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Thru: Hank Jacoby Envii Envii	y, Chief ronmental Fate and ronmental Fate and	Ground Water Effects Divis	Branch Fron (17507	C)	
Attached, please	find the EFGWB rev	view of			•
Reg./File #: <u>3</u>]	L25-EUP-ROO			×	
Chemical Name: te	e(r)buconazole		•		
Type Product: fu	ıngicide		<u>.</u>		
Product Name: va	arious			\$	
Company Name: Ba	ayer AG			-	
Purpose:sı	ubmission of field	dissipation o	data		
	3				*
ate Received:	12/31/90				
otal Reviewing T	Time (days): 2.5		•		
EFGWB#(s): <u>91-030</u>	06				
Deferrals to: Ecologic	cal Effects Branch,	EFED			
Dietary	Exposure Branch, H	IED			and the second s
Toxicolo	ogy Branch, HED				
Non-Diet	ary Exposure Branc	h, HED			
Science	Integration and Po	licy Staff. H	EFED		

1. " CHEMICAL:

chemical name: a-[2-(4-Chlorophenyl)ethyl]-a-(1,1-dimethylethyl)-1H-1,2,4-

triazole-1-ethanol

common name: te[r]buconazole, folicur trade name: Elite

structure:

CAS #:

unknown
Shaughnessy #: 128997

TEST MATERIAL:

2. TEST MATERIAL: discussed in DER

- 3. <u>STUDY/ACTION TYPE</u>: submission of soil field dissipation data
- 4. <u>STUDY IDENTIFICATION</u>:
 - Pither, K.M. <u>Dissipation of Tebuconazole in Field Soil</u>. completed 6/14/88, revised 10/10/90. performed by EN-CAS Analytical Laboratories, Winston-Salem, NC, and Analytical Bio-Chemistry Laboratories, Columbia, MO; submitted by Mobay Corp, Ag. Chem. Div., Kansas City, MO. Mobay Report No. 96779. received EPA 11/29/90 under MRID# 417174-06.
 - Pither, K.M. and Leslie, W.L. <u>Freezer Storage Stability of Tebuconazole in Soil</u>. completed 10/29/90. performed by EN-CAS Analytical Laboratories, Winston-Salem, NC, and Analytical Bio-Chemistry Laboratories, Columbia, MO; submitted by Mobay Corp, Ag. Chem. Div., Kansas City, MO. Mobay Report No. 100244. received EPA 11/29/90 under MRID# 417174-10.
- 5. REVIEWED BY:

Typed Name: Title:

E. Brinson Conerly-Perks Chemist, Review Section 3

Organization: EFGWB/EFED/OPP

E.B. Coney-Perle

6. <u>APPROVED BY</u>:

Typed Name:

Akiva Abramovitch

Title: Organization:

Section Head, Review Section 3

EFGWB/EFED/OPP

off i 1991

7. <u>CONCLUSIONS</u>:

The revised and resubmitted study is marginally acceptable to fulfill the requirement for terrestrial field dissipation data. There are several deficiencies which were noted:

- Soils were analyzed only for parent Tebuconazole. Tebuconazole has shown itself to be resistent to single degradative processes in the laboratory, and the applicant assumed that no significant degradates would be detected. Soil-bound residues, which have not been characterized or quantified, may persist, and could be bio-available.
- Stated application rates were not consistent with day-0 analyses, and a day-0 analysis was lacking for one of the four test plots. The half-life calculations were based on analyzed values.

These data indicate that parent Tebuconazole does not leach, and, in the soils tested, has half-lives of 45 days (Indiana), 91 days (Florida), and 161 days (Kansas).

8. <u>RECOMMENDATIONS</u>:

The remaining required data should be submitted as soon as possible.

BACKGROUND:

Available data indicate resistance to degradation in the environment, but mobility of parent in soil is low. Some plant uptake occurs.

GROUND WATER ASSESSMENT

Tebuconazole is resistant to most degradative processes in the environment, including hydrolysis, photolysis in water and on soil, and aerobic and anaerobic metabolism. It does not appear to be mobile, based on laboratory studies and on a field dissipation study. Therefore it does not appear to be an obvious threat to ground water under most circumstances. However, if it did reach ground water, it could be expected to be long lived. The identity, quantity, and behavior of any degradates has not been defined.

SURFACE WATER ASSESSMENT

As noted above, Tebuconazole is not susceptible to most modes of environmental degradation. Since it is well adsorbed to soil, it could be carried with soil particles into bodies of surface water during a run-off event. It could be expected to remain largely associated with the sediment, and would persist there. In this situation, bottom feeding organisms would experience the most severe exposure. The identity, quantity, and behavior of any degradates has not been defined.

DATA BASE ASSESSMENT

The status of data requirements is as follows:

- hydrolysis -- fulfilled 6/9/89 (MRID# 407009-57), stable at pH 5, 7, and 9 -- no hydrolysis after 28 days incubation
- soil photodegradation -- fulfilled 6/9/89 (MRID# 407009-58) -- slow reaction; extrapolated $t_{1/2}$ ca 191 days, producing 2 unidentified degradates (<3% of applied)
- aerobic soil metabolism -- fulfilled (MRID# 407009-59) -- additional data on product identification was required 6/9/89, but a reevaluation of available information indicates that the previously submitted study should be accepted -- resistant to metabolism -- extrapolated t_{1/2} 610 days in sandy loam soil. Residues at 1 year were Tebuconazole at 67.4%, unextractables at 29.1% [ca. 20% of this (3% of the total applied) was parent compound], an unidentified extractable material at 2.1%, extractable polar compounds at 1.1%, and CO₂ at less than 0.7%.
- anaerobic soil metabolism -- fulfilled (see aerobic soil study) -- extrapolated $t_{1/2}$ ca 400 days
- leaching/adsorption/desorption -- fulfilled as of 6/9/89 (MRID# 407009-60)
 -- in column leaching studies on sand, sandy loam, silt loam, and
 silty clay loam, little leaching occured below 6 cm.
- terrestrial field dissipation -- discussed in this report -- EFGWB has required a turf field dissipation study because of this compound's use pattern
- confined accumulation on rotational crops -- fulfilled (MRID 415958-01; EBC 4/17/91) -- uptake occurs at the exaggerated rates tested

- accumulation in field rotational crops -- partially fulfilled (MRID# 409959-23); materials were only analyzed for parent -- spinach, turnips, and wheat or sorghum were planted 30 and 120 days post-treatment in soil which had received seven applications of Tebuconazole at 3.5 ppm at 10 25 day intervals. Except for 0.11 ppm of Tebuconazole in straw from wheat planted at approximately 120 days posttreatment, Tebuconazole detected in the crops from the treated plots did not significantly exceed the apparent limits of determination of Tebuconazole in the various plant matrices. In the 0- to 6-inch soil depth from plots treated for the 30-day plant-back, Tebuconazole was 0.17-0.41 ppm immediately following the final application of Tebuconazole; 0.07-0.19 ppm at 31-33 days post-treatment, and 0.04-0.12 ppm at harvest (87-308 days posttreatment). From plots treated for the 120-day plant-back, Tebuconazole 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).
- fish bioaccumulation -- partially fulfilled (MRID #s 409959-05, 409959-06, and 409959-07, reviewed for the 9/90 registration standard). Accumulation occurs @ ca. 25x, 228x, and 99x for edible, nonedible, and whole fish tissues respectively. For the study to become completely acceptable, product identification on metabolites must be provided.
- 10. <u>DISCUSSION OF INDIVIDUAL TESTS OR STUDIES</u>: see DER
- 11. COMPLETION OF ONE-LINER: appropriate information added
- 12. CBI APPENDIX: attached to DER

DATA EVALUATION REVIEW

- I. Study Type: terrestrial field dissipation; guideline 164-1
- II. Citation:

Pither, K.M. <u>Dissipation of Tebuconazole in Field Soil</u>. completed 6/14/88, <u>revised 10/10/90</u>. performed by EN-CAS Analytical Laboratories, Winston-Salem, NC, and Analytical Bio-Chemistry Laboratories, Columbia, MO; submitted by Mobay Corp, Ag. Chem. Div., Kansas City, MO. Mobay Report No. 96779. received EPA 11/29/90 under MRID# 417174-06.

III. Reviewer:

Typed Name: Title:

Organization:

E. Brinson Conerly-Perks Chemist, Review Section 3

EFGWB/EFED/OPP

5. B. Conef. Perles 10/1/91

IV. Conclusions:

The data requirement is marginally satisfied by this study in its revised form. It is unlikely that a new study would provide significant additional information. Nevertheless, there are serious deficiencies. Tebuconazole appears to decline throughout the study period, but its fate is still not well defined -- i.e. bound residues and/or degradates were not quantified or characterized. However, barring the use of radiolabel, it would be very difficult or impossible to define a mass balance and quantify and characterize degradates. The applicant has stated that analysis for degradates was not done because results from the soil metabolism study showed that throughout the 12 month sampling period parent compound was the only significant identifiable residue, with a half-life greater than ce year. A large proportion of the residues were bound. Other laboratory studies showed similar resistance to degradation by hydrolysis and photolysis.

The data do appear to demonstrate the following:

Tebuconazole does not leach.

Dissipation half-lives for the parent range from 45 days in Indiana, to 91 days in Florida to 161 days in Kansas.

V. Materials and Methods:

Abstract

Four soil dissipation studies were conducted to delineate the persistence of parent Tebuconazole (also known as FOLICUR, ELITE, RAXIL, AND HWG 1608) residues which would result from a single broadcast spray application of FOLICUR 1.2 EC at a rate of 25 oz active ingredient (AI)/acre. Tebuconazole residues from sampling intervals to approximately 1 year are presented in this report along with the calculated half-life values which ranged from 46 to 167 days post-treatment. Since an aerobic soil study showed no significant extractable residues with half-lives over 1 year, soil samples were only analyzed for Tebuconazole residues. There were no significant Tebuconazole residues found in the 6-12" soil horizons to approximately one year of sampling, at three of the four test sites in this study. Apparent Tebuconazole residues found in the 6 to 12 inch horizons at the Indiana test site appear to be the result of possible field sampling contamination.

test material -- Tebuconazole as Folicur 1.2 EC [chemical purity 99.9% and 96.2% pure compared to analytical reference standard]

test sites -- Indiana, Kansas, Florida, and Texas (see attached map)

test protocol -- single broadcast spray at the rate of 25 oz AI/acre applied in a volume of 16 to 60 gallons/acre. 1-inch soil cores were collected through a depth of 12 inches up to a maximum sampling

interval of approximately 365 days post-treatment. Cores were divided into 0 to 6 inch and 6 to 12 inch nominal horizons. Field conditions such as water table depth, slope of the field, and daily temperature were included in the report; rainfall data for each of the four test sites are attached. Rainfall during the sample collection period was as follows:

```
Howe, IN

1987, May - December -- total of 30.12"
1988, January - December -- total of 27.72"
1989, Jan - October -- total of 28.09"

Adam's Gardens, TX
1987, May - December -- total of 14.86"
1988, January - December -- total of 27.72"
1989, January - July -- total of 9.32"

Stillwell, KS
1987, July - December -- total of 34.23"
1988, January - December -- total of 34.23"
1989, January - October -- total of 33.45"

Vero Beach, FL
1987, January - December -- total of 34.19"
1988, January - December -- total of 34.19"
1989, January - October -- total of 42.41"
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- analytical method -- (Refer to MRID no. 407009-63 for complete details)

 Tebuconazole was extracted from the soil by refluxing with methanol/water (70/30). The extract was filtered, concentrated, and partitioned 3x with methylene chloride. The methylene chloride phases were drained through anhydrous sodium sulfate, combined, and cleaned up using silica gel column chromatography. Quantitation was performed via gas chromatography using a nitrogen/phosphorus (N/P) specific detector. In this application, the automated gel permeation chromatography clean-up step was omitted.
- storage stability -- reported in MRID# 417174-10 -- As described by the investigators, soil samples from field soil dissipation trials were analyzed for residues of Tebuconazole, then held in frozen storage (-10°C) for up to 566 days, then reanalyzed. In 5/10, residues were higher when reanalyzed than they were originally. 2/10 had minimal decompositions of 2.4% and 10.7%. 3/10 showed "moderate" decompositions ranging from 23.7% to 58.3%. Per the investigators, "residues of Tebuconazole in soil were generally found to be stable in the majority of samples in this study, with minimal or no residue degradation detected ... following extended frozen storage."

VI. Study Author's Results and/or Conclusions:

1) Calculated half-life values determined from 4 to 6 observations from the combined studies ranged from 46 to 167 days. This result is shorter than the observed half-life from the laboratory soil metabolism study of greater than one year. The photochemical half-life of Tebuconazole was extrapolated to be equivalent to 191 days as presented in a previous report (MRID# 407009-58).

The apparent limit of detection (lod) was 0.01 ppm. In two separate validation procedures with fortified samples, recoveries ranged from 62% - 106% and 88% - 100%, with control (unfortified) samples all below 0.01 ppm. Response was linear between 0.005 and 0.2 ppm.

- Three of the four test sites had no significant Tebuconazole measured residues (>0.01 ppm lod) at the 6 to 12 inch soil horozon through sampling intervals up to one year, clearly indicating no potential for mobility. This lack of mobility was confirmed by a laboratory leaching study, in which less than 1% of the aged rsidues of Tebuconazole- C leached through five different types of soil columns. Apparent Tebuconazole residues were detected in the 6 to 12 inch soil horizons at day 0, 30, and 61 sampling intervals from the Howe, Indiana test site and appear to be the result of improper field sampling techniques, due to the fact that measurable amounts of Tebuconazole were found at the time "0" interval. These results are considered anomalous and not characteristic of the other 6 to 12 inch horizon samples in the study.
- 3) Under normal field use, residues of Tebuconazole would have little potential of reaching ground water levels prior to its dissipation.

VII. Reviewer's Comments:

This study was first reviewed 6/9/89. At that time, the discussion did not mention the first deficiency noted below.

The samples were only analyzed for parent. One of the stated objectives of this experiment is to <u>define patterns of formation and decline of degradation products</u>. Although Tebuconazole is long lived, it is not unreasonable to suppose that some degradates must have been formed over the course of a year, expecially in view of the fact that several processes were operating.

This appears to have been a bare soil application. The application rate was not confirmed. It was stated to be 25 oz AI/Acre, or 1.56 lb/A. This is approximately equivalent to 0.78 ppm in a 6 inch soil layer. There is no day-0 analyses for one of the soils (Adams Gardens, TX), and the other three soils range from 36% to 65% of the nominal value. There were two applications made to each plot, one year apart. It is not clear from the material included in the submission exactly which application was the one analyzed.

Re <u>investigator's conclusion 1</u> -- Based in available data, the calculated field half-life resulting from soil photolysis and aerobic metabolism has an upper limit of ca. 145 days, which is in the same order of magnitude as the observed values. The investigator's conclusion is supported, or, at least not contradicted by the data.

Re investigator's conclusion 2

Howe, IN -- Of all the data sets, these show the "best fit" to a straight line against time as the independent variable. Although residues appear in the 6 to 12 inch segment at day "O", the decline curve shows a pattern similar to that in the upper layer. The data are not inconsistent with these residues deriving from previous treatment, although the report says the screening study shows that there were none. Since there were residues detected in the top two layers, for this portion of the study to be fully satisfactory, there should have been sampling at greater depth. These data do appear to show that leaching did not occur. Further, they do seem to define a half-life of ca. 45 days.

Adams Gardens, TX -- There is no day-0 analysis, and the other data must be said to be erratic. Clearly they do not define a plausible linear or curvilinear decay curve (r²-0.4 for the "best fit" straight line). The data do appear to show that

leaching did not occur, but do not serve to define a valid half-life.

Stillwell, KS, and Vero Beach, FL -- These data sets seem reasonably self-consistent. They both appear to show that leaching does not occur, and serve to define half lives of 161 and 91 days respectively.

Re <u>investigator's conclusion 3</u>, the data are consistent with the conclusion that Tebuconazole does not leach.

VIII. CBI Information Addendum: attached

Terbuconazole 91-0306

-8-

Page is not included in this copy. Pages 9 through 18 are not included in this copy.
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.
Information about a pending registration action.
FIFRA registration data.
The document is a duplicate of page(s)
The document is not responsive to the request.
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.

RAINFALL IN HOWE, IN

	1987		1988		1989
	•	JAN	1.44"	JAN	1.40"
		FEB	1.44"	FEB	0.81"
ia.		MAR	2.23"	MAR	2.18"
		APR	2.51"	APR	3.10*
MAY	2.19"	MAY	2.20"	MAY	4.48"
JUN	4.40"	JUN	0.41"	JUN	3.39"
JUL	5.57"	JUL	3.17"	JUL	2.96"
AUG	4.05"	AUG	3.89"	AUG	5.37"
SEP	4.34"	SEP	4.25"	SEP	3.13"
ОСТ	2.61"	OCT	4.80"	OCT	1.27"
NOV	2.91"	NOV	4.43"	٠.	
DEC	4.05"	DEC	2.10"		

RAINFALL IN ADAMS GARDENS, TX

*	1987		1988		*	1989
		JAN	3.33*		JAN	1.31"
e e		FEB	1.92"	•	FEB	0.38"
		MAR	4.52"		MAR	0.03"
•		APR	0.18"		APR	3.45"
MAY	3.62	MAY	1.95"		MAY	2.39"
JUN	2.55"	JUN	1.27"		JUN	0.07"
JUL	2.76"	JUL	0.45"		JUL	1.69"
AUG	0.86"	AUG	3.48"	٠		
SEP	2.39"	SEP	9.70"		•	
ОСТ	0.46"	ОСТ	0.88"			
NOV	1.94"	NOV	0.00"			
DEC	0.28"	DEC	0.04"	•		

RAINFALL IN STILLWELL, KS

	1987		1988		1989
		JAN	0.95"	JAN	1.18"
		FEB	0.53"	FEB	0.86"
,		MAR	1.94"	MAR	2.45"
		APR	1.62"	APR	0.91"
		MAY	1.31"	MAY	5.58"
		JUN	3.34"	JUN	4.68"
JUL	2.65"	JUL	6.63"	JUL	3.75*
AUG	5.07"	AUG	2.52"	AUG	3.87"
SEP	1.19"	SEP	10.81"	SEP	4.70"
OCT	1.74"	ОСТ	0.44"	ОСТ	5.47"
NOV	3.22"	NOV	2.77"		,
DEC	2.11"	DEC	1.37"		

RAINFALL IN VERO BEACH, FL

	1987		1988		1989
JAN	3.20"	JAN	2.64"	JAN	2.09"
FEB	1.27"	FEB	1.93"	FEB	1.25"
MAR	5.87*	MAR	5.41"	MAR	5.32"
APR	0.23"	APR	0.54"	APR	3.70"
MAY	5.85"	MAY	5.59"	MAY	1.80"
JUN	4.45"	JUN	2.23*	JUN	4.02"
JUL	5.73"	JUL	13.08"	JUL	5.97"
AUG	4.61"	AUG	4.30"	AUG	5.13"
SEP	5.18"	SEP	1.37"	SEP	5.88"
OCT	7.89*	OCT	1.65"	OCT	7.25"
NOV	8.35"	NOV	2.56"		
DEC	0.60"	DEC	2.89"		

** FIFRA **

CONFIDENTIAL BUSINESS INFORMATION DOES NOT CONTAIN NATIONAL SECURITY INFORMATION (EO 12356)

Some information in the attached One Liner report may be entitled to treatment as trade secret or proprietary data under section 7(d) and section 10 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended.

Any person handling or using the attached data in any way is responsible for preventing unauthorized disclosure while it is in his possession. Section 12(a)2(D) makes it unlawful for any employee to use to his own advantage or to reveal any confidential information (except to persons needing the information for the performance of official duties). A penalty of up to \$10,000 fine and up to 3 years imprisonment may result from conviction of a violation of section 12(a)2(D).

Section 10(f) makes it a crime for any employee to disclose confidential information except as authorized by sections 7 and 10 of FIFRA. A penalty of up to \$10,000 fine and up to 9 of section 10(f).

The attached One Liner report is not to be published, reproduced, publicly discussed, included in responses to an FOI request or otherwise released without the explicit written authorization of the appropriate Division Director or his designee.

Last Update on October 8, 1991 [V] = Validated Study [S] = Supplemental Study

[U] = USDA Data

LOGOUT Reviewer: Section Head: Date: Common Name: TERBUCONAZOLE PC Code # :128997 CAS #:107534-96-3 Caswell #: Chem. Name: Action Type: BROAD SPECTRUM SYSTEMIC FUNGICIDE Trade Names: (Formul'tn):1.2 LB/GALLON EC Physical State: Use :FOR LAWNS, TURF, AND GRASS GROWN FOR SEED Patterns (% Usage): Empirical Form: Molecular Wgt.: Vapor Pressure: Torr Melting Point : °C Boiling Point: Log Kow pKa: Henry's E Atm. M3/Mol (Measured) Solubility in ... Comments Water E °C ppm Acetone E ppm a °C Acetonitrile \mathbf{E} °C ppm Benzene E ppm @ °C Chloroform E °C ppm @ Ethanol E ppm @ °C Methanol E ppm @ °C Toluene E °C ppm @ Xylene Ē °C ppm @ E ppm @ °C E ppm @ °C Hydrolysis (161-1) [V] pH 5.0:STABLE [V] pH 7.0:STABLE [V] pH 9.0:STABLE [] pH

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Photolysis (161-2, -3, -4) [V] Water: ABOUT 600 DAYS IN SUNLIGHT [] : [] : [] :
[V] Soil :191 DAYS, Sdlm, SUNLIGHT
Aerobic Soil Metabolism (162-1) [S] ABOUT 610 DAYS ON SdLm [] [] [] [] [] [] []
Anaerobic Soil Metabolism (162-2) [S] ABOUT 400 DAYS ON Sdlm [] [] [] [] [] [] []
Anaerobic Aquatic Metabolism (162-3) [] [] [] [] [] [] [] [] []
Aerobic Aquatic Metabolism (162-4) [] [] [] [] [] []

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[S] = Supplemental Study

[U] = USDA Data

Long-Term Soil Dissipation (164-5) [] Accumulation in Rotational Crops, Confined (165-1) RESIDUES ACCUMULATED IN KALE (.3-2,7 PPM), BEETS (.2-1.3 PPM), AND WHEAT (3.8-35.4 PPM, GRAIN) Accumulation in Rotational Crops, Field (165-2) RESIDUES WERE GENERALLY FOUND AT OR BELOW THE LOD []Accumulation in Irrigated Crops (165-3) Bioaccumulation in Fish (165-4) [S] ACCUMULATION AT BCFS OF 25-229, RAPID DEPURATION 1 Bioaccumulation in Non-Target Organisms (165-5) r 1 Ground Water Monitoring, Prospective (166-1) Ground Water Monitoring, Small Scale Retrospective (166-2) 1 Ground Water Monitoring, Large Scale Retrospective (166-3) []

Ground Water Monitoring, Miscellaneous Data (158.75)

Last Update on October 8, 1991
[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

Field Runoff [] []	(167-1)			
Surface Water	r Monitoring (167	-2)		
			· ·	\$
Spray Drift, [] [] [] []	Droplet Spectrum	(201-1)		••
Spray Drift, [] [] [] []	Field Evaluation	(202-1)		
Degradation 1	Products			

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[V] = Validated Study [S] = Supplemental Study [U]

[U] = USDA Data

Comments

Residues extracted from crops included terbuconazole, terbuconazole-t-butyl-hydroxy, triazole, triazolylalanine, triazolylacetic acid, and triazolyl-lactic acid.

References: EFGWB REVIEWS

Writer : PJH, UPDATED 10/9/91 BY EBC