UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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MEMORANDUM

18 FEB 1993

SUBJECT: Fenbuconazole New Chemical Registration Standard - Environmental Fate and Ground Water Branch Science Chapter

TO: Cynthia Giles-Parker, Product Manager 22
Fungicide-Herbicide Branch
Registration Division (H7505C)

THRU: Henry M. Jacoby, Chief
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

Paul J. Mastradone, Ph.D., Chief
Environmental Chemistry Review Section 1
Environmental Fate and Ground Water Branch

FROM: Arnet W. Jones, Agronomist
Environmental Chemistry Review Section 1
Environmental Fate and Ground Water Branch

Attached is the EFGWB Science Chapter for the Fenbuconazole New Chemical Registration Standard. It includes Task 1 (Review of Individual Studies), Task 2 (Executive Summary which includes the Environmental Fate Summary and Ground Water Assessment) and Data Table A, Subdivision N Environmental Fate Data Requirements. Although studies have been submitted to support the proposed uses, the registrant (Rohm and Haas) has acknowledged that additional data regarding terrestrial field dissipation are needed to assess more completely the behavior of fenbuconazole under field conditions. Please refer to the Executive Summary and the DER for the field dissipation study for details. Also, it appears that the active ingredient may exist as a mixture of stereoisomers. Information on the stereochemistry of the active ingredient should be submitted to EFGWB. If the active ingredient exists as a mixture of stereoisomers, the registrant must submit evidence that the environmental fate data presented fully describes the behavior of all isomers of the active ingredient.

Use Patterns

The use information which follows comes from labeling submitted by the registrant in connection with applications for experimental use permits (EUPs). Fenbuconazole (RH-7592) is a protectant or presymptomatic infection

treatment used for control of fungal diseases. At present it is proposed for use on stone fruits (apricots, cherries, nectarines, peaches, plums, and prunes are indicated on the sample labeling) and pecans. It is formulated as a flowable concentrate which contains 2 lb a.i./gallon. According to sample labeling received by EFGWB, the application rate varies by crop. The maximum allowable rate for a single application is 0.125 lb a.i./A; the label allows multiple applications up to a seasonal limit of 1 lb a.i./A. Fenbuconazole is applied by ground equipment, but specific application methods are not specified. EFGWB assumes that ground application includes conventional orchard (airblast or mist blower) methods. EFGWB notes that the extension of an EUP for use on stone fruits would involve aerial application (EFGWB nos. 92-0007 & 92-0307; 12/03/92).

Environmental Fate Data Requirements

The registrant (Rohm and Haas) has submitted studies in support of all of the environmental fate data requirements currently needed to support uses on stone fruits and pecans. However, EFGWB notes that the sample labeling submitted indicates that fenbuconazole is toxic to fish and aquatic invertebrates and that drift or runoff from treated areas may be hazardous to aquatic organisms in adjacent aquatic sites. Therefore, droplet size spectrum (201-1) and drift field evaluation (202-1) data may be required by EFGWB if concerns are identified by the Ecological Effects Branch or Health Effects Division.

With the exception of the terrestrial field dissipation study (164-1) which provides supplemental information, all environmental fate data requirements needed at this time to support use on stone fruits and pecans have been satisfied. The registrant has acknowledged that additional field dissipation data are needed to address more fully the dissipation of fenbuconazole under field use conditions and stated that supplementary trials were initiated in 1991 to provide this information. (Although the currently proposed uses are for pecans and stone fruits, no orchard dissipation studies were submitted. EFGWB believes, however, that the terrestrial field dissipation studies submitted adequately assess dissipation under field use conditions provided that the additional information to be submitted addresses the unresolved issues. See the DER for the terrestrial field dissipation study for details.)

The current status of the environmental fate data requirements is summarized below and outlined in detail in Table A (attached):

Data Requirement	Status	MRID No.	EFGWB#/Date
Degradation			
Hydrolysis (161-1)	Fulfilled[1]	41031246	90546; 10/12/89
Photodegradation water (161-2)	Fulfilled	41875023	92-0257;02/18/93
Photodegradation soil (161-3)	Fulfilled	41875024	92-0257;02/18/93

Data Requirement	Status	MRID No.	EFGWB#/Date
Metabolism			
Aerobic soil metab. (162-1)	Fulfilled	41031247	90546; 10/12/89
Anaerobic soil metab. (162-2)	Fulfilled	41031247	90546; 10/12/89
Mobility			
Leaching/ads./des. (163-1)	Fulfilled	41031248	90546; 10/12/89
Dissipation			
Soil dissipation (164-1)	Not fulfilled[2]	42053503	92-0257;02/18/93
		41875029	92-0257;02/18/93
Accumulation			
Confined rotat. crop (165-1)	Not Applicable[3]		
Accumulation in fish (165-4)	Fulfilled	41073509	90546; 10/12/89
		42001101	92-0257;02/18/93
Spray Drift			
Droplet size spectrum (201-1) and Drift field eval. (202-1)	Reserved[4]		

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1 An amendment to the original hydrolysis study was submitted under MRID no. 41875022. The sole purpose of this amendment was to correct the aqueous solubility of fenbuconazole which was stated as 4.1 ppm in the original hydrolysis study. The correct solubility as stated in the amendment is 2.7 ppm at 22°C. This does not affect the validity of the original study nor the conclusions of EFGWB since the original study was conducted with a fenbuconazole concentration of 0.1 ppm.

2 The terrestrial field dissipation study submitted provides supplemental information. The registrant has indicated that additional information related to the dissipation of fenbuconazole under field conditions will be submitted. This additional information may be sufficient to upgrade the study to acceptable and fulfill the data requirement for currently proposed uses.

3 Accumulation in confined rotational crops are usually required for terrestrial food crop uses. In this case, however, this data requirement does not apply because the registrant seeks registration only for use on pecans and stone fruits which are not rotated.

4 Sample labels indicate that RH-7592 is toxic to fish and aquatic invertebrates. Droplet size spectrum and drift field evaluation data may be required by EFGWB if toxicological concerns are identified by the Ecological Effects Branch and/or Health Effects Division.

Environmental Fate, Ground Water and Runoff Assessments

Fenbuconazole is moderately persistent with surface degradation half-lives ranging from 79 days for soil photolysis to 367 days for aerobic soil metabolism. Degradation of fenbuconazole at depth will also occur slowly as the compound was stable to hydrolysis at pH 5, 7, and 9 and degraded in soil under anaerobic conditions with half-lives of 451-655 days. Fenbuconazole and its degradates appear to be slightly mobile to immobile in soil with K_d's ranging from 5 to 115. The principal route of dissipation appears to be adsorption to soil, with increased adsorption associated with higher soil organic matter content. Because of its adsorption to soil, the potential for fenbuconazole to leach to ground water appears to be slight. However, the potential to contaminate ground water may be greater at vulnerable sites, i.e. where soils are low in organic matter where ground water is relatively close to the surface. Mineralization to CO_2 and soil photolysis appear to be less important routes of dissipation.

With the exception of the terrestrial field dissipation data (which is supplemental at this time), the information presented below is from acceptable studies which fulfill the respective data requirements.

Fenbuconazole is stable to hydrolysis in aqueous buffered solutions at pH 5, 7, and 9 and did not photodegrade in sterile aqueous pH 7 buffer solution irradiated with a xenon arc light. The soil photolysis half-life was reported as 79 days. Fenbuconazole is metabolized slowly in soil under aerobic ($t_{1/2}$ = 285 and 367 days in silty clay loam and sandy loam soils, respectively) and anaerobic conditions ($t_{1/2}$ = 451 and 655 days in silty clay loam and sandy loam soils, respectively). In the aerobic soil metabolism study, the metabolites RH-9129, RH-9130, RH-6467, and triazole were detected in relatively low concentrations. In the anaerobic study, small concentrations of RH-9129, RH-9130, and RH-6467 were detected. Fenbuconazole and its degradation products appear to be slightly mobile to immobile in soil (K_d values for parent ranged from 5 to 115) with the degree of adsorption positively associated with soil organic matter content. Aged residues exhibited very slight potential to leach in sandy loam columns. Supplemental terrestrial field dissipation data indicate that fenbuconazole will be persistent in the field. Reported half-lives of the parent compound at four sites ranged from 157 to 407 days. Minimal leaching of parent and degradates was observed. Fenbuconazole and degradates RH-9130, RH-9129, RH-6467, and triazole were found in a few samples in concentrations at or below the limit of quantification at depths greater than 6 inches. Because of its persistence in the field, EFGWB believes that fenbuconazole residues may accumulate in soil with repeated applications over multiple growing seasons. Its persistence and relative lack of mobility indicate that it could reach surface water via runoff following rainfall or irrigation. Moreover, if its use is extended to field crops, fenbuconazole residues may be available for uptake by rotated crops because of the persistent nature of the compound. Fenbuconazole did not bioaccumulate in bluegill sunfish (maximum bioaccumulation factors were 170X, 50X, and 330X in whole fish, fillet, and viscera tissue, respectively) and 95-98% of accumulated residues were eliminated during a 14-day depuration period.

EXECUTIVE SUMMARY

Fenbuconazole (RH-7592; fenethanil) is a protectant or presymptomatic infection treatment used for control of fungal diseases. At present it is proposed for terrestrial food crop use. Sample labeling supplied to EFGWB indicates that fenbuconazole is intended for use on stone fruits (apricots, cherries, nectarines, peaches, plums, and prunes) and pecans.

The registrant (Rohm and Haas) has submitted studies in support of all of the environmental fate data requirements currently needed to support uses on stone fruits and pecans. With the exception of the terrestrial field dissipation data requirement (164-1), all environmental fate data requirements needed to support use on stone fruits and pecans have been fulfilled. The registrant acknowledged that additional data are required to assess the behavior of fenbuconazole in the field and stated that supplementary trials were initiated in 1991 to address the issue. Refer to the DER for the field dissipation study for details. Also, it appears that the active ingredient may exist as a mixture of stereoisomers. Information on the stereochemistry of the active ingredient should be submitted to EFGWB. If the active ingredient exists as a mixture of stereoisomers, the registrant must submit evidence that the environmental fate data presented fully describes the behavior of all isomers of the active ingredient.

Fenbuconazole is moderately persistent with surface degradation half-lives ranging from 79 days for soil photolysis to 367 days for aerobic soil metabolism. Degradation of fenbuconazole at depth will also occur slowly as the compound was stable to hydrolysis at pH 5, 7, and 9 and degraded in soil under anaerobic conditions with half-lives of 451-655 days. Fenbuconazole and its degradates appear to be slightly mobile to immobile in soil with K_d's ranging from 5 to 115. Field data tend to support the results of the laboratory studies in terms of mobility and persistence. The principal route of dissipation appears to be adsorption to soil, with increased adsorption associated with higher soil organic matter content. Mineralization to CO_2 and soil photolysis appear to be less important routes of dissipation. Contamination of ground water resulting from normal agricultural use of fenbuconazole appears to be unlikely for most soils. However, ground water contamination may be possible in vulnerable areas, i.e., where soils are low in organic matter and where the water table lies near the soil surface. Because of its persistence in the field, EFGWB believes that fenbuconazole residues may accumulate in soil with repeated applications over multiple growing seasons. Its persistence and relative lack of mobility indicate that it could reach surface water via runoff following rainfall or irrigation. Moreover, if its use is extended to field crops, fenbuconazole residues may be available for uptake by rotated crops.

The studies that have met the requirements of 40 CFR part 158.290 and the guidance of Subdivision N are:

- Hydrolysis (161-1)
- Photodegradation in water (161-2)
- Photodegradation on soil (161-3)

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- Aerobic soil metabolism (162-1)
- Anaerobic soil metabolism (162-2)
- Leaching and adsorption/desorption (163-1)
- Bioaccumulation in fish (165-4)

Additional information regarding the following is required to support full registration of fenbuconazole for use on stone fruits and pecans:

- Terrestrial field dissipation (164-1)

The registrant has indicated that additional terrestrial field dissipation data will be submitted. It is possible that this additional information will upgrade the submitted study to acceptable and fulfill the data requirement to support use on stone fruits and pecans.

EFGWB notes that the labeling submitted indicates that fenbuconazole is toxic to fish and aquatic invertebrates and that drift or runoff from treated areas may be hazardous to aquatic organisms in adjacent aquatic sites. Therefore, the following data may be required by EFGWB if concerns are identified by the Ecological Effects Branch and/or Health Effects Division:

- Droplet size spectrum (201-1)
- Drift field evaluation (202-1)

ENVIRONMENTAL FATE, GROUND WATER, AND SURFACE WATER RUNOFF ASSESSMENTS

The following data summary is derived from studies deemed acceptable by EFGWB:

Hydrolysis

Fenbuconazole (0.1 ppm; ^{14}C-labeled in the triazole position) was stable in aqueous buffered pH 5, 7, and 9 solutions maintained at 25 ± 1°C in darkness for 30 days. At the end of the experiment, 98.9, 99.2, and 99.7% of the recovered radioactivity was recovered as ^{14}C-RH-7592 (fenbuconazole) at pH 5, 7, and 9, respectively. During the course of the study, parent ^{14}C-RH-7592 accounted for 97.6-100.0% of the applied radioactivity. Material balances were 94.2-103.5%

Photodegradation in Water

Uniformly phenyl ring-labeled [^{14}C]fenbuconazole at 1.5 ppm, did not degrade in sterile aqueous buffered (pH 7) solutions that were irradiated at 25 ± 1°C for 30 days (12 hours/day) using a xenon arc lamp. The intensity of light from the xenon lamp was 139.6-157.2 W/m^2 between wavelengths of 330 to 800 nm; the intensity of sunlight was reported to be 138.1 W/m^2. [^{14}C]Fenbuconazole comprised ≥97.57% of the applied at all sampling intervals, with no discernable pattern of decline. In the dark controls after 30 days, [^{14}C]-fenbuconazole was 95.95 and 101.63% of the applied in duplicate samples. [^{14}C]Residues did not volatilize from either the irradiated or dark control buffer solutions, and did not adsorb to the walls of the glass sample contain-

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er. During the study, material balances were 101.2-107.5% of the nominal application rate in all samples.

Photodegradation on Soil

Uniformly phenyl ring-labeled [^{14}C]fenbuconazole at 10 ppm, degraded with a half-life of 79 days on sandy loam soil that was irradiated at 21.2-26.5°C for 30 days (12 hours/day) with a xenon arc lamp. The intensity of light from the xenon lamp was 139.6-157.2 W/m^2 between wavelengths of 330 to 800 nm; the intensity of sunlight was reported to be 138.1 W/m^2. Fenbuconazole was 95.94-97.21% of the applied immediately posttreatment, 78.74-90.67% at 14 days, and 65.14-78.14% at 30 days. In the dark controls after 30 days, [^{14}C]fenbuconazole was the only compound isolated, and it comprised 94.7-95.66% of the applied. Two [^{14}C]degradates were isolated from the irradiated soil but were not identified; the unknown degradates comprised a maximum of 2.83 and 3.56% of the applied at 14 and 30 days posttreatment, respectively. [^{14}C]Residues remaining at the origin were a maximum of 6.09% of the applied at 30 days. In the irradiated samples, volatile radioactivity was $\leq$0.02% of the applied, and unextracted radioactivity totaled 3.98% at 30 days. During the study, material balances were 90.20-103.29% of the applied radioactivity in the irradiated samples and 100.98-105.22% in the dark controls.

Aerobic Soil Metabolism

Fenbuconazole degraded with respective half-lives of 285 and 367 days in Lawrenceville silty clay loam and Pasquotank sandy loam soils fortified with approximately 1 ppm ^{14}C-triazole or ^{14}C-phenyl-labeled RH-7592 and maintained aerobically in darkness at 25 ± 1°C for 363 days. Both soils were fortified with both labeled compounds. After 363 days of incubation, $^{14}CO_2$ accounted for 35-37% and 21% of the applied ^{14}C-phenyl-RH-7592 in the Lawrenceville and Pasquotank soils, respectively. $^{14}CO_2$ accounted for 1.2-1.5% of the applied ^{14}C-triazole-RH-7592 in both soils. After 363 days of incubation, parent RH-7592 accounted for 47.8 and 59.0% of the extractable residues from application of ^{14}C-triazole-RH-7592 in the Lawrenceville and Pasquotank soils, respectively. In the Lawrenceville silty clay loam, bound residues (both labels) increased with time and accounted for 2.3-3.5% of the applied at day 0 and increased to 24.8-27.6% of the radiolabeled residues at day 363. In the Pasquotank sandy loam, bound residues (both labels) increased from 2.6-3.4% (day 0) to 14.9-20% at day 363. Parent RH-7592 accounted for 32.9 and 50.3% of the applied in the Lawrenceville and Pasquotank soils, respectively at the end of the study. Concentrations of the metabolites RH-9129, RH-9130, and RH-6467 increased with time accounting for 2.5-9.6% of the applied radioactivity in both soils treated with both radiolabels. (RH-9129 and RH-9130 are diastereomers.) Triazole accounted for 11.2-13.6% and for 6.5-6.6% of the applied ^{14}C-triazole-RH-7592 in the Lawrenceville and Pasquotank soils, respectively. Material balances were 88.3-116% during the study.

Anaerobic Soil Metabolism

Following 30 days of aerobic incubation, fenbuconazole degraded with respective half-lives of 451 and 655 days in Lawrenceville silty clay loam and Pasquotank sandy loam soils fortified with approximately 1 ppm ^{14}C-triazole or

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^{14}C-phenyl-labeled RH-7592 and maintained anaerobically in darkness at 25 ± 1°C for 60 days. Both soils were fortified with both labeled compounds. At day 0 of anaerobic incubation (day 30 of aerobic incubation), parent RH-7592 comprised an average of 80.9% of the applied radioactivity; at day 60 it accounted for an average of 73.2% of the applied. At day 0 of anaerobic incubation, extractable residues accounted for 90.0-93.8% of the applied; at day 60 this amount declined to 76.8-78.3%. Bound residues increased from 6.2-9.7% at day 0 to 23.6% at day 60. The metabolites RH-9129 and RH-9130 (the diastereomers), and RH-6467 accounted for 0.6% of the applied radioactivity at day 0 to 7.33% at day 60. Material balances were 81.0-119% and 75.7-95.9% in the Lawrenceville and Pasquotank soils treated with ^{14}C-triazole- and ^{14}C-phenyl-RH-7592, respectively.

Leaching and Adsorption/Desorption

Based on batch equilibrium (adsorption/desorption) studies, ^{14}C-triazole-RH-7592 in 0.01M $CaCl_2$ was determined to be slightly mobile to immobile in Cecil clay, Keeton loam, Lakeland sand, Pasquotank sandy loam, and Lawrenceville silty clay loam soils. Adsorption appeared to be related to soil organic matter content. Material balances were 86.2-107.5%. The reported Freundlich K_d values and soil characteristics are outlined in the following table:

Soil Type	% OM	K_d Values Ads	Des	K_{oc}	Percent Sand	Silt	Clay	CEC (meq/100g)	pH
Clay	0.4	5.07	7.09	2185	23.2	20.8	56.0	4.5	5.3
Loam	2.4	75.21	147.66	5402	29.2	48.8	22.0	15.7	7.2
Sand	0.5	7.56	2.33	2607	93.2	0.8	6.0	2.1	7.3
Sandy loam	2.2	115.40	132.20	9042	68.8	18.0	13.2	8.7	5.4
Si Cl loam	1.2	20.08	33.0	2884	8.8	62.0	29.2	6.6	7.0

Aged Leaching

Fenbuconazole was found to have very slight potential to leach in 30-cm Pasquotank sandy loam soil columns, the upper 2 cm of which had been fortified to 1.0 ppm with ^{14}C-triazole-RH-7592 and ^{14}C-phenyl-RH-7592 and aged aerobically for 30 days at 25 ± 1°C. The columns were eluted with 997 mL of water over a 5-7 day period. In the 0-6 cm segment, 99.0-99.6% and 89.1-101.7% of the applied radioactivity was detected for the ^{14}C-triazole- and ^{14}C-phenyl-labeled treatments, respectively. The leachate contained 0.1-0.2% of the applied radioactivity; <1% of the total applied radioactivity was found below 6 cm. Less than 1% of the applied radioactivity was detected as $^{14}CO_2$ during the aging period. In the 0-6 cm segment, 78.0-89.8% of the extracted radioactivity was parent RH-7592. Three degradates, RH-9129, RH-9130, and RH-6467 accounted for 1.5-12.8% of the applied radioactivity in the upper segment. Material balances were 89.6-102.2%. (EFGWB noted that RH-7592 was adsorbed to cellulose prior to addition to the soil for the aerobic aging period, but concluded that this procedure probably did not affect the study results.)

Bioaccumulation in Fish

In a 28-day study in which bluegill sunfish were exposed to a nominal concentration of 0.01M ^{14}C-triazole-RH-7592 in a flow-through system, maximum bioaccumulation factors of 170X, 50X, and 330X were reported for fillet, whole fish, and viscera tissue, respectively. The maximum bioaccumulation factors were reported for day 7 residues for whole fish and fillet and for day 28 residues for viscera. Following a 14-day depuration period, 95-98% of the accumulated residues were eliminated. Parent RH-7592 comprised 20.6-23.0% of the extractable residues from fillet tissue; the ketone (RH-6467) and lactone A (RH-9129) comprised 8.9-13.8% and 6.9-9.9%, respectively. Three compounds identified as polar unknowns 1, 2, and 3 comprised 4.2-13.5% of the extracted radioactivity in fillet tissue. Unknown 3 comprised 23.4-28.4% of the extracted radioactivity in viscera tissue. Material balances were 76.1-96.6% for the exposure period. In a similar 28-day study in which bluegill sunfish were exposed to 0.045 ppm ^{14}C-triazole-RH-7592 in a flow-through system, the three polar metabolites were isolated and characterized. Based on TLC and HPLC comparisons with hen metabolites which had been positively identified by mass spectroscopy, unknowns 1 and 2 were characterized as stereoisomers of the sulfate conjugate of a proposed benzyl alcohol intermediate in the metabolic pathway leading to formation of the lactone (RH-9129) and ketone (RH-6467) metabolites. Based on selective hydrolysis by ß-glucuronidase, unknown 3 was identified as the glucuronide of the proposed benzylic alcohol intermediate.

The following data summary is derived from studies deemed supplemental by EFGWB:

Terrestrial Field Dissipation

Fenbuconazole (2 lb/gallon F1C, Rohm and Haas), applied twice at 0.125 lb ai/A/application, dissipated with registrant-calculated half-lives of 161 and 157 days in the 0- to 6-inch depths of bare ground plots of loam soil in Minnesota and loamy sand soil in Georgia, respectively. Fenbuconazole, applied five times at 0.2 lb ai/A/application, dissipated with a registrant-calculated half-life of 314 days in bare ground plots of clay soil in northern California (Chico) and with a calculated half-life of 407 days in vegetated plots of sandy loam soil in southern California (Madera). In general, the concentration of fenbuconazole increased with repeated applications to the soil. Four degradates, RH-9129, RH-9130, RH-6467, and 1,2,4-triazole were each <0.052 ppm in the treated plots at all sampling intervals. Minimal leaching of fenbuconazole or its degradates below the 12-inch depth was reported.

RECOMMENDATIONS

Available data indicate that fenbuconazole is moderately persistent to persistent in the environment. The submitted environmental fate data indicate that binding to soil is the major route of dissipation, with mineralization to CO_2 of secondary importance. Adsorption increases with increasing soil organic matter content. Contamination of ground water resulting from normal agricultural use of fenbuconazole appears to be unlikely for most soils. However, contamination of ground water may be possible in vulnerable areas,

i.e., where soils are low in organic matter and where ground water lies near the soil surface. Soil photolysis appears to play a minor role in the dissipation process. The long half-lives reported for the laboratory and field studies indicate that residues of fenbuconazole and its degradation products are likely to build up if multiple applications are made from season to season. If its use is extended to field crops, residues in soil may be available for rotational crop uptake because of the compound's persistence. Also, its persistence and lack of mobility indicate that fenbuconazole residues may reach surface water via runoff following rainfall or irrigation.

All environmental fate laboratory data requirements needed at the present to support registration for use on stone fruits and pecans have been fulfilled. The only environmental fate data requirement needed to support use on stone fruits and pecans that is not fulfilled at this time is terrestrial field dissipation (164-1). The registrant has indicated that additional data related to the submitted terrestrial field dissipation studies are being generated. It is possible that these additional data, when combined with the study already submitted, will fulfill the terrestrial field dissipation data requirement.

The following environmental fate data requirements are fulfilled:

Hydrolysis studies: One study (O'Dowd, 41031246) was reviewed. This study is acceptable and fulfills data requirements by providing information that fenbuconazole is stable to hydrolysis at pH 5, 7, and 9. (An amendment to the original hydrolysis study was submitted under MRID no. 41875022. The sole purpose of this amendment was to correct the aqueous solubility of fenbuconazole which was stated as 4.1 ppm in the original hydrolysis study. The correct solubility as stated in the amendment is 2.7 ppm at 22°C. This does not affect the validity of the original study nor the conclusions of EFGWB since the original study was conducted with a fenbuconazole concentration of 0.1 ppm.)

Photodegradation in Water: One study (Wang, 41875023) was reviewed. This study is acceptable and fulfills data requirements by providing information that fenbuconazole is stable to photolysis in sterile aqueous buffered solution (pH 7) irradiated for 30 days (12 hr/day) at 25 ± 1°C with a xenon arc lamp.

Photodegradation studies on soil: One study (Wang, 41875024) was reviewed. This study is acceptable and fulfills data requirements by providing information that fenbuconazole photodegraded with an estimated half-life of 79 days on a sandy loam soil irradiated for 30 days (12 hr/day) with a xenon arc lamp.

Aerobic soil metabolism studies: One study (Schieber, 41031247) was reviewed. This study is acceptable and fulfills data requirements by providing information that fenbuconazole degrades with half-lives of 285 and 367 days when incubated under aerobic conditions in Lawrenceville silty clay loam and Pasquotank sandy loam soils, respectively. Four degradates, RH-9129, RH-9130, RH-6467, and triazole were detected in small quantities during the study.

Anaerobic soil metabolism studies: One study (Schieber, 41031247) was reviewed. This study is acceptable and fulfills data requirements by providing information that fenbuconazole degrades with half-lives of 451 and 655 days when incubated anaerobically in Lawrenceville silty clay loam and Pasquotank sandy loam soils, respectively. Three degradates, RH-9129, RH-9130, and RH-6467 were detected in small quantities during the study.

Leaching and adsorption/desorption studies: Two studies were reviewed. The first study (Schieber, 41031249) is acceptable and partially fulfills data requirements by providing information that fenbuconazole is slightly mobile to immobile in five soils. The second study (Schieber, 41031248) is acceptable and partially fulfills data requirements by providing information that aged fenbuconazole residues have slight potential to leach in five soils. Together the studies fulfill the data requirement.

Laboratory studies of pesticide accumulation in fish: Two studies were reviewed. The first study (O'Dowd, 41073509) is acceptable and partially fulfills the data requirement by providing information that fenbuconazole has a low potential to accumulate in fish. The second (O'Dowd, 42001101) is acceptable and provides information regarding the characterization of residues detected in the earlier study. Together the two studies fulfill the data requirement.

The following data are required to support use on stone fruits and pecans:

Terrestrial field dissipation studies: One study (Deakyne and Stavinski, 42053503) was reviewed and provides supplemental information regarding the dissipation of fenbuconazole at four sites when used under field conditions. Additional information regarding "unexplained initial rapid dissipation" and the influence of multiple applications on field half-lives is required. The registrant stated that supplementary trials were initiated in 1991 which could address the outstanding issues regarding field dissipation.

The following data requirements are deferred or are not required for presently registered uses:

Photodegradation studies in air: No data were reviewed. No data are required at this time because the compound's vapor pressure (3.7×10^{-8} torr @ 25°C) indicates that volatility and hence photodegradation in air are not likely routes of dissipation.

Anaerobic aquatic metabolism studies: No data were reviewed. No data are required at this time because fenbuconazole has no aquatic uses.

Aerobic aquatic metabolism studies: No data were reviewed. No data are required at this time because fenbuconazole has no aquatic uses.

Laboratory volatility studies: No data were reviewed. No data are required at this time because the compound's vapor pressure (3.7×10^{-8} torr @ 25°C) indicates that volatility is not a likely route of dissipation.

Field volatility studies: No data were reviewed. No data are required at this time because the compound's vapor pressure (3.7×10^{-8} torr @ 25°C) indicates that volatility is not a likely route of dissipation.

Aquatic field dissipation studies: No data were reviewed. No data are required at this time because fenbuconazole has no aquatic uses.

Forestry dissipation studies: No data were reviewed. No data are required at this time because fenbuconazole has no forestry uses.

Dissipation studies for combination products and tank mix uses: 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 studies: No data were reviewed. Long-term field dissipation studies are required if residues do not reach 50% dissipation in soil prior to subsequent application. In three of the four terrestrial field dissipation sites, half-lives were less than one year. Although repeated applications of this compound over multiple growing seasons may result in a build-up of soil residues, EFGWB does not believe that long-term field dissipation data are required to discern the environmental fate of fenbuconazole.

Confined accumulation in rotational crops: No data were reviewed. Confined accumulation in rotational crops data are not required to support the proposed uses on stone fruits and pecans because these tree crops are not rotated with other crops. These data will be required if the compound is proposed for use on field crops which may be rotated with other crops.

Field accumulation studies on rotational crops: No data were reviewed. This data requirement is not being imposed at this time because the crops for which registration is being sought, stone fruits and pecans, are not used in rotation with other crops.

Accumulation studies on irrigated crops: No data were reviewed.

Field accumulation studies on aquatic nontarget organisms: No data were reviewed; however, data may be required if significant concentrations of the active ingredient and/or its principal degradation products are likely to occur in aquatic environments.

Field drift and drop size spectrum: These studies may be required by EFGWB if toxicological concerns are identified by the Ecological Effects Branch and/or Health Effects Division.

REFERENCES

O'Dowd, M.L. 1988. RH-7592: Hydrolysis study. Technical Report No. 34S-88-05. Rohm and Haas Company. MRID no. 41031246

O'Dowd, M.L. 1990. Amendment to RH-7592 hydrolysis study. Technical Report No. 34-90-55. Rohm and Haas Company. MRID no. 41875022

Wang, W.W. 1991a. Aqueous photolysis of ^{14}C-RH-7592. Laboratory Project ID: XBL 90004; XBL Report No. RPT0048; Rohm and Haas Technical Report No. 34-91-04. Unpublished study performed by XenoBiotic Laboratories, Inc., Princeton, NJ, and submitted by Rohm and Haas Company. MRID No. 41875023

Wang, W.W. 1991b. Soil photolysis of ^{14}C-RH-7592. Laboratory Project ID: XBL 90005; XBL Report No. RPT0049; Rohm and Haas Technical Report No. 34-91-05. Unpublished study performed by XenoBiotic Laboratories, Inc., Princeton, NJ, and submitted by Rohm and Haas Company. MRID No. 41875024

Schieber, C. 1988. Soil metabolism of RH-7592. Technical Report No. 34S-88-13. Rohm and Haas Company. MRID No. 41031247. (The study addresses both aerobic and anaerobic soil metabolism of RH-7592).

Schieber, C. 1988. Adsorption and desorption of RH-7592. Technical Report No. 34S-88-06. Rohm and Haas Company. MRID No. 41031249

Schieber, C. 1988. Aged leaching study of RH-7592. Technical Report No. 34S-88-09. Rohm and Haas Company. MRID No. 41031248

Deakyne, R.O., and S.S. Stavinski. 1991. RH-7592 (Indar) terrestrial field dissipation - final report. Laboratory Project ID: Technical Report No. 34-91-64. Unpublished study performed by Pan-Agricultural Laboratories Inc., Quality Control Laboratory, Centre Analytical Laboratories, Inc., and Rohm and Haas Company, and submitted by Rohm and Haas Company. MRID No. 42053503

Stavinski, S.S., T.F. Burnett, R.O. Deakyne, and J.J. Martin. 1991a. RH-7592 soil storage stability, soil field spikes. Laboratory Project ID: Technical Report No. 34-91-20. Unpublished study performed by Pan-Agricultural Laboratories Inc., and Rohm and Haas Company, and submitted by Rohm and Haas Company. MRID No. 41875025

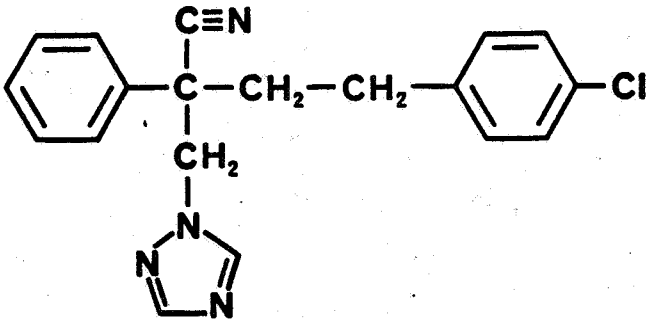
Stavinski, S.S., T.F. Burnett, R.O. Deakyne, and J.J. Martin. 1991b. RH-7592 storage stability in soil. Laboratory Project ID: Technical Report No. 34-91-18. Unpublished study performed by Craven Laboratory, Austin, TX; and Rohm and Haas Company, Spring House, PA; and submitted by Rohm and Haas Company, Spring House, PA. MRID no. 41875029 (Note: Although submitted by the registrant, this study was not used by EFGWB to support its review of the environmental fate data.)

O'Dowd, M.L. 1988. Laboratory studies of pesticide accumulation in fish; RH-7592 metabolism in bluegill sunfish. Technical Report No. 34S-88-26. Unpublished study performed by ABC Laboratories and submitted by Rohm and Haas Company. MRID No. 41073509

Dowd, M.L. 1990. Supplement to TR 34S-88-26: RH-7592 metabolism in bluegill sunfish. Unpublished study submitted by Rohm and Haas Co., Technical Report no. 34-90-14. MRID no. 42001101

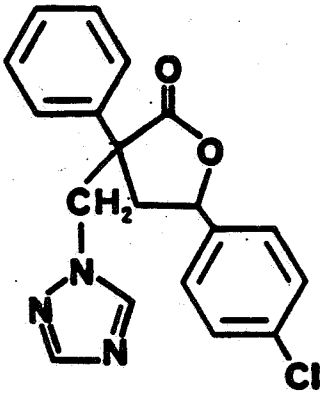
APPENDIX

FENBUCONAZOLE AND ITS DEGRADATES



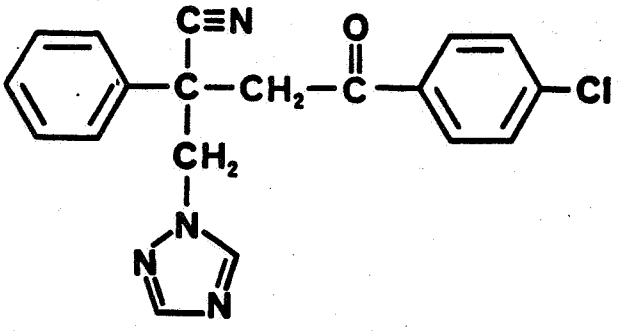
4-(4-Chlorophenyl)-2-phenyl-2-((1H-1,2,4-triazol-1-yl)methyl)butanenitrile

(Fenbuconazole, fenethanil, RH-7592)



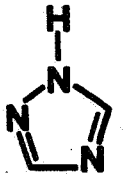
5-(4-Chlorophenyl)dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-yl)methyl)-(3H)furanone

(isomer A, RH-9129 and isomer B, RH-9130)



4-(4-Chlorophenyl)-2-(methyl-1H-1,2,4 triazole)-4-oxo-2-phenyl butanenitrile

(RH-6467)



1,2,4-Triazole

TABLE A. GENERIC DATA REQUIREMENTS FOR FENBUCONAZOLE

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
40 CFR §158.290 Environmental Fate					
DEGRADATION STUDIES -- LAB:					
161-1. Hydrolysis	PAIRA	A	YES	41031246[3]	NO
PHOTODEGRADATION:					
161-2. In Water	PAIRA	A	YES	41875023	NO
161-3. On Soil	PAIRA	A	YES	41875024	NO
161-4. In Air	PAIRA	A	NO		NO[4]
METABOLISM STUDIES:					
162-1. Aerobic Soil	PAIRA	A	YES	41031247	NO
162-2. Anaerobic Soil	PAIRA	A	YES	41031247	NO
162-3. Anaerobic Aquatic	PAIRA	NA	NO		NO
162-4. Aerobic Aquatic	PAIRA	NA	NO		NO
MOBILITY STUDIES:					
163-1 Leaching and Adsorption/Desorption	PAIRA	A	YES	41031249 41031248	NO

TABLE A. GENERIC DATA REQUIREMENTS FOR FENBUCONAZOLE (Continued).

Data Requirement		Composition	Use Pattern	Does EPA have data to satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
40 CFR §158.290 Environmental Fate						
163-2	Volatility (Lab)	TEP	A	NO		NO[5]
163-3	Volatility (Field)	TEP	A	NO		NO
DISSIPATION STUDIES -- FIELD:						
164-1	Soil	TEP	NA	NO	42053503	YES[6]
164-2	Aquatic (Sediment)	TEP	NA	NO		NO
164-3	Forestry	TEP	NA			NO
164-4	Combination and Tank Mixes	TEP	NA			NO
164-5	Soil, Long-Term	TEP	A	NO		NO[7]
ACCUMULATION STUDIES:						
165-1	Rotational Crops (Confined)	PAIRA	NA	NO		NO[8]
165-2	Rotational Crops (Field)	TEP	NA	NO		NO
165-3	Irrigated Crops	TEP	NA	NO		NO

TABLE A. GENERIC DATA REQUIREMENTS FOR FENBUCONAZOLE (Continued).

Data Requirement		Composition	Use Pattern	Does EPA have data to satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
40 CFR §158.290 Environmental Fate						
165-4	In Fish	PAIRA	A	YES	40320819 42001101	NO
165-5	Aquatic Non-Target Organisms	TEP	A	NO		
GROUNDWATER MONITORING:						
166-1.	Small Prospective	NONE		NO	NONE	RESERVED[9]
166-2.	Small Retrospective	NONE		NO	NONE	NO
166-3.	Large Retrosp.	NONE		NO	NONE	NO
SURFACE WATER:						
167-1.	Field Runoff	NONE		NO	NONE	RESERVED
167-2.	Surface Water Monitoring	NONE		NO	NONE	RESERVED[10]
40 CFR §158.440 SPRAY DRIFT						
201-1	Droplet Size Spectrum	TEP	A	NO		RESERVED[11]
202-1	Drift Field Evaluation	TEP	A	NO		RESERVED[11]

TABLE A. GENERIC DATA REQUIREMENTS FOR FENBUCONAZOLE - FOOTNOTES

1. TGAI = Technical Grade of the Active Ingredient; PAIRA = Pure Active Ingredient, Radiolabeled; TEP = 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; and NA = not applicable.

3. An amendment to the original hydrolysis study was submitted under MRID no. 41875022. The sole purpose of this amendment was to correct the aqueous solubility of fenbuconazole which was stated as 4.1 ppm in the original hydrolysis study. The correct solubility as stated in the amendment is 2.7 ppm at 22°C. This does not affect the validity of the original study nor the conclusions of EFGWB since the original study was conducted with a fenbuconazole concentration of 0.1 ppm.

4. No photolysis in air data are required at this time because the compound's vapor pressure (3.7×10^{-8} torr @ 25°C) indicates that volatility and hence photodegradation in air are not likely routes of dissipation.

5. No laboratory volatility data are required at this time because the compound's vapor pressure (3.7×10^{-8} torr @ 25°C) indicates that volatility is not a likely route of dissipation.

6. The terrestrial field dissipation studies submitted were reviewed and provide supplemental information regarding the dissipation of fenbuconazole at four sites when used under field conditions. Additional information regarding "unexplained initial rapid dissipation" prior to soil sampling and the influence of multiple applications on field half-lives is required. The registrant stated that additional information related to this would be submitted. This additional information may be sufficient to upgrade the study to acceptable thereby fulfilling the data requirement for the currently proposed uses.

7. Long-term field dissipation studies are required if residues do not reach 50% dissipation in soil prior to subsequent application. In three of the four terrestrial field dissipation sites, half-lives were less than one year. Although repeated applications of this compound over multiple growing seasons may result in a build-up of soil residues, EFGWB does not believe that long-term field dissipation data are required to discern the environmental fate of fenbuconazole.

8. Confined accumulation in rotational crops data are not required to support the proposed uses on stone fruits and pecans because these tree crops are not rotated with other crops. These data will be required if the compound is proposed for use on field crops which may be rotated with other crops.

9. Ground water monitoring studies are reserved at this time.

10. If projected aquatic residues, based on modeling scenarios, are of environmental concern, these studies may be required.

11. This study is required when aerial applications (rotary and fixed wing) and mist blower or other methods of ground application are proposed and it is estimated that the detrimental effect level of those nontarget organisms expected to be present would be exceeded. EFGWB notes that sample labels indicate that fenbuconazole is toxic to fish and aquatic invertebrates. Therefore, this study may be required by EFGWB if toxicological concerns are identified by Ecological Effects Branch or Health Effects Division.

Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
FENBUCONAZOLE (FENETHANIL, RH-7592)
Last Update on February 18, 1993
[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

LOGOUT	Reviewer:	Section Head:	Date: FEB 18 1993

Common Name:FENBUCONAZOLE (FENETHANIL, RH-7592)
Smiles Code:
PC Code # :129011 CAS #:114369-43-6 Caswell #:

Chem. Name :alpha [2-(4-chlorphenyl)ethyl]-alpha-phenyl-1H-1,2,4-triazole-1-propanenitrile
Action Type:Fungicide

Trade Names:Flowable concentrate
(Formul'tn):
Physical State:

Use Patterns (% Usage) :Stone fruits and pecans (only proposed uses at this time). Used as protectant or presymptomatic infection treatment for control of certain diseases.

Empirical Form: $C_{19}H_{17}N_4Cl$
Molecular Wgt.: 336.82 Vapor Pressure: 3.70E -8 Torr
Melting Point : 124-126C °C Boiling Point: °C
Log Kow : pKa: @ °C
Henry's : E Atm. M3/Mol (Measured) 6.07E -9 (calc'd)

Solubility in ...					Comments
Water	2.70E	ppm	@22.0	°C	
Acetone	E	ppm	@	°C	
Acetonitrile	E	ppm	@	°C	
Benzene	E	ppm	@	°C	
Chloroform	E	ppm	@	°C	
Ethanol	E	ppm	@	°C	
Methanol	E	ppm	@	°C	
Toluene	E	ppm	@	°C	
Xylene	E	ppm	@	°C	
aromatics,org.solv.	E	ppm	@	°C	soluble
aliphatic org.solv.	E	ppm	@	°C	insoluble

Hydrolysis (161-1)
[V] pH 5.0:Stable (MRID no. 41031246)
[V] pH 7.0:Stable "
[V] pH 9.0:Stable "
[ ] pH :
[ ] pH :
[ ] pH :

Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
FENBUCONAZOLE (FENETHANIL, RH-7592)
Last Update on February 18, 1993
[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

Photolysis (161-2, -3, -4)
[V] Water:Stable (MRID no. 41875023)
[ ] :
[ ] :
[ ] :

[V] Soil :t1/2 = 79 days (MRID no. 41875024)
[ ] Air :

Aerobic Soil Metabolism (162-1)
[V] tℓ = 285 days (Lawrenceville silty clay loam - MRID no. 41031247)
[V] tℓ = 367 days (Pasquotank sandy loam - " ")
[ ]
[ ]
[ ]
[ ]
[ ]

Anaerobic Soil Metabolism (162-2)
[V] tℓ = 451 days (Lawrenceville silty clay loam - MRID no. 41031247)
[V] tℓ = 655 days (Pasquotank sandy loam - " ")
[ ]
[ ]
[ ]
[ ]
[ ]

Anaerobic Aquatic Metabolism (162-3)
[ ]
[ ]
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Aerobic Aquatic Metabolism (162-4)
[ ]
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Environmental Fate & Effects Division
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FENBUCONAZOLE (FENETHANIL, RH-7592)
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[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

Soil Partition Coefficient (Kd) (163-1)

	Kd	Kdes	Koc	Soil	MRID number
[ ]					
[V]	5.07	7.09	2185	Cecil clay	41031249
[V]	75.21	147.66	5402	Keeton loam	"
[V]	7.56	2.33	2607	Lakeland sand	"
[V]	115.40	132.20	9042	Pasquotank sandy loam	"
[V]	20.08	33.0	2884	Lawrenceville silty clay loam	"

Soil Rf Factors (163-1)
[ ]
[ ]
[ ]
[ ]
[ ]
[ ]

Laboratory Volatility (163-2)
[ ]
[ ]

Field Volatility (163-3)
[ ]
[ ]

Terrestrial Field Dissipation (164-1)
[S] t1/2 = 161 days - Minnesota (2 appl. @ 0.125 lb a.i./A)
[S] " 157 days - Georgia " "
[S] " 314 days - N. Calif. (5 appl. @ 0.2 lb a.i./A)
[S] " 407 days - S. Calif. " "
[ ]
[ ] Minimal leaching of parent and degradates observed.
[ ]
[ ] MRID nos. 42053503, 41875029
[ ]
[ ]

Aquatic Dissipation (164-2)
[ ]
[ ]
[ ]
[ ]
[ ]
[ ]

Forestry Dissipation (164-3)
[ ]
[ ]

Long-Term Soil Dissipation (164-5)
[ ]
[ ]

Accumulation in Rotational Crops, Confined (165-1)
[ ]
[ ]

Accumulation in Rotational Crops, Field (165-2)
[ ]
[ ]

Accumulation in Irrigated Crops (165-3)
[ ]
[ ]

Bioaccumulation in Fish (165-4)
[V] Max BCFs = 170X, 50X, and 330X in whole fish, fillet & viscera.
[ ] 95-98% depuration after 14 days. (MRID nos. 41073509 & 42001101)

Bioaccumulation in Non-Target Organisms (165-5)
[ ]
[ ]

Ground Water Monitoring, Prospective (166-1)
[ ]
[ ]
[ ]
[ ]

Ground Water Monitoring, Small Scale Retrospective (166-2)
[ ]
[ ]
[ ]
[ ]

Ground Water Monitoring, Large Scale Retrospective (166-3)
[ ]
[ ]
[ ]
[ ]

Ground Water Monitoring, Miscellaneous Data (158.75)
[ ]
[ ]
[ ]

Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
FENBUCONAZOLE (FENETHANIL, RH-7592)
Last Update on February 18, 1993
[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

Field Runoff (167-1)
[ ]
[ ]
[ ]
[ ]

Surface Water Monitoring (167-2)
[ ]
[ ]
[ ]
[ ]

Spray Drift, Droplet Spectrum (201-1)
[ ] Reserved; may be required by EFGWB if toxicological concerns
[ ] identified by EEB or HED.
[ ]
[ ]

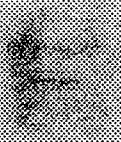
Spray Drift, Field Evaluation (202-1)
[ ] Reserved; may be required by EFGWB if toxicological concerns
[ ] identified by EEB or HED.
[ ]
[ ]

Degradation Products

RH-9129, RH-9130, & RH-6467 accounted for 2.5-9.6% of the applied radioactivity during 363-day aerobic soil metab. study.

In anaerobic soil metab. study, RH-9129 and combined RH-9130/RH-6467 accounted for 0.6% (day 0) to 7.33% (day 60).

RH-9129 and RH-9130 are stereoisomers.



Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
FENBUCONAZOLE (FENETHANIL, RH-7592)
Last Update on February 18, 1993
[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

Comments

Adsorption to soil appears to be major route of dissipation. Adsorption is dependent upon soil organic matter content. Mineralization to CO2 and soil photolysis are less impt routes of dissip.

As of 02/18/93, all env. fate data requirements needed to support proposed uses on stone fruits and pecans are fulfilled except for terrestrial field dissipation. Registrant has stated that addl. information will be submitted.

References: EPA studies
Writer : A.W. Jones

DATA EVALUATION RECORD

STUDY 1

CHEM 129011 Fenbuconazole §161-2

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 41875023
Wang, W.W. 1991a. Aqueous photolysis of ^{14}C-RH-7592. Laboratory Project ID: XBL 90004; XBL Report No. RPT0048; Rohm and Haas T.R. No. 34-91-04. Unpublished study performed by XenoBiotic Laboratories, Inc., Princeton, NJ, and submitted by Rohm and Haas Company, Spring House, PA.

DIRECT REVIEW TIME = 5

REVIEWED BY: L. Parsons TITLE: Staff Scientist

EDITED BY: K. Ferguson TITLE: Task Leader
M. Cairoli Staff Scientist

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD
TEL: 301-417-9800

APPROVED BY: A. Jones SIGNATURE:
TITLE: Agronomist
ORG: EFGWB/EFED/OPP
TEL: 703-305-7416

CONCLUSIONS:

Degradation - Photodegradation in Water

1. This study can be used to fulfill data requirements.

2. Fenbuconazole did not degrade in sterile aqueous buffered (pH 7) solutions that were irradiated for 30 days (12 hours/day) with a xenon arc lamp at 24-26 C.

3. This study is acceptable and fulfills EPA Data Requirements for Registering Pesticides by providing information on the photodegradation of phenyl ring-labeled [^{14}C]fenbuconazole in sterile aqueous buffered pH 7 solutions.

4. No additional information on the photodegradation of fenbuconazole in water is required at this time.

METHODOLOGY:

Pyrex tubes containing 39.6 mL of sterile aqueous phosphate buffer (pH 7) solution were treated with uniformly phenyl ring-labeled [^{14}C]fenbuconazole (radiochemical purity 96.2%, specific activity 20.34 mCi/g, Rohm and Haas) in 0.4 mL of methanol; the final fenbuconazole concentration was 1.5 ppm. The tubes were sealed with Teflon-lined caps; four of the tubes were wrapped in aluminum foil to serve as dark controls. All tubes were placed horizontally in a stainless steel, coolant-insulated chamber containing a water bath; the entire chamber was covered with a quartz window (Figure 3). The samples were irradiated on a 12-hour photoperiod using a Heraeus suntest xenon arc lamp that was equipped with a UV filter to block wavelengths of <290 nm. The intensity of light from the xenon arc lamp was 139.6-157.2 W/m^2 between wavelengths of 330 to 800 nm; the intensity of sunlight on June 13, 1990 (time of day and location not reported) was reported to be 138.1 W/m^2 (Figures 1 and 2 and Appendix C). During the study, the temperature inside the chamber was maintained at 25 ± 1°C, and was measured continuously using a thermocouple placed inside the photolysis chamber. Duplicate tubes were removed for analysis after 0, 3, 7, 14, 21, and 30 days of irradiation; duplicate tubes of the dark control solutions were collected after 14 and 30 days of incubation.

In order to quantify volatiles in the headspace of each sample, humidified CO_2-free air was drawn through the sample tube, then sequentially through a polyurethane foam plug, and single tubes of KOH and sulfuric acid trapping solutions at each sampling interval. It was not stated how the sample tubes, which were sealed during incubation, were attached to the volatile trapping system without the loss of volatile compounds. The polyurethane plugs were extracted with methanol; aliquots of the methanol extract and the volatile traps were analyzed for total radioactivity using LSC.

In order to quantify and identify [^{14}C]compounds in the test solutions, an aliquot of each sample solution was analyzed by LSC. The remainder of each sample was quantitatively transferred into a separatory funnel. The sample vial was rinsed with methanol, and the rinsate was analyzed using LSC. The test solutions were partitioned with ethyl acetate, and aliquots of the ethyl acetate and aqueous fractions were analyzed by LSC. The remaining ethyl acetate fractions were concentrated by rotary evaporation, and aliquots were analyzed by one-dimensional TLC on silica gel plates developed with chloroform:ethyl acetate:acidified methanol (90:5:5, v:v:v); reference standards were cochromatographed with the samples. After development, the plates were autoradiographed, and zones of silica were scraped from the plates and analyzed using LSC. Additional aliquots of the concentrated ethyl acetate fraction of "selected samples" were diluted with acetonitrile, mixed with unlabeled reference standards, and analyzed by reverse phase HPLC. For HPLC, a YMC AQ-303 C-18 column eluted with a mobile phase gradient of

water:acetonitrile was used with UV (254 nm) and radioactivity detection.

DATA SUMMARY:

Uniformly phenyl ring-labeled [^{14}C]fenbuconazole (radiochemical purity 96.2%), at 1.5 ppm, did not degrade in sterile aqueous buffered (pH 7) solutions that were irradiated at 25 ± 1 C for 30 days (12 hours/day) using a xenon arc lamp. The intensity of light from the xenon lamp was 139.6-157.2 W/m^2 between wavelengths of 330 to 800 nm; the intensity of sunlight was reported to be 138.1 W/m^2. [^{14}C]Fenbuconazole comprised ≥97.57% of the applied at all sampling intervals, with no discernable pattern of decline (Table VI). In the dark controls after 30 days, [^{14}C]fenbuconazole was 95.95 and 101.63% of the applied in duplicate samples. [^{14}C]Residues did not volatilize from either the irradiated or dark control buffer solutions, and did not adsorb to the walls of the glass sample container (Table V). During the study, material balances were 101.2-107.5% of the nominal application rate in all samples (Table V).

DISCUSSION:

1. The distance between the light source and the samples was not stated. It was unclear if the irradiance of the lamp was measured inside or outside the photolysis chamber.

2. An absorption spectra of fenbuconazole in phosphate buffer was not provided.

3. It was not stated how the sample tubes, which were sealed during incubation, were attached to the volatile trapping system without the loss of volatile compounds.

4. Two additional tubes of buffer solution, treated at 3 ppm, were removed for analysis after 30 days of irradiation. It was intended that extracts from these solutions would be used to identify degradates; however, since fenbuconazole was relatively stable to photodegradation, the high-dose solutions were unnecessary.

5. The study author calculated a photodegradation half-life of fenbuconazole in buffer solution of approximately 3.5 years. This calculation is of limited value because it involves extrapolation considerably beyond the experimental time limits of the study.

Fenbuconazole

Page_____ is not included in this copy.

Pages 31 through 39 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.

___ 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.

DATA EVALUATION RECORD

STUDY 2

CHEM 129011 Fenbuconazole §161-3

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 41875024
Wang, W.W. 1991b. Soil photolysis of ^{14}C-RH-7592. Laboratory Project ID: XLB 90005; XBL Report No. RPT0049; Rohm and Haas T.R. No. 34-91-05. Unpublished study performed by XenoBiotic Laboratories, Inc., Princeton, NJ, and submitted by Rohm and Haas Company, Spring House, PA.

DIRECT REVIEW TIME = 4

REVIEWED BY: L. Parsons TITLE: Staff Scientist

EDITED BY: K. Ferguson TITLE: Task Leader
M. Cairoli Staff Scientist

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD
TEL: 301-417-9800

APPROVED BY: A. Jones SIGNATURE:
TITLE: Agronomist
ORG: EFGWB/EFED/OPP
TEL: 703-305-7416

CONCLUSIONS:

Degradation - Photodegradation on Soil

1. This study can be used to fulfill data requirements.

2. Fenbuconazole photodegraded with a registrant calculated half-life of 79 days on sandy loam soil irradiated for 30 days (12 hours/day) with a xenon arc lamp at 21-26°C. Two unidentified degradates were isolated and quantified at a maximum of 3.56% of the applied radioactivity.

3. This study is acceptable and fulfills EPA Data Requirements for Registering Pesticides by providing information on the photodegradation of uniformly phenyl ring-labeled [^{14}C]fenbuconazole on soil.

4. No additional information on the photodegradation of fenbuconazole on soil is required at this time.

METHODOLOGY:

A slurry of sieved (2 mm) sandy loam soil (72% sand, 21% silt, 7% clay, 3.3% organic matter, pH 4.9, CEC 4.3 meq/100 g) was poured into Petri dishes and allowed to air-dry; the resulting soil layer was 1.3 mm thick. Uniformly phenyl ring-labeled [^{14}C]fenbuconazole (radiochemical purity 96.2%, specific activity 20.34 mCi/g, Rohm and Haas) in methanol was applied at 10 ppm to each plate with a syringe. Four of the treated soil plates were wrapped in aluminum foil to serve as dark controls. All plates were placed horizontally in a stainless steel, coolant-insulated chamber; the entire chamber was covered with a quartz window (Figure 3). The samples were irradiated on a 12-hour photoperiod using a Heraeus suntest xenon arc lamp that was equipped with a UV filter to block wavelengths of <290 nm. The intensity of light from the xenon lamp was 139.6-157.2 W/m^2 between wavelengths of 330 to 800 nm; the intensity of sunlight on June 13, 1990 (time of day and location not reported) was reported to be 138.1 W/m^2 (Figures 1 and 2 and Appendix C). During the study, the temperature inside the chamber was maintained at 26 $\pm$ 1 C, and was measured continuously using a thermocouple placed inside the photolysis chamber. Duplicate plates were removed for analysis after 0, 3, 7, 14, 21, and 30 days of irradiation; duplicate dark control samples were collected after 14 and 30 days of incubation.

In order to quantify volatiles that had collected in the photolysis chamber, humidified CO_2-free air was drawn through the chamber, then sequentially through a polyurethane foam plug, and single tubes of KOH and sulfuric acid trapping solutions at each sampling interval. The polyurethane plugs were extracted with methanol; aliquots of the methanol extract and the volatile traps were analyzed for total radioactivity using LSC.

The soil samples were analyzed according to the scheme presented in Figure 5. The soils were transferred from the Petri dishes into centrifuge tubes, then extracted twice by shaking with acetonitrile:acetic acid (70:30, v:v) for 15 minutes/extraction. After each extraction, the samples were centrifuged and the supernatant filtered through filter paper. Extracts from the same sample were combined, and aliquots were analyzed using LSC. The remainder was partitioned twice with ethyl acetate, and aliquots of the ethyl acetate and aqueous fractions were analyzed by LSC. The remaining ethyl acetate fractions were concentrated by rotary evaporation, and aliquots were analyzed by one-dimensional TLC on silica gel plates developed in either chloroform:ethyl acetate:acidified methanol (90:5:5, v:v:v) or ethyl acetate:isopropanol:water:acetic acid (65:25:10:2, v:v:v:v); reference standards were cochromatographed with the samples. After development, the plates were autoradiographed, and zones of silica were scraped from the plates and analyzed using LSC. Additional aliquots of the concentrated extracts were diluted with acetonitrile, mixed with unlabeled reference standards, and analyzed by reverse phase HPLC.

For HPLC, a YMC AQ-303 C-18 column eluted with a mobile phase gradient of water:acetonitrile was used with UV (254 nm) and radioactivity detection. Subsamples of extracted soil were analyzed for unextracted radioactivity using LSC following combustion. The method detection limit was 0.01 ppm.

DATA SUMMARY:

Uniformly phenyl ring-labeled [^{14}C]fenbuconazole (radiochemical purity 96.2%), at 10 ppm, degraded with a half-life of 79 days on sandy loam soil that was irradiated at 21.21-26.5 C for 30 days (12 hours/day) with a xenon arc lamp. The intensity of light from the xenon lamp was 139.6-157.2 W/m^2 between wavelengths of 330 to 800 nm; the intensity of sunlight was reported to be 138.1 W/m^2. Fenbuconazole was 95.94-97.21% of the applied immediately posttreatment, 78.74-90.67% at 14 days, and 65.14-78.14% at 30 days (Table VII). In the dark controls after 30 days, [^{14}C]fenbuconazole was the only compound isolated, and it comprised 94.7-95.66% of the applied (Table IX). Two [^{14}C]degradates were isolated from the irradiated soil but were not identified; the unknown degradates comprised a maximum of 2.83 and 3.56% of the applied at 14 and 30 days posttreatment, respectively (Table VII). [^{14}C]Residues remaining at the origin were a maximum of 6.09% of the applied at 30 days. In the irradiated samples, volatile radioactivity was $\leq$0.02% of the applied, and unextracted radioactivity totaled 3.98% at 30 days. During the study, material balances were 90.20-103.29% of the applied radioactivity in the irradiated samples and 100.98-105.22% in the dark controls (Table VI).

DISCUSSION:

1. The analytical methods presented in the text and diagramed in Figure 5 do not agree; the figure refers to an ethyl acetate partitioning step prior to TLC and HPLC analysis of the soil extracts that is not described in the text. The data tables contain references to ethyl acetate and aqueous extract fractions, which suggests that the figure accurately describes the methodology.

2. The distance between the light source and the samples was not stated. It was unclear if the irradiance of the lamp was measured inside or outside the photolysis chamber.

3. Two additional dishes of soil, treated at 40 ppm, were removed for analysis after 30 days of irradiation. It was intended that extracts from these soils would be used to identify degradates; however, since there were no significant degradates of fenbuconazole, the high dose soils were unnecessary.

4. The diagram of the photolysis chamber suggests that the chamber contained a water bath; however, according to the description in the methodology, it did not. The diagram of the apparatus appears to be generic; a similar one was used to illustrate the photolysis chamber

in the photodegradation in water study. That chamber did contain a waterbath.

5. The registrant-calculated half-life for irradiated fenbuconazole on soil was 78.84 days. This calculation is of limited value because it involves extrapolation considerably beyond the experimental time limits of the study.

Fenbuconazole

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Pages 44 through 55 are not included.

The material not included contains the following type of information:

___ Identity of product inert ingredients.

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DATA EVALUATION RECORD

STUDY 3

CHEM 129011 Fenbuconazole §164-1

FORMULATION--14--FLOWABLE CONCENTRATE (FlC)

STUDY ID 42053503
Deakyne, R.O., and S.S. Stavinski. 1991. RH-7592 (Indar) terrestrial field dissipation - final report. Laboratory Project ID: Technical Report No. 34-91-64. Unpublished study performed by Pan-Agricultural Laboratories Inc., Madera, CA; Quality Control Laboratory, Southampton, PA; Centre Analytical Laboratories, Inc., State College, PA; and Rohm and Haas Company, Spring House, PA; and submitted by Rohm and Haas Company, Spring House, PA.

STUDY ID 41875025
Stavinski, S.S., T.F. Burnett, R.O. Deakyne, and J.J. Martin. 1991a. RH-7592 soil storage stability, soil field spikes. Laboratory Project ID: Technical Report No. 34-91-20. Unpublished study performed by Pan-Agricultural Laboratories Inc., Madera, CA; and Rohm and Haas Company, Spring House, PA; and submitted by Rohm and Haas Company, Spring House, PA.

DIRECT REVIEW TIME = 40

REVIEWED BY: L. Parsons TITLE: Staff Scientist

EDITED BY: K. Ferguson TITLE: Task Leader
M. Cairoli Staff Scientist

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD
TEL: 301-417-9800

APPROVED BY: A. Jones SIGNATURE: A. Jones
TITLE: Agronomist
ORG: EFGWB/EFED/OPP
TEL: 703-305-7416

CONCLUSIONS:

Field Dissipation - Terrestrial

1. The study provides supplemental information regarding the terrestrial field dissipation of fenbuconazole.

2. The study cannot be used to fulfill data requirements at this time because the data do not demonstrate clearly the dissipation of

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fenbuconazole under field conditions. At each site there was a period of apparent rapid dissipation following the initial application. After subsequent applications the compound appears to persist under field conditions. No data were presented to explain this phenomenon.

3. In order for this study to contribute towards the fulfillment of the terrestrial field dissipation data requirements, data must be provided which explain the early dissipation and to clarify those conditions under which it would occur. The study authors noted the rapid dissipation after early applications which is followed by a period of very slow dissipation and stated "We have attempted to verify this phenomenon experimentally with two supplementary trials initiated in 1991." Data from these trials combined with the study submitted may be adequate to explain the dissipation behavior of fenbuconazole under field conditions. Refer to Discussion for details.

4. Fenbuconazole (2 lb/gallon FlC, Rohm and Haas), applied twice at 0.125 lb ai/A/application, dissipated with registrant-calculated half-lives of 161 and 157 days in the 0- to 6-inch depths of bare ground plots of loam soil in Minnesota and loamy sand soil in Georgia, respectively. Fenbuconazole, applied five times at 0.2 lb ai/A/application, dissipated with a registrant-calculated half-life of 314 days in bare ground plots of clay soil in northern California (Chico) and with a calculated half-life of 407 days in vegetated plots of sandy loam soil in southern California (Madera). In general, the concentration of fenbuconazole increased with repeated applications to the soil. Four degradates,

   5-(4-chlorophenyl)dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-yl)methyl)-2(3H)furanone (isomer A, RH-9129 and isomer B, RH-9130),

   4-(4-chlorophenyl)-2-(methyl-1H-1,2,4 triazole)-4-oxo-2-phenyl butanenitrile (RH-6467), and

   1,2,4-triazole,

   were each <0.052 ppm in the treated plots at all sampling intervals. Minimal leaching of fenbuconazole or its degradates below the 12-inch depth was noted.

Ancillary Study - Freezer Storage Stability

1. Freezer storage stability studies are not specifically required by Subdivision N guidelines.

2. Fenbuconazole and its degradates, 5-(4-chlorophenyl)dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-yl)methyl)-2(3H)furanone (isomer A, RH-9129

and isomer B, RH-9130), and 4-(4-chlorophenyl)-2-(methyl-1H-1,2,4 triazole)-4-oxo-2-phenyl butanenitrile (RH-6467) were stable in loamy sand soil stored frozen (-15 C) for 539 days.

3. This study is scientifically sound. Based on the information provided by this study, soil samples containing fenbuconazole, RH-9129, RH-9130, and RH-6467 can be stored frozen for up to 539 days prior to analysis.

4. No additional data on the stability of fenbuconazole, RH-9129, RH-9130, and RH-6467 in soil during frozen storage are needed at this time.

METHODOLOGY:

Field Dissipation - Terrestrial

Hollandale, Minnesota: Fenbuconazole (2 lb/gallon flowable concentrate, Rohm and Haas) was applied twice, at 0.125 lb ai/A/application, to three bare ground plots (20 x 100 feet) of loam soil (42% sand, 38% silt, 20% clay, 3.8% organic matter, pH 7.7, CEC 19.5 meq/100 g) in Hollandale, Minnesota, on May 18 and June 1, 1990 (2-week interval). An untreated control plot (20 x 100 feet) was located 290 feet from the treated plots. Soil cores (0- to 48-inch depth) were collected prior to and immediately after the first application, prior to and immediately after each application, and at 14 and 30 days and 2, 3, 4, 5, 6, 10.5, and 12 months after the second application.

Hawkinsville, Georgia: Fenbuconazole (2 lb/gallon FlC, Rohm and Haas) was applied twice, at 0.125 lb ai/A/application, to three bare ground plots (19 x 100 feet) of loamy sand soil (82% sand, 11% silt, 7% clay, 1.9% organic matter, pH 5.8, CEC 2.1 meq/100 g) in Hawkinsville, Georgia, on July 19 and August 2, 1989 (2-week interval). An untreated control plot (19 x 100 feet) was located 198 feet from the treated plots. Soil cores (0- to 48-inch depth) were collected prior to and immediately after each application, and at 14 and 30 days and 2, 3, 4, 5, 6, 7, 8, 10, 12, 14, 16, and 18 months after the second application.

Chico, California: Fenbuconazole (2 lb/gallon FlC, Rohm and Haas) was applied five times, at 0.2 lb ai/A/application, to three bare ground plots (20 x 100 feet) of clay soil (31% sand, 25% silt, 44% clay, 14.1% organic matter, pH 7.0, CEC 24.0 meq/100 g) in Chico, California, at 2-week intervals between August 7 and October 5, 1989. An untreated control plot (20 x 100 feet) was located 380 feet from the treated plots. Soil cores (0- to 48-inch depth) were collected prior to and immediately after each application, and at 14 and 30 days and 2, 3, 4, 5, 6, 7, 8, 10, 12, and 14 months after the fifth application.

Madera, California: Fenbuconazole (2 lb/gallon FlC, Rohm and Haas) was applied five times, at 0.2 lb ai/A/application, to three plots (20 x 100 feet) planted to a cover crop (wheat) on sandy loam soil (73% sand, 21% silt, 6% clay, 0.4% organic matter, pH 6.5, CEC 2.4 meq/100 g) in Madera, California, at 2-week intervals between August 1 and September 26, 1989. An untreated control plot (20 x 100 feet) was located 371 feet from the treated plots. Soil cores (0- to 48-inch depth) were collected prior to and immediately after each application, and at 14 and 30 days and 2, 3, 4, 5, 6, 7, 8, 10, 12, 14, 17, and 18 months after the fifth application.

Sampling and analytical procedures for all sites: Five soil cores were collected from each plot at each sampling interval. At the Georgia and California sites, the surface 6 inches were excavated using a PVC tube. The PVC tube was left in place, and a zero contamination hydraulic soil probe was used to collect samples between the 6- and 48-inch depth; these cores were divided into 6- to 12-, 12- to 18-, 18- to 24-, 24- to 36-, and 36- to 48-inch segments. The segments were composited by depth within each plot. At the Minnesota site, the surface 3 inches were excavated using a PVC tube; a zero contamination hydraulic soil probe was used to collect 3- to 6-, 6- to 12-, 12- to 18-, 18- to 24-, 24- to 36-, and 36- to 48-inch segments. The soil segments were frozen "soon after collection" and shipped frozen to the analytical laboratory, where the samples remained frozen at $\leq$0 C for up to 585 days until extraction and analysis.

The soils were analyzed according to Technical Report No. 34-90-69, "Residue analytical method for parent RH-7592 and its metabolites RH-9129, RH-9130, and RH-6467 in soil". Prior to analysis, the soil was homogenized with dry ice, then the sample was returned to the freezer while the ice sublimed. A subsample (25 g) of each composite soil segment was combined with Celite-545 filter aid, water, and methanol, then blended for 5 minutes. The soil slurry was vacuum-filtered, and the blender was rinsed with additional methanol, which was then poured through the filter cake into the filtrate. The soil extract was transferred to a separatory funnel and partitioned with methylene chloride:10% aqueous sodium chloride (150:250, v:v). The lower methylene chloride phase was removed and dried on a rotary evaporator at 45-50 C at atmospheric pressure. The resulting residues were dissolved in toluene:acetone (100:10, v:v) and chromatographed through a silica gel column. The column was rinsed with toluene:acetone (100:10, v:v), and the eluant was discarded. The column was then rinsed with toluene:acetone (100:50, v:v); this eluant was collected and dried on a rotary evaporator at 70-75 C. The resulting residues were dissolved in toluene:methanol (100:3, v:v) and analyzed by GC. Recovery efficiencies from laboratory-spiked (0.01-0.50 ppm) soil samples were 75-123% for fenbuconazole, 73-131% for RH-9129, 74-138% for RH-9130, and 76-142% for RH-6467. Detection limits and limits of quantitation were 0.003 and 0.01 ppm, respectively, for fenbuconazole, RH-9130, RH-9129, and RH-6467.

The soil samples were analyzed for triazole "primarily" according to Technical Report No. 310-86-03, with "some" analyses done according to Technical Report No. 34-90-18. Both methods were entitled "Triazole residue analytical method for soil". In both methods, portions of each soil sample were extracted twice with 0.01 M potassium phosphate buffered (pH 7) water by shaking the slurry by hand for 1-2 minutes. After each extraction, the sample was allowed to stand for 15 minutes, then was centrifuged for 20-30 minutes and the supernatant decanted. The extracts were combined and chromatographed through a copper-activated Chelex 100 column. Triazole was eluted from the column with 2.6 M ammonium hydroxide in methanol (TR-310-86-03) or with ammonium hydroxide:acetone (15:85, v:v; TR-34-90-18). The column eluants were combined and mixed with n-octanol to stabilize the triazole during evaporation, then concentrated by rotary evaporation under "diminished pressure" at 50 C. Using method TR-310-86-03, the concentrate was diluted with acetone:acetonitrile (1:1, v:v), mixed with KOH and pentafluorobenzyl bromide, swirled "gently", and allowed to stand at ambient temperatures for 1 hour. Using method TR-34-90-18, the concentrate was derivatized with acetonitrile, mixed with potassium carbonate and 2,4-dinitrofluorobenzene, and swirled "gently" in a water bath at 70 C for 15 to 20 minutes. After derivatization was complete, the solution was mixed with water (TR-310-86-03) or 0.5% EDTA (TR-34-90-18) and partitioned twice with methylene chloride. The methylene chloride phases were combined, and an aliquot (80% of the volume) was dried using a rotary evaporator at 45 C under "diminished pressure". The resulting residue was dissolved in toluene and filtered through a Bio-Sil chromatography column eluted with acetone:toluene (30:70, v:v). The acetone:toluene mixture was either analyzed directly (TR-310-86-03) or evaporated to dryness and redissolved in 5 mL of acetone:toluene (50:50, v:v; TR-34-90-18) for GLC analysis. Using TR-310-86-03, recovery of triazole from laboratory-spiked soils fortified with 0.008 to 0.50 ppm of triazole was 41-138% (average 77%); the method detection limit was 0.0025 ppm. Using TR-34-90-18, recovery of triazole from laboratory-spiked soils fortified with 0.005 to 0.47 ppm of triazole was 54-141% (average 89%); the method detection limit was 0.002 ppm and 0.003 ppm (in southern CA only).

Ancillary Study - Freezer Storage Stability

At the Georgia field site on each specified sampling day, loamy sand soil was screened to 2 mm, weighed (10 g samples) into jars, and fortified in the field with either 10 g of fenbuconazole or 10 ug each (1 ppm) of RH-9129, RH-9130, and RH-6467. The samples were handled in a manner identical to the field soil samples, which were frozen and shipped to the analytical laboratory. The frozen spiked soil samples were stored at -15 C for up to 539 days. The samples were extracted and analyzed for fenbuconazole, RH-9129, RH-9130, and RH-6467 according to Method TR-34-90-69 as described previously.

DATA SUMMARY:

Field Dissipation - Terrestrial

Fenbuconazole (2 lb/gallon FlC, Rohm and Haas), applied twice at 0.125 lb ai/A/application, dissipated with registrant-calculated half-lives of 161 and 157 days in the 0- to 6-inch depths of bare ground plots of loam soil in Minnesota and loamy sand soil in Georgia, respectively. Fenbuconazole, applied five times at 0.2 lb ai/A/application, dissipated with a registrant-calculated half-life of 314 days in bare ground plots of clay soil in northern California (Chico) and with a calculated half-life of 407 days in vegetated plots of sandy loam soil in southern California (Madera). In general, the concentration of fenbuconazole increased with repeated applications to the soil. Four degradates,

5-(4-chlorophenyl)dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-yl)methyl)-2(3H)furanone (isomer A, RH-9129 and isomer B, RH-9130),

4-(4-chlorophenyl)-2-(methyl-1H-1,2,4 triazole)-4-oxo-2-phenyl butanenitrile (RH-6467), and

1,2,4-triazole,

were each <0.052 ppm in the treated plots at all sampling intervals. Minimal leaching of fenbuconazole or its degradates below the 12-inch depth was noted.

Hollandale, Minnesota: Fenbuconazole, applied twice (2-week interval) at 0.125 lb ai/A/application, dissipated with a registrant-calculated half-life of 161 days from the 0- to 6-inch depth of three bare ground plots of loam soil in Minnesota that were treated in May/June 1990. In the 0- to 3-inch soil depth, fenbuconazole averaged 0.152 ppm immediately after the first application, 0.253 ppm immediately after the second application, and 0.119 ppm at 31 days and 0.048-0.111 ppm at 91 to 364 days following the second application with no discernable pattern (Table II). Fenbuconazole was not detected in the soil below a depth of 6 inches, except at 364 days when two of the three replicates from 6- to 12-inch segments contained fenbuconazole at 0.004-0.005 ppm (Table A). RH-9130 was infrequently detected in the upper 3 inches of soil, with a maximum concentration of 0.052 ppm immediately after the first application; RH-9130 was detected once in the 3- to 6-inch depth, at 0.006 ppm immediately after the first application. RH-9130 was not detected below a depth of 6 inches, and no other degradates were detected at any depth in any samples collected from the treated plots. During the study, air temperatures ranged from -29 to 97 F and soil temperatures (2-inch depth) ranged from 13 to 102 F. Cumulative precipitation and irrigation totaled 48.70 inches. There was no slope to the field, and the depth to the water table was 4-6 feet.

Hawkinsville, Georgia: Fenbuconazole, applied twice (2-week interval) at 0.125 lb ai/A/application, dissipated with a registrant-calculated half-life of 157 days from the 0- to 6-inch depth of three bare ground plots of loamy sand soil in Georgia that were treated in July/August 1989. In the 0- to 6-inch soil depth, fenbuconazole averaged 0.042 ppm following the second application, ranged from an average of 0.005 to 0.021 ppm with no discernable pattern between 14 and 306 days, and averaged 0.004-0.005 ppm at 366 and 429 days (Table III). Fenbuconazole was not detected below the 6-inch depth, except immediately after the second application when one replicate from the 6- to 12- inch segment contained fenbuconazole at 0.004 ppm (Table B). RH-9130 was infrequently detected in the upper 6 inches of soil, with a maximum concentration of 0.016 ppm immediately following the second application of fenbuconazole; RH-9130 was $\leq$0.006 ppm in deeper soil horizons. RH-9129, RH-6467, and triazole were recovered at 0.004-0.010 ppm in occasional samples; there was no pattern of accumulation or dissipation. Some contamination of deep soil segments, either during sampling or analysis, was noted; for example, RH-9130 was detected in the 18- to 24-inch depth only twice, at 0.012-0.013 ppm immediately after the first application and at 306 days after the second application. During the study, air temperature ranged from 12 to 105 F and soil temperatures (4-inch depth) ranged from 35 to 99 F. Cumulative precipitation and irrigation totaled 106.57 inches. The slope of the field was <1%, and the depth to the water table was 35-50 feet.

Chico, California (northern California site): Fenbuconazole, applied five times (2-week intervals) at 0.2 lb ai/A/application, dissipated with a registrant-calculated half-life of 314 days from the 0- to 6-inch depth of three bare ground plots of clay soil in California that were treated between August and October 1989. The concentrations of fenbuconazole in the soil were variable, with a general trend towards decline; in the 0- to 6-inch soil depth, fenbuconazole averaged a maximum of 0.276 ppm 14 days after the fifth application, 0.122-0.190 ppm between 29 and 183 days, 0.046-0.096 ppm between 210 and 427 days, and 0.072 ppm at 545 days (Table V). In the 6- to 12-inch soil depth, fenbuconazole was rarely detected prior to 4 months after the fifth application, but was detected in a majority of samples collected between 125 and 545 days; the maximum concentration of fenbuconazole in the 6- to 12-inch depth was 0.029 ppm at 242 days (Table C). Fenbuconazole was detected in the control and in random deep soil segments at up to 0.006 ppm. RH-9129 was detected in occasional 0- to 6-inch soil samples at up to 0.012 ppm; no pattern of accumulation or degradation was detected, and it was rarely detected below the 6-inch depth. RH-6467 was detected in several pretreatment soil samples at up to 0.013 ppm, and at a maximum of 0.032 ppm in one 0- to 6-inch soil sample collected immediately following the first application of fenbuconazole. The soil samples from Chico, California, were not analyzed for triazole. During the study, air temperatures ranged from 16 to 103 F and soil temperatures (2-inch depth) ranged from 35 to 89 F. Cumulative precipitation and

irrigation totaled 110.10 inches. The slope of the field was <1%, and the depth to the water table was 10-30 feet.

Madera, California (southern California site): Fenbuconazole, applied five times (2-week intervals) at 0.2 lb ai/A/application, dissipated with a registrant-calculated half-life of 407 days from the 0- to 6-inch depth of three vegetated (wheat) plots of sandy loam soil in California that were treated between August and September 1989. In the 0- to 6-inch soil depth, fenbuconazole averaged 0.250 ppm immediately after the fifth application, 0.146 ppm at 366 days, 0.127 ppm at 426 days, and 0.092 at 552 days (Table IV). In the 6- to 12-inch soil depth, fenbuconazole was rarely detected and was always ≤0.006 ppm, except was 0.013 ppm prior to the fifth application (Table D). In deeper soil horizons, fenbuconazole was occasionally detected at ≤0.005 ppm; there was no pattern of accumulation or dissipation. RH-9130 was detected at up to 0.015 ppm in the soil prior to treatment and in the control plot; RH-9130 was a maximum of 0.012 ppm in the soil in the treated plots (0- to 6-inch depth at 212 and 366 days after the fifth application). RH-9129 was detected in the 0- to 6-inch soil depth at most sampling intervals following the fourth application of fenbuconazole; RH-9129 reached a maximum of 0.036 ppm at 212 days and was 0.014-0.018 ppm at 552 days. RH-9129 was ≤0.005 ppm in soil depths deeper than 6 inches. RH-6467 was detected in the 0- to 6-inch soil depth at most sampling intervals following the fifth application of fenbuconazole; RH-6467 reached a maximum of 0.020 ppm at 212 days and was 0.011-0.015 ppm at 552 days. Triazole was detected at up to 0.016 ppm in control and treated soil samples at all depths from pretreatment until the fifth application; no triazole was detected at any sampling interval or depth following the fifth application. Some contamination of deep soil segments, either during sampling or analysis, was noted. During the study, air temperatures ranged from 22 to 106 F and soil temperatures (2-inch depth) ranged from 32 to 122 F. Cumulative precipitation and irrigation totaled 56.71 inches. There was no slope to the field, and the depth to the water table was 95 feet.

Ancillary Study - Freezer Storage Stability

Fenbuconazole, RH-9129, RH-9130, and RH-6467 did not degrade in loamy sand soil samples that were treated at 1 ppm in the field (Georgia), frozen, and shipped to the analytical laboratory, where they were stored frozen at -15 C for up to 539 days (Table 1). Recoveries averaged 92 ± 5% (83-104%) for fenbuconazole, 89 ± 6% (79-97%) for RH-9130, 90 ± 6% (81-101%) for RH-9129, and 100 ± 10% (89-120%) for RH-6467.

DISCUSSION:

1. The data do not demonstrate clearly the fate of fenbuconazole under field conditions. The reported half-lives of fenbuconazole at all sites may be inaccurate because of a reported (and unexplained) dissipation of fenbuconazole in the soil prior to the collection of

the time 0 samples from which half-lives were calculated. In each case, this apparent initial dissipation was inconsistent with the reported half-lives which were calculated without considering the early rapid dissipation.

The study authors recognized this problem and attributed it to "significant early dissipation" or "significant pre-sampling dissipation" at three sites (Georgia, N. Calif., and S. Calif.). They also stated that this was more prevalent when summer applications were made and reported that the half-life varied according to the number of applications made. The average half-life at sites where two applications were made was 159 days, with average half-lives of 360 days reported for the sites where five applications were made. The study indicates that multiple applications had the effect of moving the time zero from which half-lives were calculated further from the rapid dissipation observed immediately following the initial application. The study states "We have attempted to verify this phenomenon experimentally with two supplementary trials initiated in 1991." (EFGWB notes that this early rapid dissipation does not appear to be the result of a chemical degradation or metabolic process because there is no apparent increase in degradate concentration which coincides with the dissipation.)

EFGWB believes that additional information is needed in order to understand the dissipation of fenbuconazole under field conditions. Data from the trials conducted in 1991 may be sufficient to clarify the dissipation pattern of fenbuconazole in the field.

2. EFGWB notes that the soil residue data reflect the application rate most closely at the Minnesota site where the 0-3" soil segments were analyzed. Following the first application of 0.125 lb a.i./A, the concentration of parent in the 0-3" layer was 0.152 ppm, slightly above the theoretical level of 0.125 ppm. Samples analyzed immediately following the second application had a fenbuconazole concentration of 0.253 ppm, almost exactly what would be expected after two 0.125-lb applications with no dissipation occurring between them. (It should be noted that the reported residue level in soil before the second application was 0.085 ppm which indicates that some dissipation could have occurred following the initial application.) At the other three sites where 0-6" soil segments were analyzed, the initial post-application sampling did not closely reflect the theoretical soil concentration.

3. The long reported half-lives at all sites indicate that a build-up of the residues of fenbuconazole and its degradation products is likely if repeated applications are made from season to season. If the compound's use is extended to field crops, these residues may be available for uptake by rotated crops.

4. At the northern California site, soil sample weights were "normalized" because of a high coefficient of variation of sample weights. This was attributed to "inconsistent sample volumes

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(inaccurate depths) being sampled." (EFGWB believes that differences in soil bulk density among samples could contribute to wide variation among sample weights.) This correction factor was applied to the residue concentration calculations which also corrected for soil moisture content and recovery of the analyte. It is not clear to the EFGWB reviewer exactly how this "normalization" correction was made (i.e. what correction factor was used) and whether it was justified.

5. The fenbuconazole degradate 1,2,4-triazole is also a degradate of the fungicide myclobutanil (Chem. no. 128857). An adsorption/desorption study of 1,2,4-triazole was submitted to EFGWB in conjunction with myclobutanil registration. The EFGWB review of this study indicated that 1,2,4-triazole was "highly mobile in five different soils" (EFGWB no. 90255; 03/20/89). An EFGWB leaching assessment for myclobutanil (12/07/88) also concluded that the degradate 1,2,4-triazole is persistent and mobile in soil columns and therefore may leach through the soil profile. The leaching assessment also indicates that 1,2,4-triazole is found naturally in soils. (EFGWB notes that the protocol submitted for this study [EFGWB no. 90542; 05/31/89] indicates that there would be no analysis for 1,2,4-triazole in the field dissipation studies. Analyses for 1,2,4-triazole were, however, carried out for three of the four field dissipation study sites.)

   At some field dissipation study sites, the compound 1,2,4-triazole was detected in low concentrations at or near the level of detection (level of detection = 0.002 ppm; level of quantitation = 0.005 ppm). In Georgia, 1,2,4-triazole was detected in quantities of 0.004-0.006 ppm at depths of up to 48 inches. At the Madera, Calif. site where a different analytical method was used (level of detection = 0.003 ppm; level of quantitation = 0.01 ppm), pretreatment detections of up to 0.009 ppm were reported. There were other detections of 1,2,4-triazole at depths of up to 48 inches immediately following the first fenbuconazole application. Immediately following the third application at the Madera site, 1,2,4-triazole was detected in concentrations of up to 0.016 ppm in 23 of the 24 samples for which values were reported. From the fifth application of fenbuconazole until the end of the experiment (18 months later), no detections of 1,2,4-triazole were reported at any depth at the Madera site. There were no reported detections of 1,2,4-triazole in Minnesota and there was no analysis for this compound at the Chico, Calif. site.

6. Although three trials were carried out in northern California, only one was discussed in this report. The study authors stated that these three trials "were the least precisely carried out and therefore the most difficult to interpret." They also state that the two trials not reported "contain no adverse findings but the data were just too scattered for reasonable interpretation." It should be noted that it was at this site where the soil sample weights were "normalized" (see Discussion item 4).

7. The half-lives reported for these field dissipation experiments (157-407 days) are in general agreement with those reported in the aerobic soil metabolism study (258 and 367 days in Lawrenceville silty clay loam and Pasquotank sandy loam, respectively; see EFGWB no. 90546, 10/12/89).

8. The limit of detection (LOD) for fenbuconazole was 0.003 ppm; the limit of quantification (LOQ) was 0.01 ppm. At the Georgia site values below the LOQ were reported and used to calculate the half-life of 157 days.

9. The study authors stated that during each application at each site, samples of the tank mixes, water, and formulation concentrates were removed for analysis. Neither the Dynamac nor the EFGWB reviewer could locate these data in the report.

10. The degradates RH-9129 and RH-9130 are stereoisomers of the compound 5-(4-dichlorophenyl)dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-yl)methyl)-2-(3H)furanone. The study authors stated that RH-9129 and RH-9130 have different chemical and physical properties and are therefore considered to be separate degradates.

11. In this study, fenbuconazole (RH-7592) is parenthetically referred to as Indar; however, based on information provided by the Farm Chemicals Handbook (1991 edition), RH-7592 and Indar are not the same compound. RH-7592 is alpha-[2-(4-chlorophenyl)ethyl]-alpha-phenyl-1H-1,2,4-triazole-1-propanenitrile (common name fenbuconazole, CAS 114369-43-6). Indar, a discontinued Rohm and Haas chemical, is 4-n-butyl-4H-1,2,4-triazole (common name butrizol, CAS 16227-10-4).

Fenbuconazole

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Pages 67 through 151 are not included.

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DATA EVALUATION RECORD

STUDY 4

CHEM 129011 Fenbuconazole §165-4

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 42001101
Dowd, M.L. 1990. Supplement to TR 34S-88-26: RH-7592 metabolism in bluegill sunfish. Unpublished study submitted by Rohm and Haas Co., Technical Report no. 34-90-14.

Reviewer's Note: This DER supplements the review of 10/12/89 (EFGWB no. 90546). The MRID no. of the original study is 41073509.

REVIEWED BY:

Arnet W. Jones, Agronomist
Review Section I, EFGWB

Signature: Arnet W. Jones

Date: 18 FEB 1993

APPROVED BY:

Paul J. Mastradone, Ph.D.
Chief, Review Section I, EFGWB

Signature: Paul J. Mastradone

Date: 18 FEB 1993

TYPE OF STUDY: Bioaccumulation in fish (165-4) - Supplemental data

CONCLUSIONS:

General

In an earlier study, three unknown metabolites were detected in the tissue of fish which had been exposed to 0.01 ppm ^{14}C-fenbuconazole in a 28-day flow-through study. This study was conducted in an attempt to more thoroughly characterize those unknowns.

1. The study is acceptable and when combined with the original study fulfills the fish accumulation data requirement (165-4) for fenbuconazole (RH-7592). No further data on the bioaccumulation of fenbuconazole in fish are required at this time.

2. Following a 28-day study in which bluegill sunfish were exposed to 0.045 ppm ^{14}C-triazole-RH-7592 (fenbuconazole) in a flow-through system, three unknown polar metabolites which had been detected in an earlier fish accumulation study were isolated and characterized. Based on TLC and HPLC comparisons with hen metabolites which had been identified by mass spectroscopy, unknowns 1 and 2 were characterized as stereoisomers of the sulfate conjugate of a proposed benzyl alcohol intermediate in the metabolic pathway leading to formation of the lactone (RH-9129) and

ketone (RH-6467) metabolites. Based on selective hydrolysis by ß-glucuronidase, unknown 3 was identified as the glucuronide of the proposed benzylic alcohol intermediate. See the proposed metabolic pathway which is attached.

MATERIALS AND METHODS:

Bluegill sunfish (Lepomis macrochirus) were dosed for 28 days in a flow-through system with a water concentration of 0.045 ppm ^{14}C-RH-7592 uniformly labeled in the triazole ring. The original study used a ^{14}C-RH-7592 water concentration of 0.01 ppm. The higher concentration in the follow-up study was used to get sufficient quantities of metabolites to facilitate characterization. Refer to the DER for the original study (EFGWB no. 90546; 10/12/89) for details of the bioaccumulation study.

Treated fish viscera was placed into a blender and extracted with methanol. The slurry was centrifuged and the supernatant decanted. The methanol supernatant was concentrated on a rotary evaporator and 300 mL of water was added. The aqueous solution was extracted with ethyl acetate in a separatory funnel. Emulsions formed on the extracts so the layers were separated by centrifugation at 4000 rpm for 20-30 min at 5°C. The resulting aqueous layer was further extracted with n-butanol. The butanol extracts were combined and concentrated by rotary evaporation. The butanol concentrate was partially purified by TLC on a silica gel plate.

Normal phase TLCs were done on Merck silica gel plates and developed in 65/25/10 ethyl acetate/isopropanol/water for cleanup of the polar unknowns. Other systems used for comparison of the hydrolyzed unknowns with less polar standards were 75/25 ethyl acetate/hexane, 90/5/5 chloroform/methanol/ethyl acetate, and 93/7 chloroform/methanol. Reverse phase C-18 TLCs were developed in 1/1 methanol/0.5 M NaCl. HPLC analysis on a C18 column also was carried out.

Frozen hen excreta from another study were extracted three times with methanol. The extract was filtered and the filtrate combined with the supernatant. The methanol extracts were combined in a flask and the solvent was removed under reduced pressure. The concentrated residue was transferred to a centrifuge bottle and the solution diluted with 100 mL water, filtered, and partitioned three times with ethyl acetate (50 mL) and three times with n-butanol (50 mL). The n-butanol fraction was concentrated on a rotary evaporator, transferred to a vial with methanol, the methanol was removed under nitrogen, and the residue redissolved in 1 mL of methanol.

The sample of hen extract was applied to normal phase TLC plates which were eluted with 65:25:10 ethyl acetate:i-propanol:water and autoradiographed. The plate was partitioned into three bands according to the radioactivity present. The plate was scraped and the silica gel transferred to disposable pipettes plugged with glass wool. The radioactivity was contained in the vial which corresponded to band 2 of the TLC plates. This material was applied to another normal phase plate and eluted as above. The material was resolved into two bands, one of which clearly contained the majority of the radioactivity. This band was scraped, the activity eluted from the silica

gel, and labeled as hen metabolite 7.

When analyzed by C18 reverse phase TLC developed in 50:50 methanol:0.5M aqueous NaCl, hen metabolite 7 resolved into two bands which were very close together. The bands were scraped separately and labeled 7A and 7B. Metabolite 7A corresponded to the band with the higher R_f; 7B remained closer to the origin. Metabolites 7A and 7B were further cleaned up and analyzed by mass spectrometry.

The unknown fish metabolites were compared to metabolites isolated from hen excreta by TLC and HPLC.

Glucuronide hydrolysis was used to determine the identity of the compound identified as metabolite 3. In a 5 mL vial, 40 L of crude butanol fish viscera extract, 50 mg ß-glucuronidase, and 1 mL of pH 5 sodium acetate buffer were mixed. The same materials (minus the ß-glucuronidase) were placed in a control vial. A third vial was charged with 100 L of unknown 3 isolated from the normal phase TLC of the butanol extract, 50 mg ß-glucuronidase, and 1 mL of pH 5 sodium acetate buffer. The three vials were heated at 55°C for 1 hr, cooled, and extracted with ethyl acetate. The ethyl acetate extract was removed by pipette and concentrated under nitrogen.

The ß-glucuronidase hydrolysis product of unknown 3 was recovered from the normal phase TLC plate by scraping the band and eluting from the silica gel with methanol. Half of the recovered material was respotted "as is" on normal phase TLC and the other half was added to a drop of 1N HCl and then spotted on the same plate.

REPORTED RESULTS:

Viscera extracts from the redosed fish yielded TLC bands with the same retention times as those found in the original fish accumulation study. By normal phase TLC developed in 65/25/10/2 ethyl acetate/i-propanol/water/acetic acid, the butanol extracts produced two bands. The upper band (band 1) on reverse phase TLC separated into two bands referred to as unknowns 1 and 2 (upper and lower spots, respectively). The lower band on normal phase TLC was referred to as band 2 or unknown metabolite 3.

Comparisons by HPLC and TLC found that fish unknowns 1 and 2 had the same retention times as hen metabolites 7A and 7B (Table I). Mass spectral identification of the hen metabolites was carried out which identified the compound as the sulfate conjugate shown in Figure 1. Since two diasteriomers are possible for the sulfate conjugate, it was assumed that the two unknowns are the two isomers.

When fish unknown metabolite 3 was hydrolyzed with ß-glucuronidase and compared to the hydrolysis of the crude butanol extract and a control, 90% of the radioactivity became extractable into ethyl acetate which indicated an almost complete reaction (Table II). In the crude butanol extract, 43% of the activity hydrolyzed which is similar to the proportion of unknown 3 found in the butanol extract of the original study (55-60%). The control sample, which contained crude butanol extract and no ß-glucuronidase, showed

virtually no hydrolysis. TLC analysis of the hydrolysis product yielded an R_f similar to other metabolites (RH-6467 - Figure 1 - and the phenol, RH-1311, which was identified in rat and studies - structure not provided]). On exposure to acid, the ß-glucuronidase hydrolysis product formed RH-9129 and on silica gel it decomposed to RH-6468 (Figure 1). These results indicate that the glucuronide is the hydrolysis product of the benzylic alcohol shown in Figure 1.

DISCUSSION:

1. The original EFGWB review indicated that the data requirement would be fulfilled if the registrant would "provide additional characterization of the unknown polar metabolite identified in the study as metabolite 3." This supplemental data demonstrates an attempt to more accurately characterize all three unknowns which were found in fish tissues in the original fish accumulation study (see Table 2 of the original study).

2. Two of the three compounds isolated from fish viscera tissue were identified by comparison with metabolites extracted from hen excreta which had been identified by mass spectroscopy. These two fish metabolites were not positively identified by a confirmatory method such as GC/MS. It appears, then, that the hen metabolites were used as standards against which fish extract TLC and HPLC data were compared. It is not clear to EFGWB how the registrant identified the stereoisomer hen metabolites positively by mass spectroscopy. GC can separate the isomers, but the MS fragmentation pattern usually cannot distinguish between two stereoisomers. Normally NMR analysis is required for positive characterization of stereoisomers.

3. The redosed fish gave rise to TLC bands with the same retention times as those found in the earlier fish accumulation study. It was therefore assumed that the metabolites were assumed to be the same as those found in the original experiment.

4. It appears that the glucuronide (unknown 3) is formed from the esterification of glucuronic acid (which is presumed to be present in fish tissue) with the benzylic alcohol intermediate in the presence of ß-glucuronidase (which is also presumed to be present in the fish tissue).

5. The study states that "on exposure to acid the ß-glucuronidase hydrolysis product gives rise to lactone (RH-9129) and on silica gel it decomposes to the iminolactone (RH-6468)." This process is not apparent in the proposed metabolic pathway.

6. Verification of the reported HPLC results from the chromatograms presented is difficult.

7. There was no attempt to quantify the three unknown compounds. The intent of this supplemental study was only to characterize the unknowns detected in the original fish accumulation study.

Fenbuconazole

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