [¹⁴C]terbuconazole in water.
2. Terbuconazole did not significantly photodegrade over 30 days in sterile aqueous buffered solutions incubated in sunlight at 22-32 C. Regression of the data per pseudo first-order kinetics yields a decay line with a low correlation coefficient (-0.47), and an insignificant slope (-8.7×10^{-4}). The calculated half-life would be 797 days (2.2 years). This reviewer believes that assigning a numerical value to the half-life in this case is unjustified.

Degradation - Photodegradation on Soil

1. This study is acceptable and completely fulfills EPA Data Requirements for Registering Pesticides by providing information on the photodegradation of chlorophenyl-labeled [¹⁴C]terbuconazole on soil.
2. Terbuconazole was photodegraded slowly (extrapolated half-life 191 days) by sunlight on sandy loam soil at 16-27 C, producing two minor (≤3% of the applied) unidentified nonvolatile degradates and unextractable [¹⁴C]-residues.

METHODOLOGY:

Degradation - Photodegradation in Water

Chlorophenyl-labeled [¹⁴C]terbuconazole (radiochemical purity 98.14%, specific activity 25.97 mCi/mMol, Mobay Corp.), dissolved in methanol, was added to a sterile pH 7 phosphate buffered solution adjusted to pH 7; the final concentration in the solution was 22.24 ppm of terbuconazole and 0.62% methanol (v:v). The solution was divided between two photocells, one of which was covered with aluminum foil to serve as a dark control (Appendix D and E). Each cell consisted of a quartz chamber (10 x 10 x 1 cm) attached to a ethylene glycol/water cooling jacket; each photocell contained an air vent, thermocouple, and sampling port. The treated solutions were incubated outdoors in natural sunlight from September 8 through October 8, 1987. The study author stated that, on a "typical cloudless day" (e.g., day 6), the sunlight intensity reached a maximum of 84,480 μW/cm² and the total radiant energy was 31.03 Watt min/cm² (Figure 5). The total radiant energy received by the irradiated solution during the 30-day experiment was 547.7 Watt-minute/cm² at wavelengths of 300-4,800 nm. The temperature of the irradiated and dark control solutions ranged from ≈22 to 32 C. The solutions were sampled at 0, 5, 10, 18, and 30 days posttreatment by drawing ≈5 mL of solution through the sampling port of each photocell.

Triplicate aliquots of each sample were analyzed for total radioactivity using LSC. Additional aliquots were analyzed for terbuconazole and its degradates using HPLC with UV absorbance and radioactivity detection. The sensitivity of the HPLC analysis was 0.2 μg of terbuconazole.

Degradation - Photodegradation on Soil

Sandy loam soil (54% sand, 37% silt, 9% clay, 1.8% organic matter, pH 4.5, CEC 16 meq/100 g) was added (3 g/dish) to 5-cm petri dishes, wetted with distilled water (3 mL/dish), mixed, and spread evenly through the dish.

The soils were air-dried for several days; after drying, the soil layers were ≈ 0.5 mm thick with an exposed surface area of 19.6 cm^2 . The soils were treated with [^{14}C]terbuconazole (radiochemical purity 98.14%, specific activity 25.97 mCi/mMol, Mobay Corp.) at $122 \text{ }\mu\text{g/dish}$ (equivalent to 0.56 lb/A or 0.63 kg/ha). Of the eighteen treated soil samples, two were left uncovered and were analyzed at time 0. Eight dishes of treated soil were wrapped in aluminum foil to serve as dark controls. The exposed and covered petri dishes were randomly arranged in a photolysis chamber (Appendix A). Within the photolysis chamber, air was passed over the samples ($7\text{--}10 \text{ mL/minute}$) and then sequentially through a series of volatile traps containing acetone-washed XAD-2 exchange resin, 1 N potassium hydroxide, and ethylene glycol. The treated soils were incubated outdoors under natural sunlight for 35 days from July 30 through September 4, 1987; the photolysis chamber was oriented due-South for the entire study. The study author stated that, on a "typical cloudless day" (e.g., day 5), the sunlight intensity reached a maximum of $84,800 \text{ }\mu\text{W/cm}^2$ and the total radiant energy was $29.36 \text{ Watt min/cm}^2$ (Figure 3). The total radiant energy received by the irradiated solution during the 35-day experiment was $811.4 \text{ Watt-minute/cm}^2$ at wavelengths of $300\text{--}4,800 \text{ nm}$. The temperature of the irradiated and dark control solutions ranged from $\approx 16\text{--}27 \text{ C}$. Duplicate irradiated and dark control soil samples were collected at 0, 5, 13, 22, and 35 days posttreatment. At each sampling interval, the volatile traps were replaced.

Each soil sample plus its respective petri dish rinsate were mixed with methanol (1:10) for two hours with a magnetic stirrer, then filtered through Whatman 42 paper. A portion of each extract was filtered through a $0.45\text{-}\mu\text{m}$ pore filter and analyzed for total radioactivity using LSC and for specific compounds using HPLC with UV absorbance and radioactivity detection. The methanol-extracted soil was air-dried and analyzed for unextractable [^{14}C]residues using LSC following combustion.

The volatile traps were analyzed for each sampling interval. The ethylene glycol and 1 N potassium hydroxide trapping solutions were analyzed for total radioactivity using LSC. Subsamples of the exchange resin were analyzed for total radioactivity using LSC following combustion.

DATA SUMMARY:

Degradation - Photodegradation in Water

Chlorophenyl-labeled [^{14}C]terbuconazole (radiochemical purity 98.14%), at $22.24 \text{ }\mu\text{g/mL}$, was stable (calculated half-life 590 days) in sterile buffered phosphate solutions (pH 7) that were irradiated with sunlight outdoors for 30 days at $22\text{--}32 \text{ C}$. During the study, the radiant energy received by the irradiated solution totaled $547.7 \text{ Watt-minute/cm}^2$ at wavelengths of $300\text{--}4,800 \text{ nm}$. Terbuconazole was the only [^{14}C]compound detected in the irradiated solution and the dark control at all sampling intervals.

During the study, the material balance of the irradiated and dark control solutions decreased from 100% of the applied at time 0 to 94-97% at all other sampling intervals; the study author suggested that some terbuconazole adsorbed to the walls of the photocell.

Degradation - Photodegradation on Soil

Chlorophenyl-labeled [¹⁴C]terbuconazole (radiochemical purity 98.14%), at ≈0.63 kg ai/ha, photodegraded slowly (calculated half-life 191 days) in sandy loam soil that was irradiated with sunlight outdoors for up to 37 days at ≈16-27 C. Terbuconazole did not degrade in the dark controls incubated under similar conditions. After 35 days of irradiation, terbuconazole comprised 86% of the applied radioactivity, two unidentified nonvolatile degradates each comprised ≤3%, and unextractable [¹⁴C]residues comprised 5.5%. No [¹⁴C]volatiles were detected. During the study, the radiant energy received by the samples totaled 811.4 Watt-minute/cm² at wavelengths of 300-4,800 nm.

The material balances ranged from 94.5 to 103.6% of the applied for the irradiated soil and 98.7 to 101.7% for the dark controls.

COMMENTS:

General

1. The statistical estimations of the photodegradation half-life of terbuconazole reported in these experiments are of limited value because the calculations involve extrapolation considerably beyond the experimental time limits of the study. Data are often incapable of accurately predicting trends outside of their range because small differences are magnified and reactions which appear to be linear may, in fact, be curvilinear.
2. The method detection limits and recovery efficiencies from fortified samples for the HPLC analysis were not reported.
3. Un-irradiated controls were conducted for both the aqueous solutions and the soil, although no data were provided in the report. In general, it is essential to report the results of the dark controls, since they serve as cross-checks for other studies -- the aqueous dark control should yield results like those of the hydrolysis study at the corresponding pH, and, similarly, the soil dark control should agree with the aerobic soil metabolism study. In this case, the light-exposed samples did not degrade, and it is reasonable to assume that the controls would not.

Degradation - Photodegradation in Water

The study author stated that no attempt was made to measure volatilization in this portion of the study because it was assumed that, since no volatilization occurred from the irradiated treated soil, no volatilization would occur from the aqueous solutions.

Degradation - Photodegradation on Soil

During the course of the study, the study author noted that the photodetector was improperly calibrated. The study author used an authorized correction factor to transform the data and obtain results in units of W/cm^2 . The corrected values, rather than the incorrect readings, are reported in Figure 3.

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Pages 19 through 33 are not included.

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- Identity of product inert ingredients.
 - Identity of product impurities.
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DATA EVALUATION RECORD

STUDY 3

CHEM 128997 Terbuconazole 162-1, 162-2

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 40700959

Lee, S.G.K. and L.A. Hanna-Bey. 1987. The metabolism of Folicur in soil. Laboratory Project ID Report Number 94269. Unpublished study performed and submitted by Mobay Corporation, Kansas City, MO.

DIRECT REVIEW TIME = 8

REVIEWED BY: J. Harlin TITLE: Staff Scientist

EDITED BY: K. Patten TITLE: Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD
TEL: 468-2500

APPROVED BY: B. Conerly
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-5456

SIGNATURE: *E.B. Conerly* 8/6/90

CONCLUSIONS:

Metabolism - Aerobic Soil

1. This study is scientifically sound, but does not meet Subdivision N guidelines for the following reason:

the only extractable [¹⁴C] degradate, which represented up to 2.6% of the recovered (0.26 ppm), was not identified.

For this study to fulfill the aerobic soil metabolism data requirement, this degradate isolated at 6 and 12 months posttreatment must be identified. It shows persistence, like the parent compound, and could therefore be a compound of concern.

2. Terbuconazole declined with an extrapolated half-life of \approx 800 days (using pseudo first order kinetics and all data points) on sandy loam soil in-

4. In order for this study to fulfill the aerobic soil metabolism data requirement, the terbuconazole degradate isolated at 6 and 12 months posttreatment must be identified.

Metabolism - Anaerobic Soil Metabolism

1. This portion of the study cannot be used to fulfill data requirements at this time.
2. Terbuconazole degraded with a half-life of ≈ 400 days in flooded sandy loam soil incubated at 23°C . The major degradation products were unextractable residues; one extractable degradate (unidentified) was isolated at $<3\%$ of the recovered and volatilization was negligible.
3. This study is scientifically sound, but does not meet Subdivision N guidelines for the following reason:

one [^{14}C] compound, isolated at up to 2.2% of the recovered, was not identified.
4. In order for this study to fulfill the anaerobic soil metabolism data requirement, the terbuconazole degradate isolated at 60 days posttreatment must be identified.

METHODOLOGY:

Metabolism - Aerobic Soil

Sieved (2 mm) sandy loam soil (54% sand, 37% silt, 9% clay, 1.8% organic matter, pH 4.5, CEC 16 meq/100 g) was weighed (50 g) into flasks and treated with either chlorophenyl-labeled or triazole-labeled [^{14}C]terbuconazole (radiochemical purity $\approx 98.4\%$, specific activity ≈ 20 mCi/mMol, Mobay Corporation), dissolved in acetone, at 10 ppm. The acetone was allowed to evaporate, and the treated soil was thoroughly mixed and adjusted to 75% of 0.33 bar moisture. The flasks of soil were attached to a flow-through incubation apparatus (Figure 1). Humidified compressed air (rate unspecified) was passed over the soil samples, then through a 1 M potassium hydroxide solution designed to trap $^{14}\text{CO}_2$. The flasks were covered with aluminum foil and incubated in the dark at $23 \pm 2^{\circ}\text{C}$ throughout the study. Flasks containing soil treated with the chlorophenyl label and the corresponding trapping solutions were sampled in duplicate at 0, 7, 14, 28, 56, 84, and 112 days and at 6 and 12 months posttreatment. Flasks containing soil treated with the triazole label and the corresponding trapping solutions were sampled at 0, 30, and 58 days posttreatment.

Aliquots of the trapping solutions were analyzed for total radioactivity using LSC. Soil samples were sequentially extracted with methanol:water (7:3) and methanol using a magnetic stirrer. The extracts were pooled, concentrated by rotary evaporation, and analyzed for total radioactivity by LSC and for specific degradates using both HPLC with UV and radioac-

tivity detection and TLC. The TLC analysis was conducted using silica gel plates developed in: ethyl acetate:ethanol (9:1); ethyl acetate:methylene chloride (1:1) plus 1% acetic acid; ethyl acetate; and ethyl acetate:methylene chloride:toluene:ethanol (50:25:20:5). Nonlabeled reference standards were cochromatographed with the samples, and following development, were visualized under UV light. Radioactive areas were detected and quantified with a radiochromatogram scanner and/or autoradiography with LSC. Aliquots of the extracted soil were analyzed for unextractable radioactivity using LSC following combustion. The average counting efficiencies were 91.2-91.4% for LSC analysis of liquids and silica gel scrapings and 76.5-77.8% for LSC and combustion analysis of the soil samples. The detection limits were 0.002 and 0.001 ppm for LSC and for LSC following combustion, respectively.

In order to characterize unextractable [^{14}C]residues, the previously extracted 1-year soil samples were fractionated into humin, humic acid, and fulvic acid. A subsample of the soil was mixed with 0.5 M sodium hydroxide and the resulting soil solution was centrifuged. The supernatant was decanted, the soil was washed with 10-mL portions of 0.5 M sodium hydroxide, and recentrifuged. The soil was then washed three times with water using centrifugation; the remaining pellet was air-dried and analyzed for total radioactivity by LSC following combustion. The sodium hydroxide and water fractions were combined and analyzed for total radioactivity by LSC. The combined supernatant was then acidified with concentrated hydrochloric acid to pH 1 to precipitate the humic acid fraction. The mixture was centrifuged and the fulvic acid fraction was decanted. The humic acids were solubilized in 0.5 M sodium hydroxide for LSC analysis. The residual radioactivity in the soil solids was quantified by LSC following combustion. It was concluded that any radioactivity remaining in the residual soil was associated with the humin fraction.

Metabolism - Anaerobic Soil

After 30 days of aerobic incubation (described above), a portion of the soil samples treated with chlorophenyl-labeled [^{14}C]terbuconazole was disconnected from the flow-through apparatus. The treated samples were flooded with water to a depth 2.5 cm above the soil surface. The flasks were then sealed with septum stoppers secured with copper wire. Prior to sampling, each flask was purged for one-half hour by vacuum through a 1 M sodium hydroxide trapping solution to collect $^{14}\text{CO}_2$. Duplicate flasks were sampled at the time of flooding (day 0), 30, and 60 days and trapping solution were sampled at 60 days after anaerobic conditions were established.

Aliquots of the sodium hydroxide trapping solution was analyzed for total radioactivity by LSC. The aqueous layer above the soil from each sample was filtered and concentrated under azeotropic evaporation with acetonitrile; aliquots of the extracts were analyzed for total radioactivity by LSC and TLC as previously described. The soil was extracted and analyzed as previously described.

DATA SUMMARY:

Metabolism - Aerobic Soil

Chlorophenyl-labeled [^{14}C]terbuconazole (radiochemical purity 98.6%), at 10 ppm, degraded with a half-life of ≈ 610 days on sandy loam soil incubated at $23 \pm 2^\circ\text{C}$ in the dark. At 1 year posttreatment, terbuconazole comprised 67.4% of the recovered radioactivity, unidentified extractable [^{14}C]residues comprise 2.1%, extractable polar compounds (compounds remaining at the origin) comprised 1.1%, and unextractable [^{14}C]residues comprised 29.1%. During the entire study, $^{14}\text{CO}_2$ comprised $\leq 0.7\%$ of the applied radioactivity. At 1-year posttreatment, the unextractable [^{14}C]residues were distributed: 12.1% of the recovered was as humin, 9.9% was as humic acid, and 7.1% was as fulvic acid.

In sandy loam soil treated with triazole-labeled [^{14}C]terbuconazole (radiochemical purity 98.3%) at 10 ppm to and incubated at $23 \pm 2^\circ\text{C}$ in the dark for up to 58 days, the concentration of terbuconazole was variable. Terbuconazole increased from 86.8% of the applied immediately posttreatment to 91.6% of the applied at 30 days posttreatment, then decreased to 79.3% of the applied at 58 days posttreatment. At 58 days posttreatment, unextractable [^{14}C]residues were 13.5% of the applied. During the entire study, $^{14}\text{CO}_2$ was not detected in the trapping solutions of the sealed flasks containing treated soil. Based on analysis of the unextractable [^{14}C]residues from the 58-day soil samples, 5.6% of the applied was in the humic acid fraction, 4.8% was in the humin, and 3.2% was in the fulvic acid fraction.

Metabolism - Anaerobic Soil

[^{14}C]Terbuconazole degraded with a half-life of ≈ 400 days in a sandy loam soil treated with chlorophenyl-labeled [^{14}C]terbuconazole (radiochemical purity 98.6%) at 10 ppm and incubated anaerobically (flooding) at $23 \pm 2^\circ\text{C}$ in the dark for 60 days following 30 days of aerobic incubation. After 60 days of anaerobic incubation (90 days posttreatment), terbuconazole comprised 74% of the applied (soil plus flood water), an unidentified degradate comprised 2.1%, and unextractable [^{14}C]residues comprised 18.5%; $^{14}\text{CO}_2$ was not detected. Based on analysis of the unextractable [^{14}C]residues from the 60-day soil sample, 8.7% of the applied was in the humic acid fraction, 7.1% was in the humin, and 2.7% was in the fulvic acid fraction. Following acid hydrolysis of the unextractable radioactivity, 76.7% of the recovered remained bound to the soil.

COMMENTS:

General

1. One degradate of chlorophenyl-labeled [^{14}C]terbuconazole, present at up to 2.6% of the recovered (≈ 0.26 ppm) in the aerobic soil and 2.2% (≈ 0.22 ppm) in the anaerobic soil, was isolated but not identified.

2. The half-lives for the chlorophenyl label were calculated by the reviewer using linear regression analysis (there were insufficient data points to attempt to calculate the triazole label half-life). However, the statistical estimations of the half-life of terbuconazole reported in these experiments are of limited value because the calculations involve extrapolation beyond the experimental time limits of the study. Data are often incapable of accurately predicting trends outside of their range because small differences are magnified and reactions which appear to be linear may, in fact, be curvilinear.
3. In an attempt to identify unextractable [¹⁴C]residues, extracted soils from the final sampling interval of the aerobic and anaerobic portions of the study were also analyzed by acid hydrolysis. Approximately 20% of the total unextractable radioactivity was released by acid hydrolysis. Using HPLC, this 20% was identified as terbuconazole.

Metabolism - Aerobic Soil

1. Duplicate 12-month soil samples from the chlorophenyl label experiment contained 91.2% and 45.8% of the applied radioactivity (Table IV). Since recoveries for previous sampling intervals were in agreement (89.7-101% of the applied), the low recovery for the second flask appears to be an anomaly. Therefore, the reviewer did not include this data point when calculating the half-life of terbuconazole in the chlorophenyl label experiment. The reviewer-calculated half-life for chlorophenyl-labeled [¹⁴C]terbuconazole is ≈610 days, compared to the registrant-calculated half-life of 800 days.
2. The data from the triazole label experiment support half-life obtained from the chlorophenyl label experiment and address the fate of the triazole portion of the molecule. However, if the triazole label experiment was evaluated alone, it would be considered unacceptable because three sampling intervals, at 0, 30, and 58 days posttreatment, are inadequate to accurately assess the pattern of degradation for terbuconazole.
3. The air flow rate of the flow-through incubation apparatus was not specified.
4. In a glucose metabolism experiment included with the original report, microbial activity was verified by monitoring the evolution of ¹⁴CO₂ from soil treated with 10 ppm of D-[1-¹⁴C]glucose.

Metabolism - Anaerobic Soil

The test water was incompletely characterized; the pH was not reported and it was not stated whether distilled, tap or "natural" water was used to establish flooding conditions.

Page _____ is not included in this copy.

Pages 39 through 52 are not included.

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- Identity of product inert ingredients.
 - Identity of product impurities.
 - Description of the product manufacturing process.
 - Description of quality control procedures.
 - Identity of the source of product ingredients.
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DATA EVALUATION RECORD

STUDY 4

CHEM 128997

Terbuconazole

163-1

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 40995922

Fritz, R. 1988. Adsorption/desorption of Folicur (HWG 1608) on soils. Laboratory Project ID 1310222/1. Mobay report 98038. Unpublished study prepared by Bayer AG, West Germany, and submitted by Mobay Corporation, Stilwell, KS.

DIRECT REVIEW TIME = 23

REVIEWED BY: C. Little

TITLE: Staff Scientist

EDITED BY: K. Patten

TITLE: Task Leader

APPROVED BY: W. Spangler

TITLE: Project Manager

ORG: Dynamac Corporation

Rockville, MD

TEL: 468-2500

APPROVED BY: B. Conerly

TITLE: Chemist

ORG: EFGWB/EFED/OPP

TEL: 557-5456

SIGNATURE:

E.B. Conerly 8/22/90

CONCLUSIONS:

Mobility - Leaching and Adsorption/Desorption

1. This study is acceptable and partially fulfills EPA Data Requirements for Registering Pesticides by providing information on the mobility (batch equilibrium) of unaged terbuconazole in silt, sand, and two sandy loam soils. A previously submitted study, *Smyser and Lenz* MRID # 407009-60 q.v., satisfied the requirement for data on aged terbuconazole. Taken together, the two studies completely fulfill the data requirement.

2. Terbuconazole is relatively immobile in silt, sand, and sandy loam soils (k_{ds} 7.69 - 16.39, $1/n$ 0.71 - 0.74). In general, adsorption increased in soils with higher organic content and greater proportions of silt and clay.

METHODOLOGY:

Silt, sand, and two sandy loam soils were air-dried and sieved (2 mm), and preliminary experiments were conducted to determine ideal experimental conditions. Based on the results of these experiments, an equilibration time of 48 hours and a soil:water ratio of 1:10 were selected for use in the definitive experiment. Also, it was determined that adsorption of terbuconazole to the walls of the sample vessels did not occur.

For the adsorption studies, 0.01 M calcium chloride solutions were prepared containing phenyl-labeled [14 C]terbuconazole (uniformly labeled, radiochemical purity 99%, specific activity 14,882 dpm/ug, Mobay) at 16.0, 11.0, 7.4, or 1.5 mg/L. Soil (2 g) and aliquots (20 mL) of the treated calcium chloride solutions were transferred into duplicate centrifuge tubes with Teflon screw caps, and the resulting slurries were shaken in the dark at 20 ± 1 C for 48 hours. After the shaking period, the soil:water slurries were centrifuged for 15 minutes. Aliquots of the supernatant were removed and measured for radioactivity using LSC. Additional aliquots of the supernatant were removed and analyzed using one-dimensional TLC on silica gel plates developed in methylene chloride:ethyl acetate:ethanol:acetic acid (40:40:15:5).

Desorption of terbuconazole was determined by adding 20 mL of pesticide-free calcium chloride solution to the soil residue (from the adsorption experiments) and shaking the tubes for 48 hours in the dark at 20 ± 1 C. The slurries were then centrifuged for 15 minutes and the supernatant was analyzed using LSC. The concentration of [14 C]residues that remained adsorbed to the soil after desorption was determined using LSC analysis following combustion. The material balance was calculated by summing the LSC data from each phase of the study.

DATA SUMMARY:

Based on batch equilibrium studies, phenyl-labeled [14 C]terbuconazole (radiochemical purity 99%), at 16.0, 11.0, 7.4, and 1.5 mg/L, was determined to be relatively immobile in silt, sand, and two sandy loam soil:calcium chloride solution slurries (1:10) that were equilibrated in the dark for 48 hours at 20 ± 1 C. The amount of parent compound adsorbed to the soil ranged from 28 to 46% for the sand soil and from 42 to 67% for the silt and sandy loam soils. K_{ads} values were 7.69 for the sand soil (organic carbon content 0.75%), 16.39 for the silt soil (organic carbon content 1.8%), and 15.89 and 12.69 for the two sandy loam soils (organic carbon content 1.3-1.4%);

respective K_{oc} values were 1025, 911, 1251, and 906. Adsorption $1/n$ values for all soils were 0.71-0.74. In general, adsorption increased in soils with a higher organic content and greater proportions of silt and clay.

The amount of parent compound desorbed from the soil in pesticide-free calcium chloride solution (1:10 soil:solution ratio) following a 48-hour equilibration period at 20 ± 1 C in the dark, ranged from 41 to 56% for the sand soil and from 22 to 47% for the silt and sandy loam soils. K_{des} values were 11.83 for the sand soil, 22.27 for the silt soil, and 23.76 and 18.27 for the two sandy loam soils; respective K_{oc} values were 1577, 1237, 1871, and 1341. Desorption $1/n$ values for all soils were 0.77-0.83. The material balance ranged from 96 to 104% recovery of the applied radioactivity.

COMMENTS:

The test compound was found to be relatively immobile under test conditions based on an evaluation of the K_{ads} (i.e., K_d) values according to 44 FR 53 (16 March 1979) Table III: "The General Relationship Between the Soil/Solution Partition Coefficient, K_d , R_f , and Soil Mobility".

STUDY AUTHOR(S) 'S RESULTS AND/OR CONCLUSIONS

Page _____ is not included in this copy.

Pages 57 through 69 are not included.

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- Identity of product inert ingredients.
 - Identity of product impurities.
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DATA EVALUATION RECORD

STUDY 5

CHEM 128997 Terbuconazole 163-1

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 40700960

Smyser, B.P. and C.A. Lenz. 1987. Leaching of aged residues of Folicur-¹⁴C. Laboratory Project ID 94801. Unpublished study performed and submitted by Mobay Corporation, Kansas City, MO.

DIRECT REVIEW TIME = 4

REVIEWED BY: J. Harlin TITLE: Staff Scientist

EDITED BY: K. Patten TITLE: Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD

TEL: 468-2500

APPROVED BY: B. Conerly
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-5456

SIGNATURE: *E.B. Conerly* 8/22/90

CONCLUSIONS:

Mobility - Column leaching

1. This study is acceptable and fulfills EPA Data Requirements for Registering Pesticides by providing information on the mobility (column leaching) of aged terbuconazole in sand, sandy loam soil, silt loam, and silty clay loam soils. Since most of the applied radiolabel was recovered as unchanged parent compound after the aging period, no additional data would have been required on the mobility of unaged terbuconazole. However, the applicant submitted a batch equilibrium study on unaged compound subsequent to this review, which is reviewed elsewhere in this document. It is also acceptable, and the results support the conclusions reached in this study.
2. Aged (30 or 90 days) [¹⁴C]terbuconazole residues were relatively immobile in 30-cm columns of sand, sandy loam, silt loam, and silty clay loam soils, [$\leq 0.5\%$ of the applied was in the leachates]. The majority of the

radioactivity (71.0-128.2% of the applied) was in the treated soil section plus the upper 6 cm of soil. In all of the soil columns, terbuconazole comprised 69.2-110% of the applied, unextractable [¹⁴C]residues were 11.2-21.1% of the applied, and ≤6.1% of the applied was unidentified [¹⁴C]residues.

METHODOLOGY:

Sandy loam soil (54% sand, 37% silt, 9% clay, 1.8% organic matter, pH 4.5, CEC 16 meq/100 g) was treated with 8.8 or 10.4 ppm of chlorophenyl-labeled [¹⁴C]terbuconazole (radiochemical purity 99.4%, specific activity 25.97 mCi/mMol, Mobay Corporation) dissolved in ethyl acetate. The solvent was evaporated under a stream of nitrogen and the treated soil was thoroughly shaken. Subsamples of the soil were analyzed for total radioactivity by LSC following combustion to confirm the application rate. The remaining soil was adjusted to 75% of 0.33 bar moisture and transferred to an amber glass jar that was connected to a volatile trap containing a 10% sodium hydroxide solution; humidified air was drawn over the soil and through the trap. The soil was incubated at room temperature for 30 (8.8 ppm) or 90 (10.4 ppm) days. Following incubation, soil subsamples were analyzed for total radioactivity by LSC following combustion. The remaining soil was divided into 40-g subsamples and stored frozen until preparation of the soil columns.

Glass soil columns (internal diameter 5.4 cm, height 44.5 cm) were prepared by layering the bottom of each column with a glass microfiber disk, followed by a 2 cm layer of sea sand and another glass microfiber disk. Five soils, ranging in texture from sand to silty clay loam (Table 1) were sieved (2-mm) and packed in the soil columns to a height of 30 cm. Water was drained through each soil column to determine void volume, then the soil was moistened from the bottom with 0.01 M calcium chloride solution. The columns were topped sequentially with a glass microfiber disk, a 40-g portion of treated aged soil, and a second microfiber disk. Four columns of each soil type were prepared for the 30- and 90-day aged soil; there were duplicate columns for each aging interval. The columns were leached with 0.01 M calcium chloride solution, equivalent to 20 inches of rainfall, over a 2-day period. The leachate was collected in 25-mL fractions and analyzed for total radioactivity by LSC. Soil segments (five 6-cm segments) were thoroughly mixed, and subsamples were analyzed for total radioactivity using LSC following combustion. The average counting efficiencies were 94.2% for LSC and 82.3% for LSC following combustion.

Subsamples of those soil segments that contained >3% of the recovered radioactivity were extracted with methanol:water (3:7) twice for 90 minutes. The extracts were combined, and aliquots were analyzed for total radioactivity by LSC. The remaining extracts were concentrated under a stream of nitrogen. Aliquots were cochromatographed with reference standards using one-dimensional TLC on silica gel plates developed in ethyl acetate and, in some cases, acetonitrile:methanol (95:5); radioactive areas were scraped from the plates and quantified using LSC. Some methanol extracts were also analyzed using HPLC/MS. Unextracted radioactivity

remaining in the methanol-extracted soil was quantified using LSC following combustion.

DATA SUMMARY:

Based on column leaching techniques, aged [¹⁴C]terbuconazole residues were relatively immobile in columns (≈30-cm) of sand, sandy loam, silt loam, and silty clay loam soil that were leached with 20 inches of 0.01 M calcium chloride solution over a 2 day period. Prior to leaching, the columns were topped with sandy loam soil that had been treated with chlorophenyl-labeled [¹⁴C]terbuconazole (radiochemical purity 99.4%) at ≈9.5 ppm and aged aerobically for 30 or 90 days. In the columns treated with 30-day aged [¹⁴C]residues, 44-70% of the applied material remained in the treated soil layer; an additional 34-60% of the applied material was found in the upper 6 cm of untreated soil (Table III). In the columns treated with 90-day aged [¹⁴C]residues, 34-51% of the applied remained in the treated soil layer; an additional 24-79% of the applied was found in the upper 6 cm of untreated soil (Table III).

Terbuconazole residues were most mobile in the silty clay loam soil; after 30 or 90 days of aging, 26% of the applied [¹⁴C]residues were detected in depths below 6 cm. Total radioactivity in the leachates was ≤0.5% of the applied for all of the soil columns.

In all of the soil columns, terbuconazole comprised 78.6-87.7% of the recovered radioactivity, unextractable [¹⁴C]residues were 9.5-16.5%, and unidentified extractable [¹⁴C]residues were ≤6.1%. No volatilization was detected. Material balances for the five soils aged 30 or 90 days ranged from 84.7 to 128.5% of the applied.

COMMENTS:

1. During the aging period, the incubation temperature and the air flow rate for the gas collection system were not specified.
2. The final length of the soil column could not be determined, since the study authors did not state the thickness of the treated soil layer; it was only stated that 40-g portions of the treated soil were placed on top of the soil columns. However, the length of the soil columns was adequate since the length was 30 cm prior to the addition of the treated soil layer; Subdivision N guidelines specify that soil columns be 30-300 cm in length.
3. The [¹⁴C]residues were not characterized prior to leaching; however, since terbuconazole has a half-life of >>1 year in aerobic soil (Study 3) it is unlikely that the [¹⁴C]residues detected after 2 days of leaching differed from the residues present in the aged soil prior to leaching.
4. One of the soils was classified by the study authors as a "mixed" sand. The term "mixed" was not explained; the soil is a sand according to the USDA Soil Textural Classification System and is referred to as such in this review.

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Pages 73 through 79 are not included.

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- Identity of product inert ingredients.
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 - Description of the product manufacturing process.
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DATA EVALUATION RECORD

STUDY 6

CHEM 128997

Terbuconazole

164-1

FORMULATION--12--EMULSIFIABLE CONCENTRATE (EC)

STUDY ID 40700962

Pither, K. 1988. Dissipation of Folicur in field soil. Mobay Report No. 96779. Laboratory Project ID FR830087R02. Unpublished study performed by EnCas Analytical Laboratories, Winston-Salem, NC, and submitted by Mobay Corporation, Kansas City, MO.

STUDY ID 40700963

Maasfeld, W. 1986. Method for gas chromatographic determination of residues of the fungicide FOLICUR (HWG 1608) in plant materials, soil, and water. Laboratory Project ID Report No. 94295. Unpublished study performed by Bayer AG, Monheim, Federal Republic of Germany, and submitted by Mobay Corporation, Kansas City, MO.

DIRECT REVIEW TIME = 12

REVIEWED BY: L. Binari

TITLE: Staff
Scientist

EDITED BY: K. Patten

TITLE: Task Leader

APPROVED BY: W. Spangler

TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD
TEL: 468-2500

APPROVED BY: B. Conerly

TITLE: Chemist

ORG: EFGWB/EFED/OPP

TEL: 557-5456

SIGNATURE:

E.B. Conerly 8/6/90

CONCLUSIONS:

Field Dissipation - Terrestrial

1. This study cannot be used to fulfill data requirements at this time.
2. The data are considered to be of uncertain value and should not be used to predict the environmental behavior of terbuconazole.

SP

3. This study is unacceptable because analytical results were too variable to define accurately the concentration of terbuconazole in the soil. This may be due to an inadequate analytical method; recovery efficiencies from fortified soil samples ranged from 60 to 195% of the applied. In addition, this study would not meet Subdivision N guidelines for the following reasons: storage conditions of the soil samples were not described; adequate storage stability data must be submitted; the Kansas portion of the study may have been terminated before the decline of terbuconazole was accurately established; and soil from the Florida site was not sampled to a depth sufficient to define the extent of leaching.
4. In order to support the turf use, a turf field dissipation is required.
5. In order for this study to fulfill the "bare ground" part of the general terrestrial field dissipation data requirement, the registrant could reanalyze the soil samples from the four sites by a method with more consistent recoveries, if they are still available. If the variability of the field data can not be reduced, new studies will be necessary. Also, the registrant should submit information on the sample storage conditions and conduct an adequate storage stability experiment.

METHODOLOGY:

Terbuconazole (Folicur, 1.2 lb/gallon EC) was broadcast surface sprayed at ≈ 1.5 lb ai/A (25 oz ai/A) to field plots in four states:

to sandy clay loam soil (plot size 21.7 x 98.4 feet) located in Adams Gardens, Texas, on January 12, 1987;

to sand soil (plot size 18 x 80 feet) located in Vero Beach, Florida, on January 12, 1987;

to sandy loam soil (plot size 12 x 120 feet) located in Howe, Indiana, on May 6, 1987; and

to silty clay soil (plot size 18 x 72 feet) located in Stillwell, Kansas, on July 17, 1987.

The soil characteristics are presented in Table 3. Four soil cores (1-inch diameter; 0- to 6- and 6- to 12-inch depths) were taken from each plot immediately prior to treatment, immediately posttreatment, and at 30, 60, 120-152, 270 (TX only), and 365 (TX and FL only) days posttreatment. It was implied that samples were stored frozen until analysis.

Each soil sample was refluxed for 4 hours with methanol:water (70:30). The extract was filtered, concentrated, and partitioned three times with methylene chloride. The methylene chloride phases were drained through anhydrous sodium sulfate, combined, cleaned up by silica gel column chromatography, and analyzed for terbuconazole by GC with alkali flame (N/P) detection. The detection limit was 0.01 ppm. Recovery efficiencies from soil samples fortified with terbuconazole at 0.01 to 1.0 ppm ranged from 60 to 195% (average 94%) of the applied.

DATA SUMMARY:

Terbuconazole (Folicur, 1.2 lb/gallon EC), at ≈ 1.5 lb ai/A, dissipated with half-lives ranging from 40 to 170 days in the 0- to 6-inch depth of field plots located in Indiana, Kansas, Florida, and Texas. Downward movement of terbuconazole into the 6- to 12-inch soil depth was apparent in the sand soil at the Florida site.

In Howe, Indiana, terbuconazole dissipated with a half-life of 40 days ($r^2 = 0.99$) from the upper 6 inches of a field plot of sandy loam soil that was treated on May 6, 1987. In the 0- to 6-inch soil layer, terbuconazole declined from 0.35 ppm immediately posttreatment to 0.20 ppm at 30 days, 0.14 ppm at 60 days, and 0.03 ppm at 152 days. In the 6- to 12-inch soil depth, terbuconazole declined from 0.08 ppm immediately posttreatment to <0.01 ppm at 152 days.

In Stilwell, Kansas, terbuconazole dissipated with a half-life of 125 days ($r^2 = 0.60$) from the upper 6 inches of a field plot of silty clay soil that was treated on July 17, 1987. In the 0- to 6-inch soil layer, terbuconazole declined from 0.60 ppm immediately posttreatment to 0.26 ppm by 63 days and was 0.28 ppm at 124 days. Terbuconazole was not detected (<0.01 ppm) in the 6- to 12-inch soil depth at any interval.

In Vero Beach, Florida, terbuconazole increased from 0.29 to 0.60 ppm in the 0- to 6-inch depth of a field plot of sand soil during the 30 days following treatment on January 12, 1987. Terbuconazole declined to 0.24 ppm at 60 days, 0.04 ppm at 120 days, and 0.02 ppm at 365 days posttreatment. The calculated half-life was 79 days ($r^2 = 0.77$). In the 6- to 12-inch soil depth, terbuconazole reached a maximum of 0.12 ppm at 30 days posttreatment, then declined to ≤ 0.01 ppm by 120 days.

In Adams Garden, Texas, terbuconazole was 0.89 ppm in the 0- to 6-inch soil depth immediately following treatment of a field plot of sandy clay loam soil on January 12, 1987. Terbuconazole varied from 0.23 to 1.3 ppm between 30 and 120 days posttreatment with no discernable pattern, then declined to 0.21 ppm at 270 and 365 days. The calculated half-life was 170 days ($r^2 = 0.45$). In the 6- to 12-inch soil depth, terbuconazole was ≤ 0.01 ppm at all intervals except for 0.03 ppm at 270 days.

COMMENTS:

1. The analytical method was not adequate to accurately determine the concentration of terbuconazole in the soil. Recovery efficiencies from fortified soil samples ranged from 60 to 195% of the applied (Appendix E). The data from the Texas, Florida, and Kansas sites show low correlation with time ($r^2 = 0.45$, 0.77, and 0.60 respectively), which may be a reflection of erratic recoveries. The data from the Indiana site seem to be the most reliable, and appear to indicate a non-first-order decay pattern, possibly bi- or tri-phasic.

Also, reported modifications to the analytical method (Appendix E) did not agree with the summarized analytical methods reported in the Experimental section of the study. For this report, the modifications presented in Appendix E were summarized.

2. The treated plots were only sampled 4-6 times during the study; the sampling intervals ranged from 30 to 245 days in length. The lack of a sufficient number of sampling intervals makes it difficult to accurately assess the dissipation of terbuconazole, because a single aberrant value can have a major effect on the calculations. Also, fewer data points (fewer degrees of freedom) tend to bias the r^2 value towards 1.
3. Storage conditions for the soil cores between sampling and analysis were not described; it was implied that the soil was stored frozen. In Appendix G, the registrant reported that soil collected from a terbuconazole-treated field plot (not from this study) was stored for 802 days at -10 C. Prior to storage, 84% of the recovered radioactivity in the soil was extractable (of which >99% was terbuconazole) and 16% was not extractable. After 802 days of storage, 77.8% of the recovered radioactivity was extractable (of which 96.7% was terbuconazole) and 22.2% was not extractable. This information was apparently provided in lieu of a complete freezer storage stability study. However, the information provided does not demonstrate freezer stability because some degradation may have occurred (extractable radioactivity decreased, and terbuconazole decreased from 99 to 97% of the extractable residues), and the data were reported in terms of "percent of recovered" rather than "percent of applied" (radioactivity may have been lost from the soil while the relative amounts of extractable and unextractable residues remained similar). Also, the determination of storage stability should not be based on a single sample analyzed at one interval. A typical freezer storage stability study should be submitted.
4. At the Kansas site, the study may have been terminated before the pattern of decline of the test substance was established. The study was terminated at 124 days posttreatment; the calculated half-life was 125 days.
5. The soils at the Florida and Texas sites were not sampled to a depth sufficient to define the extent of leaching. At the Florida site, terbuconazole was up to 0.12 ppm in the 6- to 12-inch depth at 30 days posttreatment. At the Texas site, terbuconazole was 0.01 and 0.03 ppm at 120 and 270 days posttreatment.

Terbuconazole was also detected in the 6- to 12-inch depth of the Indiana site at a maximum 0.08 ppm; however, the terbuconazole may be contamination since it was detected immediately posttreatment.

6. Soil samples were only analyzed for parent terbuconazole. In the soil photodegradation (MRID # 407009-58) and aerobic soil metabolism studies (MRID # 407009-50), the only extractable degradate was < 3% of the applied material, and was not identified. Most degradates were unextractable. Some effort should have been made to determine the total quantity of the unextractable degradates in this study -- i.e. by combustion.

7. For all test sites, the depth to the water table and slope of the field were not reported. Preparation of the test plots was not described; the TX and FL sites were described as being bare soil. Except for the application of additional pesticides, field maintenance practices during the studies were not described.

The IN site received one application of Roundup (7/28/87), the TX site received one application of Prowl 4 plus Paraquat (1/12/87) and three applications of Roundup (4/1, 6/1, and 9/1/87), the FL site received four applications of Roundup (3/16, 5/20, 7/30, and 9/28/87), and the KS site received no additional pesticides.

8. During the study (5/6-10/5/87) at the IN site, rainfall totaled 17 inches, air temperatures ranged from 31 to 98 F, and soil temperatures (depth unspecified) ranged from 47 to 90 F. At the KS site (7/17-11/18/87), rainfall totaled 10.2 inches and soil temperatures (8-inch depth, measured 190 miles from the test site) ranged from 38 to 92 F; air temperatures were not provided. At the FL site (1/12/87-1/12/88), rainfall totaled 52 inches, air temperatures ranged from 32 to 97 F, and soil temperatures (4-inch depth, measured 100 miles from the test site) ranged from 42 to 106 F. At the TX site (1/12/87-1/12/88), rainfall totaled 24.6 inches and soil temperatures (4-inch depth, measured 80 miles from the test site) ranged from 40 to 103 F; air temperatures were not provided.

Page _____ is not included in this copy.

Pages 85 through 93 are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
 - Description of the product manufacturing process.
 - Description of quality control procedures.
 - Identity of the source of product ingredients.
 - Sales or other commercial/financial information.
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DATA EVALUATION RECORD

STUDY 7

CHEM 128997 Terbuconazole 165-1

FORMULATION--12--EMULSIFIABLE CONCENTRATE (EC)

STUDY ID 40700964

Leimkuehler, W., C. Lenz, and J. Delk. 1988. Radioactive residues of ¹⁴C-Folicur in rotational crops. Laboratory Project ID 95638. Unpublished study performed and submitted by Mobay Corporation, Stilwell, KS.

DIRECT REVIEW TIME = 10

REVIEWED BY: L. Binari TITLE: Staff Scientist

EDITED BY: K. Patten TITLE: Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD

TEL: 468-2500

APPROVED BY: B. Conerly
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-5456

SIGNATURE:

E.B. Conerly 8/6/90

CONCLUSIONS:

Confined Accumulation - Rotational Crops

1. This study cannot be used to fulfill data requirements. Because of the deficiencies listed below, it is uncertain whether it provides enough information to allow development of a suitable protocol for a field study.
 - 1) [¹⁴C]residues in the crops were not adequately characterized (the investigator assumed that day 120 samples represented all time periods);
 - 2) storage stability data were not provided for the plant and soil substrates;
 - 3) total radioactivity in the soil was not determined prior to the soil surface treatment and at the time of harvest of the rotational crops;

- 4) [¹⁴C]terbuconazole in the soil were quantified but not identified immediately posttreatment; the test substance was not analytical grade or purer;
 - 5) the analytical methodology was not adequately described.
2. For this study to fulfill the accumulation in confined rotational crops data requirement, the registrant must do the following: characterize organosoluble and water-soluble [¹⁴C]residues in all crops from all three rotations; provide storage stability data for the plant and soil substrates; if samples are still available, quantify [¹⁴C]residues in the soil prior to the soil surface treatment and at the time of harvest of the rotational crops and characterize [¹⁴C]residues from those two intervals plus [¹⁴C]residues in the soil immediately after the soil surface application; and provide additional details about the analytical methodology and the plant growing conditions (refer to Comments 6 and 8).
3. [¹⁴C]Terbuconazole residues accumulated in kale, beets, and wheat planted 29, 122, and 273 days after sandy loam soil was treated with terbuconazole at 500 g ai/ha. In general, accumulation was greatest in crops from the 122-day rotation and least in the crops from the 29-day rotation. Residues in the kale ranged from 0.3 to 2.7 ppm; in beets from 0.2 to 1.3 ppm (tops and roots); and in wheat from 3.8 to 35.4 ppm (grain) and 1.1 to 4.2 ppm (straw). [¹⁴C]Residues extracted from the crops included terbuconazole, terbuconazole-t-butyl-hydroxy, triazole, triazolylalanine, triazolylacetic acid, and triazolyl-lactic acid. In the soil, terbuconazole (the only extractable [¹⁴C]compound) decreased from 0.43 to 0.02 ppm between the 29- and 273-day posttreatment plantings; total residues decreased from 0.52 to 0.16 ppm during the same period.

METHODOLOGY:

Triazole ring-labeled [¹⁴C]terbuconazole (radiochemical purity 98.8%, specific activity 17.42 mCi/mMol, Mobay) was mixed with unlabeled terbuconazole (Folicur, 22.5% dry flowable), "22.5% dry flowable formulation blank", and water; the formulated test substance contained 3.1% radioactive ai. The formulated test substance was applied as a foliar spray at 500 g ai/ha (equivalent to ≈1.1 lb ai/A) to wheat (boot stage) growing on sandy loam soil (70% sand, 26% silt, 4% clay, 2.8% organic matter, pH 5.2, CEC 21 meq/100 g) contained in one galvanized tub (8 x 2.5 x 2.5 feet) in a greenhouse. At 50 days posttreatment, the wheat was harvested and the formulated test substance was applied again at 500 g ai/ha directly to the soil surface. The soil was cultivated to a depth of 1 inch and allowed to age for 29 days.

At 29 days following the application of terbuconazole to the soil surface, the soil was planted to kale, beets and wheat; each crop covered one-third of the soil (Table II). Kale and beets were harvested at maturity (58 days postplanting); wheat was harvested when immature (41 days postplanting) and at maturity (93 days postplanting). At 122 days posttreatment, the soil used for the 29-day rotation was again planted to kale, beets, and wheat. Kale and beets were harvested at maturity (85 days post-

planting); wheat was harvested when immature (43 days postplanting) and at maturity (85 days postplanting). At 273 days posttreatment, the soil used for the 29- and 122-day rotations was again planted to kale, beets, and wheat. Kale and beets were harvested at maturity (60 and 107 days postplanting, respectively); wheat was harvested when immature (30 days postplanting) and at maturity (99 days postplanting).

Crops were separated into their various parts, homogenized with dry ice (except for wheat grain), and stored frozen (-10 C) until analysis; wheat grain was stored intact. Soil samples (6-inch cores) were taken immediately following the application of terbuconazole to the soil surface (second application) and at each planting interval; storage conditions for the soil samples were not described.

Plant samples, except for wheat grain, were extracted twice with methanol:water (1:1) (Figure 2). Extracts were filtered, combined, concentrated, and partitioned twice with methylene chloride:acetonitrile (2:1). For the 29-day plant samples, the organic phase was analyzed by reverse-phase radio-HPLC with UV detection and GC/MS; the aqueous phase was not analyzed. For the 122-day plant samples, the organic phase was not analyzed and the aqueous phase was applied to a cation exchange column; radioactivity that was not initially retained on the column was collected. Radioactivity remaining on the column was eluted with a 100 mM to 1 M linear gradient of sodium chloride; fractions containing radioactivity were pooled, concentrated, then derivatized with 3 N hydrochloric acid in n-butanol and heptafluorobutyric anhydride. Following the derivatization, the sample was evaporated to dryness, dissolved in acetonitrile, and analyzed by HPLC and GC/MS as described above. Radioactivity that was not initially retained by the cation exchange column was adjusted to pH 4-7, applied to an anion exchange column, eluted with the sodium chloride gradient, derivatized with n-butanolic hydrochloric acid, then analyzed by HPLC and GC/MS.

Wheat grain was ground to a fine powder, then extracted with methanol followed by a 2-hour reflux with 1 N hydrochloric acid (Figure 3). Extracts were filtered, combined, concentrated, applied to a cation exchange column, eluted with the linear sodium chloride gradient, derivatized, and analyzed by HPLC and GC/MS as described above.

Soil samples were analyzed for total radioactivity by LSC following combustion. Additional samples of the soil were extracted for 2 hours with methanol. The extract was filtered, concentrated, and analyzed by TLC (type of plates unspecified) using acetonitrile:methanol:acetic acid (90:10:1). Unlabeled terbuconazole was cochromatographed with the samples. Following development, radioactive areas were located using autoradiography.

DATA SUMMARY:

[¹⁴C]Terbuconazole residues accumulated in kale, beets, and wheat planted 29, 122, and 273 days after the second of two 500 g ai/ha applications of formulated triazole ring-labeled [¹⁴C]terbuconazole (radiochemical purity

98.8%); the first application was to wheat growing in a tub of sandy loam soil and the second application, 50 days later, was directly to the sandy loam soil surface. The concentration of [¹⁴C]residues in crops from the 122-day rotation was ≈4 to 9x greater than the concentration in crops from the 29-day rotation; the concentration of [¹⁴C]residues in crops from the 273-day rotation was generally ≈2-4x greater than the concentration in crops from the 29-day rotation.

In crops planted at 29 days posttreatment, [¹⁴C]residues at harvest were 0.3 ppm in kale, 0.2 ppm in beet tops and roots, and 3.8 and 1.1 ppm in wheat grain and straw. Organosoluble residues ranged from 0.4 to 22.9% of the recovered radioactivity, water-soluble residues ranged from 51.1 to 88.6%, and unextractable residues ranged from 5.8 to 29.7%. In the organosoluble fraction,

terbuconazole -- comprised 20.7% of the total radioactivity in kale; 15.2 and 5.6% in beet tops and roots, 22.9% in immature wheat, and 5.4% in mature wheat straw; terbuconazole was not detected in the wheat grain. In addition, in the mature wheat straw,

terbuconazole-t-butyl hydroxy -- comprised 9.3% of the recovered radioactivity.

Five unknowns (0.4-1.6%) were detected. Water-soluble [¹⁴C]residues were not characterized.

In crops planted at 122 days posttreatment, [¹⁴C]residues at harvest were 2.7 ppm in kale; 1.3 and 0.8 ppm in beet tops and roots; and 35.4, 4.2, and 15.0 ppm in wheat grain, straw, and chaff. Organosoluble residues ranged from 0.6 to 8.1% of the recovered radioactivity, water-soluble residues ranged from 85.5 to 100%, and unextractable residues ranged from 0 to 13%. In the water-soluble fraction, the primary degradate in all crops was

triazolylalanine -- detected at 1.1 ppm in kale, 0.16 and 0.3 ppm in beet tops and roots, 0.7 ppm in immature wheat, and 0.51 and 12.7 ppm in mature wheat straw and grain. Another degradate found in all crops was

triazolylacetic acid -- detected at 0.04 ppm in kale, 0.05 and 0.03 ppm in beet tops and roots, 1.5 ppm in immature wheat, and 0.4 and 3.1 ppm in mature wheat straw and grain.

Triazolyl-lactic acid -- detected in beet tops (0.37 ppm) and roots (0.01 ppm) and wheat straw (0.8 ppm), and

triazole -- detected in beet roots (0.02 ppm).

Organosoluble [¹⁴C]residues were not characterized.

In crops planted at 273 days posttreatment, [¹⁴C]residues at harvest were 2.0 ppm in kale; 1.0 and 0.9 ppm in beet tops and roots; and 7.6, 2.6, and 6.0 ppm in wheat grain, straw, and chaff. Organosoluble residues ranged from 0.2 to 2.8% of the recovered radioactivity, water-soluble residues ranged from 79.0 to 96.4%, and unextractable residues ranged from 2.7 to 20.0%. Organosoluble and water-soluble [¹⁴C]residues were not characterized.

In the 0- to 6-inch soil depth, total [¹⁴C]residues were 1.5 ppm immediately following application of formulated [¹⁴C]terbuconazole to the soil surface, 0.52 ppm at 29 days posttreatment, 0.29 ppm at 122 days posttreatment, and 0.16 ppm at 273 days posttreatment. Between 29 and 273 days posttreatment, extractable [¹⁴C]residues decreased from 84 to 14% of the total radioactivity; terbuconazole was the only compound detected in extracts from the 29- and 122-day soil samples (quantitative data were not provided).

COMMENTS:

1. [¹⁴C]Residues in the crops were not adequately characterized. Although the relative amounts of organosoluble, water-soluble, and unextractable residues in all plant parts was determined, only the organosoluble fraction from the 29-day rotational crops and the water-soluble fraction from the 120-day rotational crops were analyzed for specific [¹⁴C]compounds. The study author assumed that the composition of the organosoluble and water-soluble fractions were identical for the three rotational intervals.
2. Freezer storage stability data were not provided for the plant substrates; it was also not specified how long samples were stored frozen prior to analysis. Storage conditions for the soil samples were not described. The freezer storage data for soil supplied in Study 6 (MRID 40700962) was unacceptable.
3. Although it was stated that the soil was sampled when the rotational crops were harvested, no data were provided. For the 29- and 122-day rotations, the date of final harvest is near to the date of planting for the next rotation, so the planting date concentrations should be valid; however, data for the 273-day rotation harvest are needed.

Also, no soil samples were collected after the wheat treatment or before the application to the soil surface. The contribution of the first application to the "time 0" concentration in the soil (the sampling immediately after the soil surface was treated) could not be determined. The concentration in the 0- to 6-inch soil depth at time 0, 1.5 ppm, was much higher than the expected 0.55 ppm (assuming an application of 1.1 lb ai/A and 1 acre containing 2 million pounds of soil).

4. It was reported that only terbuconazole was detected following TLC of the 29- and 122-day soil extracts; however, quantitative data were not

provided. [¹⁴C]Residues in the 0- and 273-day soil sample were not characterized. Time 0 should have been analyzed because [¹⁴C]residues may have remained from the application to the wheat. The study author stated that insufficient extractable material from the 273-day interval was available for analysis.

5. The test substance was formulated (final purity unspecified) and, therefore, was not analytical grade or purer.
6. The analytical methodology was not adequately described; a) the type of TLC plate used was not specified, b) it was not specified how unlabeled terbuconazole was detected following TLC, c) it was not always clear what compounds were being derivatized to, and d) it was not clear at what stage of the methodology the plant extracts were analyzed for free triazole (which apparently required a separate derivatization step). Recovery efficiencies of terbuconazole and degradates from fortified soil and plant samples were not provided.
7. Immature kale and beets were not analyzed.
8. A description of the growing conditions, such as watering schedule, air temperatures, and relative humidity, was not reported.
9. The experimental design was not typical. It could not be determined why terbuconazole was applied first to a growing crop, then to the soil surface. Also, the same tubs of soil are generally not used for all three rotation intervals, rather soil that has been unvegetated for the entire rotation interval is used.
10. A confined accumulation rotational crop study using phenyl ring-labeled [¹⁴C]terbuconazole may be required.
11. The study author refers to 30-, 120-, and 270-day rotations in the text and tables. In fact, the rotations were 29, 122, and 273 days.

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Pages 100 through 112 are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
 - Description of the product manufacturing process.
 - Description of quality control procedures.
 - Identity of the source of product ingredients.
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DATA EVALUATION RECORD

STUDY 8

CHEM 128997 Terbuconazole 165-2

FORMULATION--12--EMULSIFIABLE CONCENTRATE (EC)

STUDY ID 40995923

Leslie, W.L. 1988. Folicur residues in field rotational crops. Laboratory Project ID 122-003/Mobay Project ID Folicur objective No. 8500. Unpublished study performed by EPL Bio-Analytical Services, Inc., Decatur, IL, and submitted by Mobay Corporation, Stilwell, KS.

DIRECT REVIEW TIME = 14

REVIEWED BY: L. Binari TITLE: Staff Scientist

EDITED BY: K. Patten TITLE: Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD
TEL: 468-2500

APPROVED BY: B. Conerly
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-5456

SIGNATURE:

E.B. Conerly 8/6/90

CONCLUSIONS:

Field Accumulation - Rotational Crops

1. This study cannot be used to fulfill data requirements at this time. It is scientifically sound, but does not meet Subdivision N guidelines for the following reasons:
 - crop samples were only analyzed for parent terbuconazole;
 - storage stability data were not provided for the plant and soil substrates;
 - crop residue data were incomplete; and
 - field test data were incomplete.

2. In order for this study to fulfill the accumulation in field rotational crops data requirement, the registrant must submit the following information: degradates (as identified in the confined accumulation rotational crop study) in all crops from both rotations should be quantified; storage stability data should be provided for the plant and soil substrates; if available, residue data for the crops specified (refer to Comment 6) should be provided; and details concerning the experimental procedures and field test data (refer to Comments 7-12) should be provided.
3. Terbuconazole did not appear to accumulate in spinach, turnips, and wheat or sorghum planted approximately 30 and 120 days after sandy loam/sandy clay loam and silt loam/silty clay loam soil received seven applications at 10- to 25-day intervals of terbuconazole at 3.5 oz ai/A. At harvest, terbuconazole was detected in the spinach at 0.02 ppm; in the turnips at <0.01-0.03 ppm (tops and roots); in the wheat at 0.01 ppm (grain), 0.03-0.11 ppm (straw), and 0.05 ppm (forage); and in the sorghum at 0.01-0.03 ppm (grain), 0.02-0.04 ppm (straw), and 0.01 ppm (forage).

METHODOLOGY:

Terbuconazole (Folicur, 1.2 lb/gallon EC) was broadcast surface sprayed at 3.5 oz ai/A (250 g ai/ha) seven times at 10- to 25-day intervals to field plots of:

sandy loam/sandy clay loam soil (plot size 12 x 120 feet) planted to spring rye located in Howe, Indiana, during April 14-July 7, 1986 (for 31-day plant-back of spinach and turnips), June 3-August 25, 1986 (for 32-day plant-back of wheat), and September 12-December 8, 1986 (for 126-day plant-back; all crops); and

silt loam/silty clay loam soil (plot size 18 x 50 feet) located in Stilwell, Kansas, during December 12, 1986-March 12, 1987 (for 124-day plant-back), and January 8-April 23, 1987 (for 33-day plant-back).

The soil characteristics are presented in Table 1. At approximately 30 and 120 days posttreatment, spinach, turnips, and either wheat (IN) or sorghum (KS) were planted in the treated plots. Crops were harvested at maturity: 45-119 days postplanting for spinach, 56-73 days for turnips, 87-276 days for wheat, and 121-140 days for sorghum. In addition, wheat and sorghum forage were harvested at 45 days postplanting. Soil cores (diameter unspecified, 0- to 6-inch depth) were taken following the final (seventh) application, when the crops were planted (approximately 30 and 120 days posttreatment), and at mature crop harvests (87-308 days posttreatment). Samples were stored frozen for an "average of 456 days" until analysis.

Plant samples were extracted with acetone:water (3:1). The extracts were filtered, then each was partitioned with methylene chloride and sodium chloride (ratios not reported). The organic phase was evaporated to dryness, and the resulting residue was redissolved in ethyl acetate and fractionated by gel permeation chromatography. The eluate was evaporated to dryness, redissolved in toluene, and applied to a silica gel column. The column was eluted with hexane:ethyl acetate (1:1), and the eluate was evaporated to dryness. The residues were redissolved in methanol:water (1:9) and applied to a Sep-Pak C-18 column. The column was eluted with methanol:water (7:3), and the eluate was evaporated to dryness. The residues were redissolved in ethyl acetate and analyzed for terbuconazole by GC with nitrogen-phosphorous detection. The detection limit was 0.01 ppm. Recovery efficiencies from plant samples fortified with terbuconazole at 0.01 to 0.05 ppm were 68.5-117% of the applied in spinach; 55.6-125 and 70.3-111% in turnip tops and roots, respectively; and 83-168, 65.3-98.3, and 55.4-160% in sorghum forage, grain, and straw, respectively. Recovery efficiencies were not reported for wheat.

Soil samples were extracted with methanol:water (7:3), then the extract was partitioned with methylene chloride. The organic phase was evaporated to dryness, redissolved in ethyl acetate:cyclohexane (1:1), and fractionated by gel permeation chromatography. The eluate was evaporated to dryness, and the resulting residues were redissolved in methanol:water (1:9) and applied to a Sep-Pak C-18 column. The eluate was evaporated to dryness, redissolved in ethyl acetate, and analyzed by GC as described above. The detection limit was 0.01 ppm. Recovery efficiencies from soil samples fortified with terbuconazole at 0.01 to 0.05 ppm ranged from 63.1 to 160% of the applied.

DATA SUMMARY:

Terbuconazole was ≤ 0.03 ppm in spinach leaves, turnip roots and tops, and wheat or sorghum grain planted approximately 30 and 120 days after seven applications at 10- to 25-day intervals of terbuconazole (Folicur, 1.2 lb/gallon EC) at 3.5 oz ai/A (250 g ai/ha) to sandy loam/sandy clay loam soil located in Indiana and silt loam/silty clay loam soil located in Kansas. Except for 0.11 ppm of terbuconazole in straw from wheat planted at approximately 120 days posttreatment, terbuconazole detected in the crops from the treated plots did not significantly exceed the apparent limits of determination of terbuconazole in the various plant matrices.

In crops planted at approximately 30 days posttreatment, terbuconazole at harvest was 0.02 ppm in spinach; 0.02-0.03 and 0.01-0.03 ppm in turnip tops and roots, respectively; 0.01 and 0.03 ppm in wheat grain and straw (IN site), respectively; and 0.03 and 0.04 ppm in sorghum grain and straw (KS), respectively. In immature sorghum forage harvested at 45 days postplanting, terbuconazole was 0.01 ppm.

In crops planted at approximately 120 days posttreatment, terbuconazole was 0.02 ppm in spinach (KS site only); <0.01 ppm in turnip tops (KS site only); 0.01-0.02 ppm in turnip roots; 0.01 and 0.11 ppm in wheat grain and straw, respectively; and 0.01 and 0.02 ppm in sorghum grain and straw, respectively. In immature wheat forage harvested at 45 days postplanting, terbuconazole was 0.05 ppm.

In control crops, apparent terbuconazole was 0.01-0.02 ppm in spinach; <0.01-0.02 and 0.01-0.03 ppm in turnip tops and roots, respectively; 0.02 and 0.01 ppm in wheat forage and grain; and 0.01, 0.01, and 0.02-0.06 ppm in sorghum forage, grain, and straw, respectively.

In the 0- to 6-inch soil depth from plots treated for the 30-day plant-back, terbuconazole was 0.17-0.41 ppm immediately following the final application of terbuconazole; 0.07-0.19 ppm at 31-33 days posttreatment, and 0.04-0.12 ppm at harvest (87-308 days posttreatment). From plots treated for the 120-day plant-back, terbuconazole in the soil (0- to 6-inch depth) was 0.21-2.42 ppm immediately following the final application, 0.19-0.35 ppm at 124-126 days posttreatment, and 0.01-0.10 ppm at harvest (171-245 days posttreatment).

COMMENTS:

1. Crop samples were only analyzed for parent terbuconazole. In a confined accumulation rotational crop study [Dynamac review dated 5/3/89, Study 7 (40700964)], terbuconazole plus the degradates terbuconazole-t-butyl-hydroxy, triazolylalanine, triazolylacetic acid, triazolyl-lactic acid, and triazole were detected in kale, beets, and wheat planted 29, 129, and 273 days after two 500-g ai/ha applications of terbuconazole were made to sandy loam soil. Soil samples were also only analyzed for terbuconazole; however, in photodegradation on soil and aerobic soil metabolism studies [Dynamac review 5/3/89, Studies 2 (40700958) and 3 (40700959)], no extractable degradates were identified; terbuconazole was shown to degrade primarily to unextractable compounds.
2. Freezer storage stability data were not provided for the plant substrates and soil. It was reported that the samples were stored for an "average" of 456 days; the actual length of time that the samples were stored must be provided. It was also reported that there was no "significant" degradation of terbuconazole in peanut vines that were stored frozen for 189 days; however; this is irrelevant because the crops used in this study were not of a similar plant matrix, the storage length exceeded 189 days, and no actual storage data were provided for the peanut vines.

3. It was reported that interference studies were conducted to determine the specificity of the method (Mobay Report No. 95680); however, this information was not provided and is necessary to verify the reported limits of determination of terbuconazole in the various plant substrates.
4. At the KS site, it appears that the test substance was not evenly applied to the test plot used for the 120-day plant-back (concentrations ranged from 0.21 to 2.42 ppm terbuconazole following final application); however, there was no apparent effect on the pattern of terbuconazole uptake by the various crops.
5. Immature spinach and turnips were not analyzed.
6. At the IN site, data for the wheat forage sample planted 30 days posttreatment and the spinach and turnip tops planted 120 days posttreatment were not provided. At the KS site, data for the sorghum forage sample planted 120 days posttreatment were not provided. No explanation was provided as to why the samples were not available for analysis.
7. It could not be determined exactly how many test plots were treated or the actual size of the plots. From the Residue Study Field Report Forms, it appears that at the IN site, a total of three plots, each 12 x 120 feet, were used. At the KS site, it appears that two plots, each 18 x 50 feet, were used.
8. Preparation of the test plots was not described. It was reported that the test substance was applied as a soil incorporated, broadcast spray, but it was not described how the test substance was "incorporated". At the IN site, the test substance was applied to spring-planted rye; vegetation cover at the KS site was not described. Field maintenance practices during the studies were not described.
9. Although data for crops and soil from control plots were provided, the size and location of the control plots in relation to the test plots were not provided.
10. The actual number of soil cores taken at each sampling interval could not readily be determined. It appears that a single core was taken for each crop at each sampling interval.
11. At the KS site, the depth to the water table was 6 feet; the depth to the water table at the IN site was not reported. For both sites, the slope of the field was not reported.
12. At the IN site, some meteorological data were provided, but were not collected on a daily basis; for the 30-day plant-back of wheat (6/3/86-6/29/86), rainfall plus irrigation totaled 40.8 inches, air temperatures ranged from -19 to 98 F, and soil temperatures (depth unspecified) ranged from 30 to 90 F; for the 30-day plant-back of spinach and turnips (4/14/86-10/2/86), rainfall plus irrigation to-

taled 26.2 inches, air temperatures ranged from 23 to 93 F, and soil temperatures ranged from 40 to 88 F; for the 120-day plant-back (9/12/86-7/9/87), rainfall plus irrigation totaled 28.4 inches, air temperatures ranged from -19 to 93 F, and soil temperatures ranged from 30 to 90 F. At the KS site for the 30-day plant-back (1/8/87-10/13/87) and the 120-day plant-back (12/11/86-11/12/87), rainfall totaled 32.1 and 33.9 inches, respectively; air and soil temperatures were not provided.

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Pages 119 through 127 are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
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 - Description of quality control procedures.
 - Identity of the source of product ingredients.
 - Sales or other commercial/financial information.
 - A draft product label.
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DATA EVALUATION RECORD

STUDY 9

CHEM 128997
165-4

Terbuconazole

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 40995905

Suprenant, D.C. 1988. Bioconcentration and elimination of 14C- residues by bluegill (*Lepomis macrochirus*) exposed to HWG 1608. Report No. 88-1-2623. Study #274-1186-6131-140. Unpublished study performed by Springborn Life Sciences, Inc., Wareham, MA, and submitted by Mobay Corporation, Stilwell, KS.

STUDY ID 40995906

Mulford, D.J. 1988. Identification of residues from bluegill sunfish exposed to folicur. Laboratory Project No. FR03F01. Mobay Report No. 98037. Unpublished study performed and submitted by Mobay Corporation, Stilwell, KS.

STUDY ID 40995907

Howard, K.S. 1988. The bridging of studies involving the uptake, depuration, and bioaccumulation of folicur in bluegill sunfish, and the identification of residues in the tissues. Mobay Report No. 98311. Unpublished study performed by Springborn Life Sciences, Inc., Wareham, MA and Mobay Corporation, Stilwell, KS, and submitted by Mobay Corporation, Stilwell, KS.

DIRECT REVIEW TIME = 20

REVIEWED BY: J. Harlin

TITLE: Staff Scientist

EDITED BY: K. Patten

TITLE: Task Leader

APPROVED BY: W. Spangler

TITLE: Project Manager

ORG: Dynamac Corporation

Rockville, MD

TEL: 468-2500

APPROVED BY: B. Conerly

TITLE: Chemist

ORG: EFGWB/EFED/OPP

TEL: 557-5456

SIGNATURE:

E.R. Conerly
8/6/90

CONCLUSIONS:

Laboratory Accumulation - Fish

1. This study only partially fulfills the requirement for data on fish bioaccumulation at this time. It is scientifically sound, but does not meet Subdivision N guidelines for the following reason:

radioactive residues were incompletely characterized in the fish; specifically, seven degradates, each at 70-600 ppb, were not identified in the nonedible tissues.

2. In order for this study to fulfill the accumulation in laboratory fish data requirement, the registrant must completely characterize radioactive residues in the fish tissues; Metabolites 1, 2, 3, 4, 6, and 8 must be identified since each comprised >50 ppb of the total residues in the nonedible tissues.
3. Terbuconazole residues accumulated in bluegill sunfish exposed to 60 ppb of terbuconazole, with maximum mean bioconcentration factors of 24.8x, 228.6x, and 98.6x for edible, nonedible, and whole fish tissues, respectively. The degradate HWG-2061 glucuronide was identified in the edible tissues at up to 130 ppb (day 35) and in the nonedible tissues at up to 5380 ppb (day 28). Seven major unidentified degradates, each at 70-600 ppb, were isolated in the nonedible tissues. Depuration was rapid, with 99-100% of the accumulated [¹⁴C]residues eliminated from the fish tissues by day 15 of the depuration period.

METHODOLOGY:

Juvenile bluegill sunfish (Lepomis macrochirus; mean length and weight 70 mm and 4.97 g, respectively) were held in culture tanks on a 16-hour photoperiod (Vitalite fluorescent lights) for >14 days prior to the initiation of the study. Flow-through aquatic exposure systems were prepared using 75-L aquaria (75 x 40 x 30 cm). Aerated well water (17 ± 1 C, pH 6.9-7.0, dissolved oxygen content 84-87% of saturation, total hardness 32-36 mg/L as CaCO₃, and alkalinity 29-41 mg/L as CaCO₃), was provided to each aquarium at a rate of 8 turnovers per day (90% replacement/7 hours). The flow-through systems were allowed to equilibrate prior to the start of the study (length of equilibration not specified).

Then, 120 fish were transferred into each of four aquaria, three of which were continually treated with triazole ring-labeled [¹⁴C]terbuconazole (radiochemical purity 99.5%, specific activity 2 mCi/mmol, Mobay) at 60 ppb. The fourth aquarium served as an untreated control. The fish were fed dry pelleted food daily except for the 24 hours prior to sampling. The treated water was sampled on days 1 and 2 of equilibration and at hour 0 of exposure. During treatment,

water samples and [¹⁴C]terbuconazole-treated fish (5) were taken from the treated aquaria after 1, 3, 7, 10, 14, 21, 28, and 35 days of exposure. Control fish (5) were collected at 0 hour and on day 28 of the exposure period. Following a 28-day exposure period, 32 fish from the treated aquaria were transferred to an untreated aquarium for a 15-day depuration period. Also at the 28-day interval, 148 fish were taken from the treated aquaria, eviscerated and filleted into edible and nonedible portions, frozen, and shipped to Mobay for metabolite identification. The fish remaining in the treated aquaria (approximately 140) were exposed for an additional 7 days before being taken for metabolite identification. During the depuration period, water samples and [¹⁴C]terbuconazole-treated fish (5) were collected on days 1, 3, 7, 10, and 15; control fish (5) were collected on day 15.

On days 1 and 2 of the equilibration period and at each sampling interval, aliquots (5 mL) of the water samples were analyzed for total [¹⁴C]residues using LSC. The detection limit was 1.5 ppb. Recovery efficiencies from fortified water samples ranged from 84.7 to 124%.

Pooled samples (5 fish) of whole fish, edible tissues (muscle, skin and skeleton), and nonedible tissues (fins, head, and internal organs) were homogenized with dry ice and kept frozen at -5 C until analyzed (duration of storage not specified). Aliquots of the pooled samples were analyzed for total radioactivity using LSC following combustion. Recovery rates of the oxidizer determined prior to sample analyses were 97.1-99.8%; the data were not corrected for percentage recovery. Recovery efficiencies from fortified fish tissues ranged from 86.8 to 117%. The detection limit for the fish tissues was 10 ppb.

Edible tissues from fish sampled on day 28 of the exposure period were analyzed in order to determine the relative distribution of non-polar and polar [¹⁴C]residues. Each of three sets of approximately 10 fish were homogenized with dry ice, and mixed with hexane and centrifuged; the hexane extract was decanted, evaporated under a stream of nitrogen, and analyzed for total radioactivity using LSC. The hexane-extracted tissue was then extracted with methanol; the methanol extract was filtered, evaporated under a stream of nitrogen, and analyzed for total radioactivity using LSC. Following extraction, the remaining tissue was analyzed for unextractable [¹⁴C]-residues by LSC following combustion.

Samples of edible and nonedible tissues from fish taken on days 28 and 35 of the exposure period were extracted and analyzed as shown in Figure 2. The fish tissues were extracted sequentially with acetonitrile and acetonitrile:water (4:1). The solids remaining after extraction were separated from the extracts by suction filtration, dried, and analyzed by LSC following combustion. Following radioassay by LSC, the filtrates from each extraction were partitioned three times with hexane. Both the organic and aqueous phases were

analyzed for total radioactivity using LSC and were reduced to dryness using a rotary evaporator at 35 C.

The hexane-extracted acetonitrile and acetonitrile:water phases were then subjected to batch method adsorption chromatography, in which adsorbent beads (Biobeads SM-7) were added, with a small amount of water, to the dry extract samples. Following agitation for a few minutes, the beads were removed from the solution by filtering, and any adsorbed components were eluted from the beads with methanol. The beads were added back to the aqueous solution for a second extraction, followed by elution with methanol, followed by acetone. After each solid phase extraction, aliquots of the aqueous and organic fractions were analyzed by LSC. The organic fractions from both extractions were combined and reduced to dryness using a rotary evaporator at 35 C. The sample extracts were analyzed by TLC on silica gel plates developed in acetonitrile:methanol:glacial acetic acid (90:10:1; Solvent A) and ethyl acetate (Solvent B). Following development, radioactive zones on the plates were located using autoradiography or a TLC scanner. Unlabeled reference compounds were visualized using UV light. Radioactive areas were quantified by scraping the radioactive zones and analyzing by LSC. Residues in the sample extracts were further analyzed for terbuconazole and its degradates using HPLC and GC/MS.

In addition, the hydrolysis of metabolic conjugates was used as a means of identification. Aliquots of the sample to be hydrolyzed were transferred with methanol to two Erlenmeyer flasks (sample and negative control) and the methanol was evaporated under a stream of nitrogen; a third flask containing phenolphthalein (sic) glucuronic acid served as the positive control. An aliquot of purified beta-D-Glucuronide glucuronosohydrolase (EC 3.2.1.31; from *E. coli*) in a 4 mM phosphate buffer (pH 6.8) was added to the sample flask and the positive control flasks; in the negative control, the enzyme solution was treated with D-saccharic acid 1,4 lactone to inhibit the enzyme before addition to the flask. All of the flasks were incubated in a shaking water bath at 37 C for 18 hours. To separate the aglycone after incubation, the solution was applied to a column of Porapak Q. The column was eluted with water followed by methanol, and the methanol and water fractions were each analyzed for total radioactivity by LSC. The solution from the negative control flask was applied to a Porapak Q column to separate the intact glucuronic acid from the enzyme mixture. The methanol fractions were reduced to dryness with a rotary evaporator at 35 C; the resulting residues were redissolved in methanol and analyzed by HPLC.

DATA SUMMARY:

[¹⁴C]Terbuconazole residues accumulated in bluegill sunfish exposed to triazole ring-labeled [¹⁴C]terbuconazole (radiochemical purity 99.5%) at 60 ppb for 28 days under flow-through conditions. The maximum mean bioconcentration factors were 24.8x for edible tissues

(muscle, skin, skeleton), 228.6x for nonedible tissues (fins, head, internal organs) and 98.6x for whole fish (Table 1). Maximum mean concentrations of total [¹⁴C]residues were 1800 ppb for edible tissues (day 1), 16000 ppb for nonedible tissues (day 7), and 6900 ppb for whole fish (day 7). The mean concentration of [¹⁴C]residues in the water during the exposure period was 67 ppb.

In order to isolate and identify the residues in the 28- and 35-day fish tissues, a combination of batch method adsorption chromatography, TLC, HPLC, enzyme hydrolysis of metabolic conjugates, and GC/MS was used. Total residue concentrations in the edible tissues were 520-530 ppb, and were comparatively higher in the nonedible tissues at 8530 ppb on day 28 and 6610 ppb on day 35 (Table 5). In the edible tissues, terbuconazole was the major compound at 190-200 ppb. The degradate

HWG-2061 glucuronide (Metabolite 5),

a glucuronic acid conjugate of t-butyl hydroxy terbuconazole, was isolated in the edible tissues at 110-130 ppb, and four unidentified degradates (Metabolites 2 and 6-8) were 20-40 ppb (Table 9). In the nonedible tissues, Metabolite 5 was the major degradate at 3870-5380 ppb; terbuconazole was isolated at 570-740 ppb, and seven unidentified degradates (Metabolites 1-4 and 6-8) were 70-600 ppb (Table 7). Unextractable [¹⁴C]residues comprised $\leq 2.4\%$ of the recovered radioactivity in the edible and nonedible tissues (Tables 6 and 8).

By day 15 of the depuration period, 99-100% of the accumulated [¹⁴C]-residues were eliminated from the fish tissues (Table 1). The apparent half-life for elimination of [¹⁴C]residues from whole fish was <3 days.

Throughout the study, the temperature of the treated and untreated water was 17-18 C, the pH ranged from 6.7 to 7.9, and the dissolved oxygen content ranged from 6.2 to 9.9 mg/L (65 to 102% of saturation). Total [¹⁴C]residues in the treated water ranged from 64 to 83 ppb during the exposure period.

COMMENTS:

1. Radioactive residues in the fish were incompletely characterized; seven degradates (Metabolites 1-4 and 6-8), each detected at 70-600 ppb in the 28- and 35-day nonedible tissues, were not identified. Although it was stated that each of these isolated metabolites comprised <10% of the recovered radioactivity in the nonedible tissues and therefore were not identified, Subdivision N guidelines require that degradates detected at >50 ppb be identified.

2. Radioactive residues in the water were not characterized. Since terbuconazole is relatively stable to hydrolysis, photodegradation, and microbial metabolism under both aerobic and anaerobic conditions, it is probable that the majority of the [¹⁴C]residues in the water was parent material.
3. Bioconcentration factors for edible, nonedible, and whole fish tissues were calculated by the reviewer by dividing the mean measured concentration of [¹⁴C]residues in the fish tissue by the mean measured water concentration up to and including the respective sampling day during the exposure period. This method enabled the reviewer to determine the maximum mean bioconcentration factors for each tissue type by providing bioconcentration factors for each sampling interval. In contrast, the registrant calculated mean steady-state bioconcentration factors by dividing the mean measured equilibrium ¹⁴C-tissue concentration for each type by the mean measured water concentration for the entire exposure period. Based on these calculations, the bioconcentration factors were 13x for edible tissue, 150x for nonedible tissue, and 78x for whole fish.
4. The detection limits varied for both the water and fish samples, and were dependent upon counting efficiency, sample size, and background levels of radiation for the liquid and combusted samples.
5. During the accumulation period, seven of the 360 fish in the treated aquaria and one of the 120 control fish died.
6. Control data from analyses of untreated water and fish were not provided.
7. It is recommended that a preliminary study be conducted to determine that the concentration of the test substance to be used in the experiment does not exceed 1/10 of the 96-hour LC₅₀ of bluegill sunfish.
8. It was stated that the dissolved oxygen concentration ranged from 6.2 to 9.9 mg/L (65-102% of saturation) except on day 13 of the exposure period when a diluter malfunction occurred and the dissolved oxygen concentration was 44% of saturation for a few hours.

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Pages 134 through 152 are not included.

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- Identity of product inert ingredients.
 - Identity of product impurities.
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EXECUTIVE SUMMARY

In summary, terbuconazole is

resistant to hydrolysis

resistant to photodegradation in water

slowly photodegraded on soil (half-life approximately 191 days). The primary degradation products are unextractable compounds; volatilization is negligible. No extractable degradates have been identified.

resistant to biological (aerobic and anaerobic) degradation

relatively immobile in silt, sand, and two sandy loam soils using batch equilibrium techniques on unaged compound

relatively immobile in sand, sandy loam, silt loam and silty clay loam using column leaching techniques on aged residue, which was primarily terbuconazole

accumulated in confined small grain, leafy vegetable and root crops planted into treated soil 30, 122, and 273 days posttreatment. Terbuconazole residues included triazolylalanine, triazolylacetic acid, triazolyl-lactic acid, and triazole).

found mostly at or near the level of detection in field studies using unlabeled terbuconazole, in spinach, turnips, and wheat or sorghum planted approximately 30 and 120 days posttreatment. The only materials in which terbuconazole was reliably detected were wheat straw planted 120 days post treatment and sorghum straw planted 30 days post treatment.

accumulated in bluegill sunfish exposed to 60 ppb of terbuconazole with maximum mean bioconcentration factors of 24.8x, 228.6x, and 98.6x for edible, nonedible, and whole fish tissues, respectively. Residues included terbuconazole, HWG-2061 glucuronide, and several unidentified degradates. Depuration was rapid, with 99-100% of the accumulated [¹⁴C]residues eliminated from the fish tissues by day 15 of the depuration period.

DATA BASE ASSESSMENT

The following data are REQUIRED:

Aerobic soil metabolism: characterization of the unidentified degradate in *Lee and Hanna-Bey*, MRID # 407009-50 could complete this data requirement. Otherwise a new study will be necessary.

Anaerobic soil metabolism: No data are required for current use patterns, but this is a requirement for the proposed grape use. Characterization of the unidentified degradate in *Lee and Hanna-Bey*, MRID # 407009-50 could complete this data requirement. Otherwise a new study will be necessary.

Terrestrial field dissipation: A turf field dissipation study must be done to support the currently registered use. *Pither*, MRID # 407009-62 and the analytical method in *Maasfeld*, MRID # 407009-63, were unacceptable. A vineyard study is required for the proposed grape use.

Confined accumulation in rotational crops: No data are required for current use patterns, but this is a requirement for the proposed grape use. One study (*Leimkuehler et al.*, MRID # 407009-64) has been reviewed. This study is scientifically sound, but did not meet Subdivision N guidelines for reasons detailed in the DER.

Field accumulation in rotational crops: No data are required for current use patterns, but this is a requirement for the proposed grape use. One study (*Leslie*, MRID # 409959-23) was reviewed. This study is scientifically sound, but does not meet Subdivision N guidelines for reasons detailed in the DER.

Bioaccumulation in fish: characterization of unidentified degradates in the reviewed study (*Suprenant*, MRID # 409959-05; *Mulford*, MRID # 409959-06; *Howard*, MRID # 409959-07) could make it acceptable for fulfilling the data requirement. Otherwise a new study will be necessary.

The following data requirements are FULFILLED:

Hydrolysis: Based on an acceptable study (*Coffman and Sietsema*, MRID # 407009-57), no additional data are required at this time.

Photodegradation in water: Based on an acceptable study (*Coody*, MRID # 407009-58), no additional data are required at this time.

Photodegradation on soil: Based on an acceptable study (*Coody*, MRID # 407009-58), no additional data are required at this time.

Leaching and adsorption/desorption: Three studies were reviewed. One study (*Fritz*, MRID # 409959-22) provides information on the mobility (batch equilibrium) of unaged terbuconazole in silt, sand, and two sandy loam soils. Another study (*Smyser and Lenz*, MRID # 407009-60) provides information on the mobility (column leaching) of aged terbuconazole in sand, sandy loam soil, silt loam, and silty clay loam soils. The third study (*Kavanaugh and Obrist*, MRID # 407009-61) is unacceptable for several reasons detailed in the DER.

The following data requirements are DEFERRED OR ARE NOT REQUIRED for presently registered uses:

Photodegradation in air: No data were reviewed. No data are required at this time because the test substance does not appear to pose a potentially significant exposure to workers.

Anaerobic aquatic metabolism: No data were reviewed. No data are required for current use patterns.

Aerobic aquatic metabolism: No data were reviewed. No data are required for current use patterns.

Laboratory volatility: No data were reviewed. No data are required for current use patterns.

Field volatility: No data were reviewed. No data are required for current use patterns.

Aquatic field dissipation: No data were reviewed. No data are required for current use patterns.

Forestry dissipation: No data were reviewed. No data are required for current use patterns.

Dissipation of combination products and tank mixes: No data were reviewed; however, no data are required because data requirements for combination products and tank mix uses are currently not being imposed.

Long-term field dissipation: No data were reviewed. No data are required for current use patterns.

Accumulation in irrigated crops: No data were reviewed. No data are required for current use patterns.

Field accumulation in aquatic nontarget organisms: No data were reviewed. No data are required for current use patterns.

ENVIRONMENTAL FATE ASSESSMENT:

Hydrolysis -- (requirement FULFILLED by *Coffman and Sietsema*, MRID # 407009-57; reviewed 5/3/89)

Phenyl-labeled [¹⁴C]terbuconazole (radiochemical purity >99%), at 18 ppm, was stable in aqueous phosphate-buffered solutions (pH 5, 7, and 9) that were incubated at 25 ± 1 C in the dark for 28 days. The data did not appear to show any time-dependent trend -- extrapolation to a theoretical half-life appears unjustified based on low correlation coefficients and very small slopes for the theoretical regression line. During the study, material balances ranged from 97.3 to 106.9% of the applied.

Photodegradation in water -- (requirement FULFILLED by *Coody*, MRID #07009-58; reviewed 5/3/89)

Chlorophenyl-labeled [¹⁴C]terbuconazole (radiochemical purity 98.14%), at 22.24 ug/mL, was stable (calculated half-life 590 days) in sterile buffered phosphate solutions (pH 7) that were irradiated with sunlight outdoors for 30 days at 22-32 C. During the study, the radiant energy received by the irradiated solution totaled 547.7 Watt-minute/cm² at wavelengths of 300-4,800 nm. Terbuconazole was the only [¹⁴C]compound detected in the irradiated solution and the dark control at all sampling intervals.

During the study, the material balance of the irradiated and dark control solutions decreased from 100% of the applied at time 0 to 94-97% at all other sampling intervals; the study author suggested that some terbuconazole adsorbed to the walls of the photocell.

Photodegradation on soil -- (requirement FULFILLED by *Coody*, MRID # 407009-58; reviewed 5/3/89)

Chlorophenyl-labeled [¹⁴C]terbuconazole (radiochemical purity 98.14%), at approximately 0.63 kg ai/ha, photodegraded slowly (calculated half-life 191 days) on sandy loam soil that was irradiated with sunlight outdoors for up

to 37 days at approximately 16-27 C. Terbuconazole did not degrade in the dark controls incubated under similar conditions. After 35 days of irradiation, terbuconazole comprised 86% of the applied radioactivity, two unidentified nonvolatile degradates, each comprised $\leq 3\%$, and unextractable [^{14}C]-residues comprised 5.5%. No [^{14}C]volatiles were detected. During the study, the radiant energy received by the samples totaled 811.4 Watt-minute/cm² at wavelengths of 300-4,800 nm.

The material balances ranged from 94.5 to 103.6% of the applied for the irradiated soil and 98.7 to 101.7% for the dark controls.

Aerobic soil metabolism -- (requirement partially fulfilled by *Lee and Hanna-Bey*, MRID # 407009-50; reviewed 5/3/89)

Chlorophenyl-labeled [^{14}C]terbuconazole (radiochemical purity 98.6%), at 10 ppm, degraded with a half-life of approximately 610 days on sandy loam soil incubated at 23 ± 2 C in the dark. At 1 year posttreatment, terbuconazole comprised 67.4% of the recovered radioactivity, unidentified extractable [^{14}C]residues comprised 2.1%, extractable polar compounds (compounds remaining at the origin) comprised 1.1%, and unextractable [^{14}C]residues comprised 29.1%. During the entire study, $^{14}\text{CO}_2$ comprised $\leq 0.7\%$ of the applied radioactivity. At 1-year posttreatment, the unextractable [^{14}C]residues were distributed as follows: 12.1% of the recovered was as humin, 9.9% was as humic acid, and 7.1% was as fulvic acid.

In sandy loam soil treated with triazole-labeled [^{14}C]terbuconazole (radiochemical purity 98.3%) at 10 ppm and incubated at 23 ± 2 C in the dark for up to 58 days, the concentration of terbuconazole was variable. Terbuconazole increased from 86.8% of the applied immediately posttreatment to 91.6% of the applied at 30 days posttreatment, then decreased to 79.3% of the applied at 58 days posttreatment. At 58 days posttreatment, unextractable [^{14}C]residues were 13.5% of the applied. During the entire study, $^{14}\text{CO}_2$ was not detected in the trapping solutions of the sealed flasks containing treated soil. Based on analysis of the unextractable [^{14}C]residues from the 58-day soil samples, 5.6% of the applied was in the humic acid fraction, 4.8% was in the humin, and 3.2% was in the fulvic acid fraction.

Anaerobic soil metabolism -- (requirement partially fulfilled by *Lee and Hanna-Bey*, MRID # 407009-50; reviewed 5/3/89)

[^{14}C]Terbuconazole degraded with a half-life of approximately 400 days on a sandy loam soil treated with chlorophenyl-labeled [^{14}C]terbuconazole (radiochemical purity 98.6%) at 10 ppm and incubated anaerobically (flooding) at 23 ± 2 C in the dark for 60 days following 30 days of aerobic incubation. After 60 days of anaerobic incubation (90 days posttreatment), terbuconazole comprised 74% of the applied (soil plus flood water), an unidentified degradate comprised 2.1%, and unextractable [^{14}C]residues comprised 18.5%; $^{14}\text{CO}_2$ was not detected. Based on analysis of the unextractable [^{14}C]residues from the 60-day soil sample, 8.7% of the applied was in the humic acid fraction, 7.1% was in the humin, and 2.7% was in the fulvic acid fraction. Following acid hydrolysis of the unextractable radioactivity, 76.7% of the recovered remained bound to the soil.

Leaching and adsorption/desorption

Unaged -- (requirement FULFILLED by Fritz, MRID # 409959-22; reviewed 1/12/90)

Based on batch equilibrium studies, phenyl-labeled [^{14}C]terbuconazole (radiochemical purity 99%), at 16.0, 11.0, 7.4, and 1.5 mg/L, was determined to be relatively immobile in silt, sand, and two sandy loam soil:calcium chloride solution slurries (1:10) that were equilibrated in the dark for 48 hours at 20 ± 1 C. The amount of parent compound adsorbed to the soil ranged from 28 to 46% for the sand soil and from 42 to 67% for the silt and sandy loam soils. K_{ads} values were 7.69 for the sand soil (organic carbon content 0.75%), 16.39 for the silt soil (organic carbon content 1.8%), and 15.89 and 12.69 for the two sandy loam soils (organic carbon content 1.3-1.4%); respective K_{oc} values were 1025, 911, 1251, and 906. Adsorption 1/n values for all soils were 0.71-0.74. In general, adsorption increased in soils with a higher organic content and greater proportions of silt and clay.

The amount of parent compound desorbed from the soil in pesticide-free calcium chloride solution (1:10 soil:solution ratio) following a 48-hour equilibration period at 20 ± 1 C in the dark, ranged from 41 to 56% for the sand soil and from 22 to 47% for the silt and sandy loam soils. K_{des} values were 11.83 for the sand soil, 22.27 for the silt soil, and 23.76 and 18.27 for the two sandy loam soils; respective K_{oc} values were 1577, 1237, 1871, and 1341. Desorption 1/n values for all soils were 0.77-0.83. The material balance ranged from 96 to 104% recovery of the applied radioactivity.

Aged -- (requirement FULFILLED by Smyser and Lenz, MRID # 407009-60; reviewed 5/3/89)

Based on column leaching techniques, aged [^{14}C]terbuconazole residues were relatively immobile in columns (approximately 30-cm) of sand, sandy loam, silt loam, and silty clay loam soil that were leached with 20 inches of 0.01 M calcium chloride solution over a 2-day period. Prior to leaching, the columns were topped with sandy loam soil that had been treated with chlorophenyl-labeled [^{14}C]terbuconazole (radiochemical purity 99.4%) at approximately 9.5 ppm and aged aerobically for 30 or 90 days. In the columns treated with 30-day aged [^{14}C]residues, 44-70% of the applied did not leach out of the treated soil layer; an additional 34-60% of the applied did not move out of the upper 6 cm of untreated soil. In the columns treated with 90-day aged [^{14}C]residues, 34-51% of the applied did not leach out of the treated soil layer; an additional 24-79% of the applied did not move out of the upper 6 cm of untreated soil. Terbuconazole residues were most mobile in the silty clay loam soil; after 30 or 90 days of aging, 26% of the applied [^{14}C]residues was detected in depths below 6 cm. Total radioactivity in the leachates was $\leq 0.5\%$ of the applied for all of the soil columns.

In all of the soil columns, terbuconazole comprised 78.6-87.7% of the recovered radioactivity, unextractable [^{14}C]residues were 9.5-16.5%, and unidentified extractable [^{14}C]residues were $\leq 6.1\%$. No volatilization was detected. Material balances for the five soils aged 30 or 90 days ranged from 84.7 to 128.5% of the applied.

Confined accumulation in rotational crops -- (requirement partially fulfilled by Leimkuehler et al., MRID # 407009-64; reviewed 5/3/89)

[¹⁴C]Terbuconazole residues accumulated in kale, beets, and wheat planted 29, 122, and 273 days after the second of two 500 g ai/ha applications of formulated triazole ring-labeled [¹⁴C]terbuconazole (radiochemical purity 98.8%); the first application was to wheat growing in a tub of sandy loam soil and the second application, 50 days later, was made directly to the sandy loam soil surface. The concentration of [¹⁴C]residues in crops from the 122-day rotation was approximately 4 to 9x greater than the concentration in crops from the 29-day rotation; the concentration of [¹⁴C]residues in crops from the 273-day rotation was generally 2-4x greater than the concentration in crops from the 29-day rotation.

In crops planted at 29 days posttreatment, [¹⁴C]residues at harvest were found in kale, beet tops and roots, and wheat grain and straw. Organosoluble residues ranged from 0.4 to 22.9% of the recovered radioactivity, water-soluble residues ranged from 51.1 to 88.6%, and unextractable residues ranged from 5.8 to 29.7%. In the organosoluble fraction, terbuconazole comprised 20.7% of the total radioactivity in kale, 15.2 and 5.6%, respectively, in beet tops and roots, 22.9% in immature wheat, and 5.4% in mature wheat straw; terbuconazole was not detected in the wheat grain. In addition, in the mature wheat straw, terbuconazole-t-butyl hydroxy comprised 9.3% of the recovered radioactivity and five unknowns (0.4-1.6%) were detected. Water-soluble [¹⁴C]residues were not characterized.

In crops planted at 122 days posttreatment, [¹⁴C]residues at harvest were found in kale; beet tops and roots; in wheat grain, straw, and chaff. Organosoluble residues ranged from 0.6 to 8.1% of the recovered radioactivity, water-soluble residues ranged from 85.5 to 100%, and unextractable residues ranged from 0 to 13%. In the water-soluble fraction, the primary degradate in all crops was triazolylalanine, detected at 1.1 ppm in kale, 0.16 and 0.3 ppm in beet tops and roots, 0.7 ppm in immature wheat, and 0.51 and 12.7 ppm in mature wheat straw and grain, respectively. Another degradate found in all crops was triazolylacetic acid, detected in kale, in beet tops and roots, 1.5 ppm in immature wheat, and mature wheat straw and grain. Triazolyl-lactic acid was detected in beet tops and roots, and wheat straw, and triazole was detected in beet roots. Organosoluble [¹⁴C]residues were not characterized.

In crops planted at 273 days posttreatment, [¹⁴C]residues at harvest were found in kale; beet tops and roots; and wheat grain, straw, and chaff. Organosoluble residues ranged from 0.2 to 2.8% of the recovered radioactivity, water-soluble residues ranged from 79.0 to 96.4%, and unextractable residues ranged from 2.7 to 20.0%. Organosoluble and water-soluble [¹⁴C]residues were not characterized.

In the 0- to 6-inch soil depth, total [¹⁴C]residues were 1.5 ppm immediately following application of formulated [¹⁴C]terbuconazole to the soil surface, 0.52 ppm at 29 days posttreatment, 0.29 ppm at 122 days posttreatment, and 0.16 ppm at 273 days posttreatment. Between 29 and 273 days posttreatment, extractable [¹⁴C]residues decreased from 84 to 14% of the total radioactivity; terbuconazole was the only compound detected in extracts from the 29- and 122-day soil samples (quantitative data were not provided).

Field accumulation in rotational crops -- (requirement partially fulfilled by Leslie, MRID # 409959-23; reviewed 1/12/90)

Terbuconazole was ≤ 0.03 ppm in spinach leaves, turnip roots and tops, and wheat or sorghum grain planted approximately 30 and 120 days after seven applications at 10- to 25-day intervals of terbuconazole (Folicur, 1.2 lb/gallon EC) at 3.5 oz ai/A (250 g ai/ha) to sandy loam/sandy clay loam soil located in Indiana and silt loam/silty clay loam soil located in Kansas. Except for 0.11 ppm of terbuconazole in straw from wheat planted at approximately 120 days posttreatment, terbuconazole detected in the crops from the treated plots did not significantly exceed the apparent limits of determination of terbuconazole in the various plant matrices.

In crops planted at approximately 30 days posttreatment, terbuconazole at harvest was 0.02 ppm in spinach; 0.02-0.03 and 0.01-0.03 ppm in turnip tops and roots, respectively; 0.01 and 0.03 ppm in wheat grain and straw (IN site), respectively; and 0.03 and 0.04 ppm in sorghum grain and straw (KS), respectively. In immature sorghum forage harvested at 45 days postplanting, terbuconazole was 0.01 ppm.

In crops planted at approximately 120 days posttreatment, terbuconazole was 0.02 ppm in spinach (KS site only); < 0.01 ppm in turnip tops (KS site only); 0.01-0.02 ppm in turnip roots; 0.01 and 0.11 ppm in wheat grain and straw, respectively; and 0.01 and 0.02 ppm in sorghum grain and straw, respectively. In immature wheat forage harvested at 45 days postplanting, terbuconazole was 0.05 ppm.

In control crops, apparent terbuconazole was 0.01-0.02 ppm in spinach; < 0.01 -0.02 and 0.01-0.03 ppm in turnip tops and roots, respectively; 0.02 and 0.01 ppm in wheat forage and grain; and 0.01, 0.01, and 0.02-0.06 ppm in sorghum forage, grain, and straw, respectively.

In the 0- to 6-inch soil depth from plots treated for the 30-day plant-back, terbuconazole was 0.17-0.41 ppm immediately following the final application of terbuconazole; 0.07-0.19 ppm at 31-33 days posttreatment, and 0.04-0.12 ppm at harvest (87-308 days posttreatment). From plots treated for the 120-day plant-back, terbuconazole in the soil (0- to 6-inch depth) was 0.21-2.42 ppm immediately following the final application, 0.19-0.35 ppm at 124-126 days posttreatment, and 0.01-0.10 ppm at harvest (171-245 days posttreatment).

Pesticide accumulation in fish -- (requirement partially fulfilled by Suprenant, MRID # 409959-05; Mulford, MRID # 409959-06; Howard, MRID # 409959-07; reviewed 1/12/90)

[14 C]Terbuconazole residues accumulated in bluegill sunfish exposed to triazole ring-labeled [14 C]terbuconazole (radiochemical purity 99.5%) at 60 ppb for 28 days under flow-through conditions. The maximum mean bioconcentration factors were 24.8x for edible tissues (muscle, skin, skeleton), 228.6x for nonedible tissues (fins, head, internal organs) and 98.6x for whole fish. Maximum mean concentrations of total [14 C]residues were 1800 ppb for edible tissues (day 1), 16000 ppb for nonedible tissues (day 7), and 6900 ppb for whole fish (day 7). The mean concentration of [14 C]residues in the water during the exposure period was 67 ppb.

In order to isolate and identify the residues in the 28- and 35-day fish tissues, a combination of batch method adsorption chromatography, TLC, HPLC, enzyme hydrolysis of metabolic conjugates, and GC/MS was used. Total residue concentrations in the edible tissues were 520-530 ppb, and were comparatively higher in the nonedible tissues at 8530 ppb on day 28 and 6610 ppb on day 35. In the edible tissues, terbuconazole was the major compound at 190-200 ppb. The degradate HWG-2061 glucuronide (Metabolite 5), a glucuronic acid conjugate of t-butyl hydroxy terbuconazole, was isolated in the edible tissues at 110-130 ppb, and four unidentified degradates (Metabolites 2 and 6-8) were 20-40 ppb. In the nonedible tissues, Metabolite 5 was the major degradate at 3870-5380 ppb; terbuconazole was isolated at 570-740 ppb, and seven unidentified degradates (Metabolites 1-4 and 6-8) were 70-600 ppb. Unextractable [¹⁴C]residues comprised <2.4% of the recovered radioactivity in the edible and nonedible tissues.

By day 15 of the depuration period, 99-100% of the accumulated [¹⁴C]residues were eliminated from the fish tissues. The apparent half-life for elimination of [¹⁴C]residues from whole fish was <3 days.

Throughout the study, the temperature of the treated and untreated water was 17-18 C, the pH ranged from 6.7 to 7.9, and the dissolved oxygen content ranged from 6.2 to 9.9 mg/L (65 to 102% of saturation). Total [¹⁴C]residues in the treated water ranged from 64 to 83 ppb during the exposure period.

GROUND WATER ASSESSMENT

It should be noted, in considering the following characteristics, that terbuconazole is a relatively low-dosage pesticide, used at a seasonal limit of 1.35 lb a.i./A for turf. Other proposed applications are considerably lower. According to available information, terbuconazole is highly stable to environmental degradative processes, both chemical and biological, with half-lives up to several years. It has been shown to be relatively immobile ($K_{d\ ads}$ 7 - 16) in batch equilibrium studies on unaged compound. After 30 days aging, the radiolabelled material is still more than 80% parent terbuconazole. In column leaching studies on "aged" compound, 35 - 60% eluted out of the treated layer into the first 6 cm of the column, and as much as 15% eluted into the second 6 cm. Mobility is greatest in soils of low organic content. Based on these criteria, terbuconazole has little potential to reach ground water, except possibly in the most vulnerable areas, soils which are high in sand and have little organic matter. Once there, it could persist for an unknown length of time.

SURFACE WATER ASSESSMENT

Terbuconazole is stable to most environmental degradative processes, and is relatively immobile. Based on these data, a runoff event could carry the soil-adsorbed compound into adjacent bodies of surface water, where it would probably remain in the sediment phase. There it would be resistant to the known routes of dissipation. Sensitized photolysis is a potential means of dissipation which was not investigated in available studies. However, even if it is rapid, it would probably not be much of a factor under these conditions. Therefore, terbuconazole in sediment could persist long enough to affect resident biota, particularly bottom feeders.

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Fish Bioaccumulation

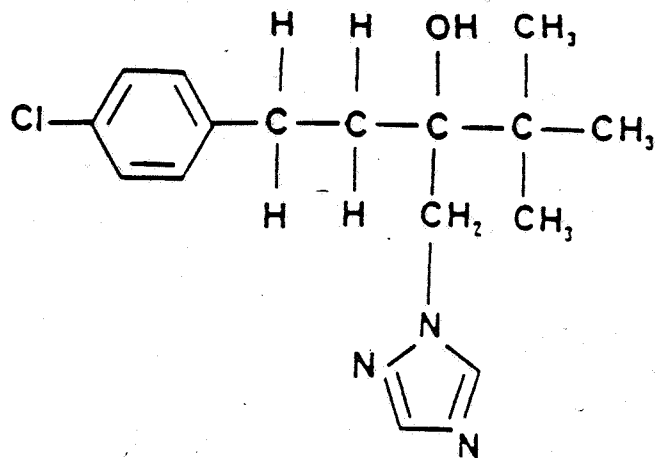
Howard, K.S. 1988. The bridging of studies involving the uptake, depuration, and bioaccumulation of folicur in bluegill sunfish, and the identification of residues in the tissues. Mobay Report No. 98311. Unpublished study performed by Springborn Life Sciences, Inc., Wareham, MA and Mobay Corporation, Stilwell, KS, and submitted by Mobay Corporation, Stilwell, KS. (MRID # 409959-07)

Mulford, D.J. 1988. Identification of residues from bluegill sunfish exposed to folicur. Laboratory Project No. FR03F01. Mobay Report No. 98037. Unpublished study performed and submitted by Mobay Corporation, Stilwell, KS. (MRID # 409959-06)

Suprenant, D.C. 1988. Bioconcentration and elimination of ^{14}C -residues by bluegill (Lepomis macrochirus) exposed to HWG 1608. Report No. 88-1-2623. Study #274-1186-6131-140. Unpublished study performed by Springborn Life Sciences, Inc., Wareham, MA, and submitted by Mobay Corporation, Stilwell, KS. (MRID # 409959-05)

Other

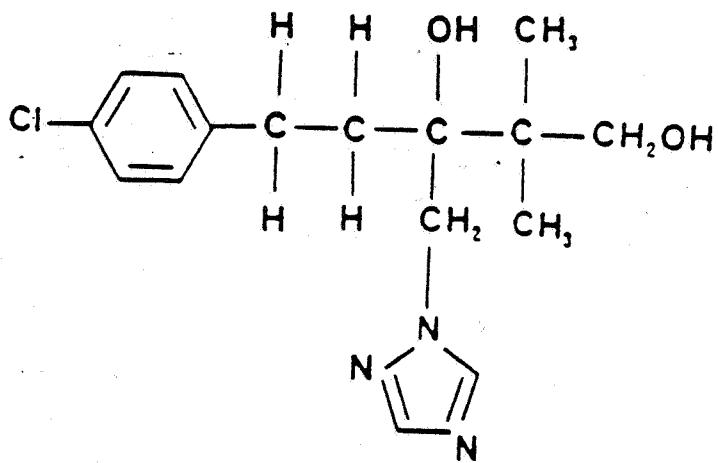
Maasfeld, W. 1986. Method for gas chromatographic determination of residues of the fungicide FOLICUR (HWG 1608) in plant materials, soil, and water. Laboratory Project ID Report No. 94295. Unpublished study performed by Bayer AG, Monheim, Federal Republic of Germany, and submitted by Mobay Corporation, Kansas City, MO. (MRID # 407009-63)



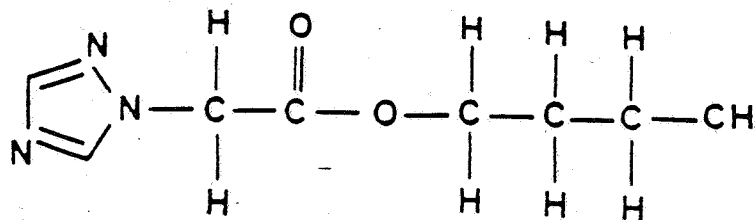
α -[2-(4 Chlorophenyl)ethyl]- α -(1,1-dimethylethyl)-
1H-1,2,4-triazole-1-ethanol

Folicur (HWG 1608)

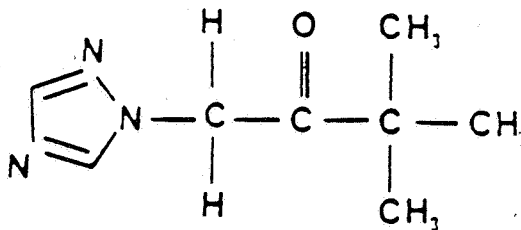
Terbuconazole



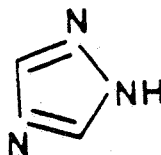
HWG 2061



Triazolylacetic acid n-butyl ester

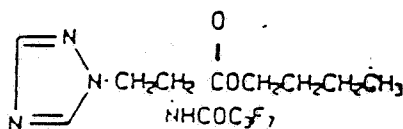


Triazolylpinacolone

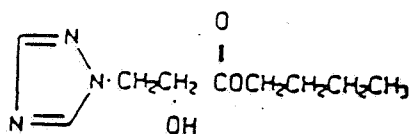


1,2,4-Triazole

For the following two degradates, the chemical names and structures provided by the registrant were incorrect. It could not be determined what the correct chemical names and structures were.



N-heptafluoroacetyl n-butyl ester
of triazolyalanine



Triazolyl-lactic acid n-butyl ester

