12-28-93

Chemical Code: 129011 Date Out: 27 DEC 1993

ENVIRONMENTAL FATE AND GROUND WATER BRANCH

Review Action

To: Cynthia Giles-Parker, Dolphine Wilson, PM 22
Registration Division (7505C)

From: Paul J. Mastradone, Ph.D. Chief
Environmental Chemistry Review Section 1
Environmental Fate & Ground Water Branch/EFED (7507C)

Thru: Henry M. Jacoby, Chief
Environmental Fate & Ground Water Branch/EFED (7507C)
Henry M Jacoby 12/28/93

Attached please find the EFGWB review of...

DP Barcode:	D195135, D195609, D196143, D197082, D196142		
Common Name:	Fenbuconazole (RH-7592)	**Trade name:**	Indar
Company Name:	Rohm and Haas Company		
ID #:	000707		
Purpose:	Review: (1) Terrestrial field dissipation data (164-1); (2) Summary of meeting notes prepared by registrant; (3) Registrant's response to EFGWB review of 02/18/93; and (4) Letters from registrant and Spray Drift Task Force re. fulfillment of spray drift data requirements.		

Type Product:	Action Code:	EFGWB #(s):	Review Time:
Fungicide	101	93-1045, 94-0015, 94-0046, 94-0120	6.0 days

STATUS OF STUDIES IN THIS PACKAGE:

Guideline #	MRID	Status[1]
164-1	42914701	C

STATUS OF DATA REQUIREMENTS:

	Status[2]
	S

[1]Study Status Codes: A=Acceptable U=Upgradeable C=Ancillary I=Invalid.
[2]Data Requirement Status Codes: S=Satisfied P=Partially satisfied N=Not satisfied R=Reserved.

1.0 CHEMICAL:

Common Name: Fenbuconazole, RH-7592

Chemical Name: alpha-(2-[4-chlorophenyl]-ethyl)-alpha-phenyl-3-(1H-1,2,4-triazole)-1-propanenitrile

2.0 TEST MATERIAL: see attached DER

3.0 STUDY/ACTION TYPE:

D195135 - Review terrestrial field dissipation study; D195609 - Review notes of meeting at request of registrant; D196143 - Review response to earlier EFGWB review; D197082 - Review proposal to fulfill spray drift data requirements by joining the Spray Drift Task Force.

4.0 STUDY IDENTIFICATION:

D195135. Deakyne, R.O., and S.S. Stavinski. 1993. RH-7592 (Fenbuconazole) single application terrestrial field dissipation study. Laboratory Report No. 34-93-35. Unpublished study performed by Pan-Agricultural Laboratories Inc., Madera, CA and submitted by Rohm and Haas Company, Spring House, PA. MRID 42914701

D195609. Letter of 08/09/93 from R. Costlow, Rohm and Haas, to F. Sanders and C. Giles-Parker, OPP/RD, summarizing a meeting held between Rohm & Haas, RD/FHB, EEB, and EFGWB on 07/28/93.

D196143. Stavinski, S.S. 1993. Rohm and Haas Company response to EPA HED and EFGWB fenbuconazole reviews of Stone Fruit Petition No. 1F 3989 and Pecan Petition No. 1F 3995. Laboratory ID TR 34-93-86. MRID 42948101.

D197082. Letters of 11/04/93 (from R. Costlow, Rohm and Haas Co.) and 11/05/93 (from R. Stanton, Spray Drift Task Force) to C. Giles-Parker, OPP/RD, regarding the fenbuconazole spray drift data requirement for pecans.

5.0 REVIEWED BY:

Arnet W. Jones, Agronomist
Review Section 1
OPP/EFED/EFGWB

Signature: Arnet W. Jones

Date: 27 DEC 1993

6.0 APPROVED BY:

Paul J. Mastradone, Ph.D.
Chief, Review Section 1
OPP/EFED/EFGWB

Signature: Paul J Mastradone

Date: 27 DEC 1993

7.0 CONCLUSIONS:

7.1 With the exception of 201-1 (Droplet size spectrum) and 202-1 (Drift field evaluation), all environmental fate data requirements needed to support terrestrial food, terrestrial nonfood, and greenhouse nonfood uses of fenbuconazole have been fulfilled.

2

7.2 Terrestrial Field Dissipation (164-1)

Field dissipation experiments reviewed previously used multiple applications of fenbuconazole which are typical of actual use. In these studies the authors noted rapid dissipation of fenbuconazole after early applications followed by a period of very slow dissipation. The authors stated "We have attempted to verify this phenomenon experimentally with two supplementary trials initiated in 1991." The study reviewed (see attached DER) presents the results of the two supplementary trials in which single applications of fenbuconazole at high (1.0 lb a.i./A) and low (0.25 lb a.i./A) rates were made to bare-ground plots in Madera, CA.

(a) The study provides supplemental information and when combined with a previously submitted study (MRID 42053503; EFGWB no. 92-0256; 02/18/93) fulfills the terrestrial field dissipation data requirement (164-1) for fenbuconazole. No additional terrestrial field dissipation data are needed at this time to support terrestrial food, terrestrial nonfood, and greenhouse nonfood uses of fenbuconazole.

(b) In a 362-day study, fenbuconazole was applied once at high (1 lb a.i./A) and low (0.25 lb a.i./A) rates to separate bare-ground plots of a sandy loam soil in Madera, CA. Fenbuconazole dissipated from the 0-6 inch soil layer with registrant-calculated half-lives of 187 and 206 days for the high and low application rates, respectively. Dissipation appeared to proceed at a slightly greater rate during the first 60 days than in the latter stages of the study. The degradates 5-(4-chlorophenyl) dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-yl) methyl)-2(3H)furanone (isomer A - RH-9129; isomer B - RH-9130) and 4-(4-chlorophenyl)-2-(methyl-1H-1,2,4 triazole)-4-oxo-2-phenyl butanenitrile (RH-6467) were detected in quantities up to 0.060, 0.079, and 0.059 ppm, respectively, in the high application rate experiment; lesser quantities were detected in the low rate experiment.

(c) The study confirms the results of earlier field dissipation studies which found fenbuconazole to be moderately persistent to persistent (field half-lives were 157-407 days) in soil under actual use conditions. Applications of fenbuconazole over multiple growing seasons may result in soil residue accumulation. These soil residues may be available for rotational crop uptake or be transported with sediment in runoff.

7.3 Review of Rohm and Haas Summary of the Meeting of 07/28/93

The Rohm and Haas meeting summary is attached. The summary appears to reflect accurately EFGWB's participation in the meeting.

7.4 Rohm and Haas Company Response to EFGWB Fenbuconazole Reviews

The EFGWB science chapter for the fenbuconazole new chemical registration standard (02/18/93) requested additional information regarding: (1) the need for additional field dissipation data; and (2) the stereochemistry of fenbuconazole and the environmental fate behavior of the stereoisomers. The field dissipation data were submitted and are reviewed with this package (see 7.2 above and the attached DER).

The registrant's description of the stereochemistry of fenbuconazole is attached. The active ingredient is chiral but is produced as a racemic mixture of the isomers. The starting material in the manufacturing process is chiral; the process does not employ optically active solvents or

reagents and does not resolve enantiomers. The analytical techniques used in the fate studies do not resolve enantiomers, hence the fate data fully describe the behavior of all isomers of the active ingredient.

Based on the registrant's assertion that the active ingredient exists as a racemic mixture of the stereoisomers and that the analytical methods are not isomer-specific, EFGWB concludes that the environmental fate data submitted adequately describe the behavior of both stereoisomers of fenbuconazole in the environment.

7.5 Spray Drift Data Requirements for Fenbuconazole

Rohm and Haas proposed to fulfill the fenbuconazole spray drift data requirements (201-1 - Droplet size spectrum and 202-1 - Drift field evaluation) through the Spray Drift Task Force (SDTF). It is very likely that the droplet size spectrum data requirement (201-1) can be fulfilled through the SDTF. It is also likely that the drift field evaluation requirement for stone fruit, apple, almond, and field crop use patterns can be fulfilled through the SDTF. However, because of the unique characteristics of a pecan canopy (the trees are very tall and may reach heights of 80 to 90 feet or more) and because the SDTF is not likely to conduct spray drift experiments on pecan canopies, it is not possible at this time to determine whether the drift field evaluation data requirement for the pecan use pattern can be fulfilled through the SDTF. To fulfill completely the drift field evaluation data requirement for fenbuconazole through the SDTF, drift field evaluation studies on pecan canopies must be conducted or a validated model must be submitted (and accepted by the Agency) which predicts spray drift from air blast applications to pecan canopies. If at least one of these conditions is not met, Rohm and Haas Company will need to conduct drift field evaluation studies on pecans for fenbuconazole. See Discussion for details.

7.6 Environmental Fate Assessment

The principal route of fenbuconazole dissipation appears to be adsorption to soil, with increased adsorption associated with higher soil organic matter content. Mineralization to CO_2 of the phenyl moiety and soil photolysis appear to be less important routes of dissipation. The triazole moiety of the molecule appears to be persistent.

Fenbuconazole is moderately persistent to 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 appears to be slightly mobile to immobile in soil with K_ds ranging from 5 to 115; adsorption increased with increasing soil organic matter. Aged residues exhibited slight potential to leach in sandy loam columns. Acceptable terrestrial field dissipation data indicate that fenbuconazole will be moderately persistent to persistent in the field (half-lives at four sites were from 157 to 407 days); minimal leaching of parent and degradates was observed. 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. The long aerobic soil and terrestrial field dissipation half-lives indicate that fenbuconazole applied over multiple growing seasons may result in soil residue accumulation. These residues may be available for rotational

4

crop uptake or be transported with sediment in runoff. Fenbuconazole did not bioaccumulate significantly in bluegill sunfish; 95-98% of accumulated residues were eliminated during a 14-day depuration period.

8.0 RECOMMENDATIONS: See Conclusions.

9.0 BACKGROUND:

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), pecans, almonds, apples, bananas, greenhouse and field-grown ornamentals, and wheat (seed and foliar treatment). 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.

10.0 DISCUSSION:

10.1 Spray Drift Data Requirements for Fenbuconazole

Letters sent to RD by Rohm and Haas and the Spray Drift Task Force (SDTF) concerning spray drift data to support the pecan use pattern of fenbuconazole are attached. The Rohm and Haas letter indicates that they were advised by RD and SRRD that joining the SDTF would satisfy all spray drift data requirements, but OPP could impose additional requirements for fenbuconazole after reviewing the final SDTF data.

It is likely that droplet size spectrum (201-1) data to support fenbuconazole uses will be submitted by the SDTF. However, fulfillment of the drift field evaluation (202-1) data requirement by the SDTF is less certain. Correspondence submitted by the SDTF states "The SDTF is not conducting studies for this crop [pecans], but is addressing air blast application through tests on multiple representative canopies. The SDTF intends to extrapolate to pecans and other untested crop canopies from data on at least four specific crops: grapes, almonds, peaches, and apples, which represent a wide range of canopy types." Because pecan trees are very tall - they may reach heights of 80 to 90 feet or more - it is unclear how drift data from the relatively low canopies which will be tested can be extrapolated to very tall trees such as pecans. Although it is likely that an air blast model will be submitted by the SDTF, it is not certain that the model will be able to simulate with scientific validity off-target drift following air blast applications to pecans.

This reviewer discussed this issue in detail with C. Giles-Parker and D. Wilson of RD and by phone with representatives of Rohm and Haas Co. RD and Rohm and Haas were advised that it is likely that the SDTF will submit acceptable droplet size spectrum data for all uses and drift field evaluation data for stone fruits and field crops. However, it was emphasized to RD and the registrant that Rohm and Haas Co. should determine whether drift field evaluation data applicable to pecan canopies will be developed prior to assuming that this fenbuconazole data requirement will be fulfilled by the SDTF.

11.0 COMPLETION OF ONE-LINER: Updated One-Liner attached.

12.0 CBI APPENDIX: NA

6

INDEPENDENCE MALL WEST PHILADELPHIA, PA. 19105, U.S.A. TELEPHONE (215) 592-3000
CABLE ADDRESS: ROHMHAAS TELEX 845-247 TWX 710-670-5335 TELECOPIER (215) 592-3377

ROHM AND HAAS COMPANY

09 August 1993

Mr. Frank Sanders
Ms. Cynthia Giles-Parker
US EPA OPP Registration Division (H7505C)
Document Processing Desk **(Correspondence)**
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Mr. Sanders and Ms. Giles-Parker:

SUBJECT: **Fenbuconazole (Indar®) Fungicide:**
Meeting Summary EFED and RD

On behalf of the Rohm and Haas Company I thank you for setting up the meeting held on 28~~AUG~~93 between Rohm and Haas Company and EFED to discuss the environmental risk assessment and registration of fenbuconazole. The Fungicide-Herbicide Branch (FHB) of the Registration Division (RD), and the Ecological Effects (EEB) and Environmental Fate Ground Water Branches (EFGWB) of Environmental Fate and Effects Division (EFED) were represented. Attached is a copy of the agenda used at the meeting and the attendees are listed below. A discussion document [RH Report RDC-93-093; (MRID 428471-01)] was supplied to EPA prior to the meeting.

EPA	Rohm and Haas Company
Mr. Frank Sanders	Dr. William Hurt
Ms. Cynthia Giles-Parker	Dr. Kevin Reinert
Ms. Dolphine Wilson	Dr. Richard Costlow
Mr. Jones	Dr. Stanley Stavinski
Mr. Paul Mastrodone	Mr. Michel Castagner
Mr. Les Touart	Dr. Ed Carley
Mr. Anthony Maciorowski (in part)	

The Rohm and Haas clearly expressed that we did not want the final stage of the US fenbuconazole registration to be a protracted or confrontational process. It was our intention to understand EFED clearly, to cooperate fully with EEB regarding their data requests, and proceed along a mutually agreeable path. We hoped to get help from and provide help to EEB in addressing a risk they perceived to achieve the mutual goal of responsible environmental stewardship, and our need for a registration while we generate the data.

The focus of the meeting was the review of fenbuconazole by the EEB and the components of the risk assessment calculations derived from the EFGWB. There was no uncertainty regarding the data requests made by the EEB. RH presented their view of the review and committed to complete all of the studies requested by the reviewer (as noted in item II of the agenda). We asked for a conditional registration because EEB requested data which we did not anticipate and can not possibly provide before 1995. We proposed risk reduction measures to implement while the conditional rgistration was in force. In summary, discussion of possible risk reduction was inconclusive and the RD indicated that the EEB would have to provide to them an opinion on conditional registration.

DETAILS

Rohm and Haas has submitted or will shortly submit all of the available data or studies in progress (as noted in item II of the agenda). The unavailable studies are Tier III and were not anticipated based on the risk assessment paradigms in use prior to the submission of the Section 3 petitions. We asked both EEB and EFGWB for help in making exposure reductions to mitigate any perceived risks while we generate these data. A discussion of label modifications was initiated with Mr. Touart. When Mr. Maciorowski indicated that, for the EEB paradigm [Risk = Hazard x Exposure], no exposure reductions should be implemented until all studies which address the hazard component were found acceptable to EEB, we felt that there may be some misunderstanding of our intent, but did not have sufficient time to pursue this because Mr. Maciorowski had to leave.

Dietary risk assessment for terrestrial non-target species was addressed. The issue was the need for USFWS consultation and the potential delay in the registration. Rohm and Haas noted that one of the most-sensitive-case parameters used by EEB, foliar half-life in grass, could be modified based on data already reviewed by EPA. The half life in grass (wheat) is significantly less than the surrogate (soil) used by EEB to predict foliar half-life in the short range grass component of the risk assessment. Use of the wheat data produced an assessment which indicated no unacceptable avian dietary risk exists, and we concluded that no consultation with USFWS was needed. There was a consensus on this point. The gentleman from EFGWB, Mr. Mastrodone, questioned the use of these data for risk assessment in EFED on the basis that the EFGWB do not review foliar residue decline or plant metabolism studies. We understood him to mean that EFGWB did not provide an evaluation of these data to EEB. We noted that a single application, residue decline study was specifically recommended to Rohm and Haas by the EFGWB in a discussion of the protocol for environmental dissipation of myclobutanil residues in food items for non-target species. While EFGWB did not review the wheat study, we believe there is ample support for it being relevant data for the risk assessment, *vis a vis* the request to generate it for myclobutanil.

We agreed with EEB that an algae study in Scenedesmus would probably fulfill the guideline when considered with the Selenastrum study. We noted the estuarine studies were first requested by EEB in a review for a wheat EUP. They are in progress (range finding studies at nominal concentrations are complete), but technical difficulties associated with method validation and analytical verification of fenbuconazole in sea water, as required by GLP, are delaying initiation of the definitive studies.

Persistence of fenbuconazole in the environment was discussed. The field dissipation data for fenbuconazole requested by EFGWB have been submitted. As Dr. Stavinski noted, they show that the decline of fenbuconazole is biphasic with a first phase half-life of approximately 55 days. The second phase half-life is longer. This behavior complicates the analysis when multiple applications are used. Even when fit to a pseudo-first-order equation, the half lives average only 178d, far less than the 367 day value from the soil metabolism studies. We explained that our experience with this class of compound suggests that, while fenbuconazole may have a relatively long soil half-life, it is not likely to accumulate.

We stated that fenbuconazole will be a preferred alternative to other fungicides in several markets for disease control, and it offers significant reductions in risk potential for both man and the environment compared to the alternatives. We and EPA recognize that it is not a "perfect" product, but it represents the substantial improvement that EPA's reduced risk policies were designed to encourage and support.

Rohm and Haas Company and EPA are committed to responsible environmental stewardship. Having fulfilled all the requirements we anticipated, we believe an appropriately controlled conditional registration is consistent with this mutual objective. The EPA agreed to review a letter documenting why we could not have anticipated the Tier III requirements. We petitioned EEB to act favorably in this regard when they receive our justification. If there are any additions or corrections to this meeting summary, please call me at (215) 592-3581 to discuss them. If this is not necessary, I would appreciate a confirmation of the meeting summary.

Best Regards,

Richard D. Costlow

Richard D. Costlow, Ph.D., D.A.B.T.
Product Registration Manager
Agricultural Chemicals Registration and
Regulatory Affairs Department

FENBUCONAZOLE
Meeting with EEB and EFGWB
28 July 1993

I Issues

- Our commitment to cooperation with EPA
  - Invented: March 1983
  - Development: November 1986 [80 months and still going]
  - Section 3 Filings 22 April 1991 (stone fruit)
    15 May 1991 (pecans)
- Situation on data generation and submission
- Our understanding of the reviews [EEB and EFGWB]
- Cooperative effort to obtain conditional registrations

II Discussion Points

- Situation on data generation

Study	[reason for data request]	Status
Field Dissipation	[upgrade]	available
Storage Stability	[upgrade]	available
Algae	[upgrade]	available
Estuarine/Marine	[crop]	in progress
Droplet size spectrum	[air]	not available
Spray drift	[air]	not available
Fish life cycle	[air]	not available

III Risk Assessment

EEB safety criteria Dr. Reinert

IV Discussion

Label amendments to meet "safe" criterion EEB
Conditional Registration

V Review of tentative resolution

Action points for RH
Action points for EPA

9

B5

429481-01

TITLE

Rohm and Haas Company Response to EPA HED and EFGWB Fenbuconazole Reviews of Stone fruit Petition No. 1F 3989 and Pecan Petition No. 1F 3995.

DATA REQUIREMENT

Response to EPA Reviews of Fenbuconazole Petitions 1F 3989 and 1F 3995.

AUTHOR

S. S. Stavinski

DATE

August 30, 1993

PERFORMING LABORATORY

Rohm and Haas Company
727 Norristown Road
Spring House, PA 19477

SPONSOR

Rohm and Haas Company
727 Norristown Road
Spring House, PA 19477

Laboratory Project ID

TR 34-93-86

10

Fenbuconazole

Page_____ is not included in this copy.

Pages 11 through 13 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.

INDEPENDENCE MALL WEST PHILADELPHIA
CABLE ADDRESS ROHMHAAS TELEX 84

ROHM AND HAAS COMPANY

4 November, 1993

Ms. Cynthia Giles-Parker VIA TELEFAX
Product Manager (PM22)
US EPA OPP Registration Division (H7505C)
Document Processing Desk (CORRESPONDENCE)
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Ms. Giles-Parker:

SUBJECT: **Indar™/Enable™ 2F** Agricultural Fungicide **(707-EGR)**
RH-7592 Technical Fungicide (707-EGN)
Petition for Tolerances on Stone Fruit (PP 1F3989) and Pecans (PP 1F3995)

This letter is intended to document several conversations recently held between Rohm and Haas Company and EPA regarding the data requirements for the Conditional Registration of fenbuconazole on Stone Fruit (PP 1F3989) and Pecans (PP 1F3995).

Rohm and Haas Company filed a petition for a Conditional Registration 14OCT93 and to fulfill the requirements for droplet size spectrum and spray drift, Guideline Requirements 201-1 and 202-1, we proposed to join the US Spray Drift Task Force (SDTF). The EPA informed me, in conversations with Mr. Jay Ellenberger (SRRD) and Mr. Frank Sanders (RD), that joining the SDTF would satisfy all data requirements, but that the EPA would have the right, after reviewing the SDTF data, to impose additional requirements as necessary. In the interim, any requirements for these data would be made conditional and registrations would be unimpeded by these requirements.

The EPA (EEB through RD) inquired if the SDTF was conducting studies of air blast application in pecan groves. The SDTF is not conducting studies for this crop, but is addressing air blast application. I relayed to Mr. Sanders information from the SDTF that pilot studies in pecans had been attempted in 1992, but the technical barriers in this crop made tests on this canopy type impossible under the current protocol and study design. The study design is fully supported by EPA. The SDTF intends to extrapolate to pecans from data on four other crop canopies: grapes, almonds, peaches, and apples.

I proposed to send to you a letter from the Chairman of the Technical Committee of the SDTF, Dr. Richard Stanton, restating the information above, and I was told by Mr. Sanders that this letter would address the concern regarding the spray drift in pecans.

Our understanding of the implications of these actions for fenbuconazole registrations are that the request for data on spray drift is now an impediment to Conditional Registration

for pecans or stone fruit and will not be an impediment to any subsequent registration unless and until the EPA reviews the data from the SDTF. If the EPA finds the data from the SDTF deficient in the support of a fenbuconazole registration, it would make a specific request for additional data from the registrant.

It is critical that Rohm and Haas Company clearly understand its obligations to EPA in order to respond appropriately and in a timely manner. If our understanding, as presented above, is not in concert with that of EPA please call me immediately, so that we may take appropriate action to comply with EPA's requests. My phone number is (215) 592-3581.

Best Regards,

Richard D. Costlow, Ph.D., D.A.B.T.
Product Registration Manager
Agricultural Chemicals Registration
and Regulatory Affairs Department

CC:

Mr. Jay Ellenberger
Special Review and Reregistration Division (H7508W)
Room 266A Crystal Mall #2
US. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

SPRAY DRIFT TASK FORCE

Donald R. Flint, Ph.D.
Chrmn, Administrative Comm
Miles Inc.
17745 South Metcalf
Stilwell, KS 66085-9104
TEL: (913) 897-9300
FAX: (913) 897-5215

Richard H. Stanton, Ph.D.
Chrmn, Technical Comm
Valent USA Corporation
1401 Eye Street, N.W.
Suite 305
Washington, D.C. 20005
TEL: (202) 872-4681
FAX: (202) 872-4689

Mr. Nick Somma
Treasurer
Rhone-Poulenc Ag Company
P.O. Box 12014
Research Triangle Park, NC 27709
TEL: (919) 549-2372
FAX: (919) 549-2545

David R. Johnson, Ph.D.
Project Manager
Stewart Agricultural
Research Services, Inc.
P.O. Box 509
Macon, MO 63552
TEL: (816) 762-4240
FAX: (816) 762-4295

Mr. Charles A. O'Connor, III
Secretary/Counsel
McKenna & Cuneo
1575 Eye Street, N.W.
Washington, D.C. 20005
TEL: (202) 789-7586
FAX: (202) 789-7756

Mr. Denis Hayley
Controller
Hayley-Whilden Associates
698 Holly Drive
Annapolis, MD 21401-5502
TEL: (410) 757-9488
FAX: (410) 626-8952

November 5, 1993

Ms. Cynthia Giles-Parker
Product Manager (PM22)
U.S. Environmental Protection Agency
OPP Registration Division (H7505C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Information From The
Spray Drift Task Force

Dear Ms. Giles-Parker:

This letter is intended to document to the Registration Division the intentions of the US Spray Drift Task Force (SDTF) with regard to data generation on air blast applications. The information is of particular concern to the Rohm and Haas Company and the impact on data requirements for the Conditional Registration on fenbuconazole (707-EGN) on Stone Fruit (PP 1F3989) and Pecans (PP1F3995). Rohm and Haas Company has recently stated their intention to join the Spray Drift Task Force, and is entitled to reference the data generated by the SDTF once the legal details of their membership are completed.

The data being generated by the SDTF are intended to address the issues of droplet size spectrum and spray drift, Guideline Requirements 201-1 and 202-1, such that any requirements for these data are addressed, and registrations for SDTF-member companies would be unimpeded by these requirements for all product uses.

I understand that the EPA inquired of Rohm and Haas Company if the SDTF was specifically conducting studies of airblast application in pecan groves. The SDTF is not conducting studies for this crop, but is addressing air blast application through tests on multiple representative canopies. The SDTF intends to extrapolate to pecans and other untested crop canopies from data on at least four specific crops: grapes, almonds, peaches, and apples which represent a wide range of canopy types. We fully expect that these extrapolations will adequately address EPA's concerns for untested crops and allow for appropriate risk assessments to be made.

If you require any additional information, please contact Dr. Costlow at Rohm and Haas Company or me at (202) 872-4681. Dr. Costlow's number is (215) 592-3581.

Best Regards,

Richard H. Stanton
SDTF Technical Committee
Chairman

cc: J. Ellenberger
R. Costlow

Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
FENBUCONAZOLE (FENETHANIL, RH-7592)
Last Update on December 27, 1993
[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

LOGOUT	Reviewer:	Section Head:	Date: 12/27/93

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, pecans, apples, bananas, almonds, greenhouse & field-grown ornamentals, wheat (seed and foliar treatment)

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 December 27, 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] $t\ell$ = 285 days (Lawrenceville silty clay loam - MRID no. 41031247)
[V] $t\ell$ = 367 days (Pasquotank sandy loam - " ")
[ ]
[ ]
[ ]
[ ]
[ ]

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

Anaerobic Aquatic Metabolism (162-3)
[ ]
[ ]
[ ]
[ ]
[ ]
[ ]
[ ]

Aerobic Aquatic Metabolism (162-4)
[ ]
[ ]
[ ]
[ ]
[ ]
[ ]
[ ]

Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
FENBUCONAZOLE (FENETHANIL, RH-7592)
Last Update on December 27, 1993
[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)
[V] t1/2 = 161 days - Minnesota (2 appl. @ 0.125 lb a.i./A)
[V] " 157 days - Georgia " "
[V] " 314 days - N. Calif. (5 appl. @ 0.2 lb a.i./A)
[V] " 407 days - S. Calif. " "
[S] " 187-206 days - S. Calif; single application studies.
[ ] Data reqmt fulfilled with submission of last supplemental study.
[ ] Minimal leaching of parent and degradates reported.
[ ] MRID nos. 42053503, 41875029, 42914701
[ ]
[ ]

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

Forestry Dissipation (164-3)
[ ]
[ ]

Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
FENBUCONAZOLE (FENETHANIL, RH-7592)
Last Update on December 27, 1993
[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

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)
[ ]
[ ]
[ ]

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

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

Spray Drift, Droplet Spectrum (201-1)
[ ] EEB asked EFGWB to request these data. Registrant wishes to ful-
[ ] data reqmt through Spray Drift Task Force. See 12-pointer dated
[ ] 12/27/93.
[ ]

Spray Drift, Field Evaluation (202-1)
[ ] Same as 201-1 above.
[ ]
[ ]
[ ]

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 December 27, 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 12/27/93 all env. fate data requirements needed to support proposed uses (terrestrial food/nonfood, greenhouse nonfood) have been fulfilled except spray drift (201-1, 202-1). Registrant has proposed to fulfill spray drift data reqmts through Spray Drift Task Force. See 12-pointer of 12/27/93 for details.

References: EPA studies
Writer : A.W. Jones

DATA EVALUATION RECORD

CHEM 129011 Fenbuconazole §164-1

MRID 42914701
Deakyne, R.O., and S.S. Stavinski. 1993. RH-7592 (Fenbuconazole) single application terrestrial field dissipation study. Laboratory Report No. 34-93-35. Unpublished study performed by Pan-Agricultural Laboratories Inc., Madera, CA and submitted by Rohm and Haas Company, Spring House, PA.

REVIEWED BY:

Arnet W. Jones, Agronomist
Review Section 1
OPP/EFED/EFGWB

Signature: Arnet W. Jones
Date: 27 DEC 1993

APPROVED BY:

Paul J. Mastradone, Ph.D.
Chief, Review Section 1
OPP/EFED/EFGWB

Signature: Paul J Mastradone
Date: 27 DEC 1993

CONCLUSIONS:

Single applications of fenbuconazole at high (1.0 lb a.i./A) and low (0.25 lb a.i./A) rates were made to bare-ground plots in Madera, CA to provide information on early dissipation and overall persistence. Earlier field dissipation experiments used multiple applications of fenbuconazole which are typical of actual use.

1. The study provides supplemental information and when combined with a previously submitted study (MRID 42053503; EFGWB no. 92-0256; 02/18/93) fulfills the terrestrial field dissipation data requirement (164-1) for fenbuconazole. No additional terrestrial field dissipation data are needed at this time to support terrestrial food, terrestrial nonfood, and greenhouse nonfood uses of fenbuconazole.

2. In a 362-day study, fenbuconazole was applied once at high (1 lb a.i./A) and low (0.25 lb a.i./A) rates to separate bare-ground plots of a sandy loam soil in Madera, CA. Fenbuconazole dissipated from the 0-6 inch soil layer with registrant-calculated half-lives of 187 and 206 days for the high and low application rates, respectively. Reviewer-calculated half-lives for the 0-3 inch soil depth were 192 and 216 days for the high and low rate studies, respectively. Dissipation appeared to proceed at a slightly greater rate during the first 60 days than in the latter stages of the study. The degradates 5-(4-chlorophenyl) dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-yl) methyl)-2(3H)furanone (isomer A - RH-9129; isomer B - RH-9130) and 4-(4-chlorophenyl)-2-(methyl-1H-1,2,4 triazole)-4-oxo-2-phenyl butanenitrile (RH-6467) were detected in quantities up to 0.060, 0.079, and 0.059 ppm, respectively, in the high application rate experiment; lesser quantities were detected in the low rate experiment. Most degradate detections were in the 0-3 inch depth; small quantities of degradates were detected at 3-6 inches in the high application rate experiment. There were no detections of any monitored degradate at the 3-6 inch depth in the low application rate experiment.

3. The study confirms the results of earlier field dissipation studies which found fenbuconazole to be moderately persistent to persistent (half-lives were 157-407 days) in soil under actual use conditions.

METHODOLOGY:

The test soil was a Hanford fine sandy loam (69.3% sand, 24.0% silt, and 6.7% clay) with the following characteristics: organic matter - 0.5%; CEC - 5.6 meq/100 g; pH - 5.8; bulk density - 1.41 g/cm^2; and 10.8% moisture at 1/3 bar. The site has <1% slope; the water table is at 88-107 ft.

Three 15 X 60 ft subplots were used for each of three treatments - control, high rate, and low rate. Each plot was divided into 100 - 3 X 3 ft sampling areas. A randomized grid was used to designate five sampling areas from each subplot. Samples were taken pretreatment and on day zero (immediate post-treatment), 14, 29, 60, 90, 120, 150, 180, 210, 240, 300 & 362. On each sampling day, soil was sampled to a depth of 6 inches and divided into 0-3 and 3-6 inch segments. Samples from the five subplot sampling areas were composited by date and depth. The 0-3 inch samples were removed by a 3-inch diameter PVC sleeve inserted into the soil. The 3-6 inch samples were removed by a 2-inch diameter probe. Soil samples were placed in an ice chest and then transferred to a field walk-in freezer and stored at -23.3 to -10.6°C.

Samples were processed using a hammer mill. Sample analysis was carried out using the Rohm and Haas method TR 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. The limit of quantitation was 0.01 ppm; the limit of detection was 0.003 ppm for all compounds.

Raw ppm values were determined from a standard curve during each analysis day. The values were reported to the study director with (chromatographic data) without correction. The study director then applied a correction factor based on recovery of each analyte (see Data Summary). A final ppm value (dry weight) was calculated based on percent solids in the sample. Values below the 0.003 ppm limit of detection were reported as zero and averaged as such. The study author indicated that values above the LOD but below the LOQ were corrected and reported, "although their true significance is dubious."

Field spike, tank mix, and day zero spray card samples were taken but not analyzed.

DATA SUMMARY:

In a 362-day study, fenbuconazole was applied one time at high (1 lb a.i./A) and low (0.25 lb a.i./A) rates to separate bare-ground plots of a Hanford fine sandy loam in Madera, CA. Tables I & II and Figures I & 2

summarize the study results for parent. Fenbuconazole dissipated from the 0-6 inch soil layer with registrant-calculated half-lives of 187 and 206 days for the high and low application rates, respectively. Dissipation appeared to proceed more rapidly in the early part of the experiment (days 0-60) than in the later stage. In the high application rate experiment, fenbuconazole residues in the 0-6 inch soil layer declined from 0.378 to 0.065 ppm in 362 days. In the low application rate experiment, residues declined from 0.122 to 0.027 ppm in 362 days. In the 0-3 inch layer, residues declined from 0.720 to 0.130 ppm in the high rate experiment and from 0.237 to 0.054 ppm in the low rate experiment. Reviewer-calculated half-lives for the 0-3 inch soil depth were 192 and 216 days for the high and low rate studies, respectively.

The degradates 5-(4-chlorophenyl) dihydro-3-phenyl-3-(1H-1,2,4-triazole-1-yl) methyl)-2(3H)furanone (isomer A - RH-9129; isomer B - RH-9130) and 4-(4-chlorophenyl)-2-(methyl-1H-1,2,4 triazole)-4-oxo-2-phenyl butanenitrile (RH-6467) were monitored during the study. In the high application rate study, the highest level of RH-9130 detected in individual samples in the 0-3 inch depth was 0.079 ppm (day 14). RH-9130 was also detected at 0-3 inches in individual samples at several other sampling times. RH-9129, the stereoisomer of RH-9130, was first detected at 0-3 inches in the day 60 samples at 0.044 ppm in the high rate study. RH-9129 was detected at all sampling intervals from day 60 to day 362; its highest detected concentration during the study (0.060 ppm) was reached at day 90. RH-6467 was present at 0-3 inches at each sampling interval from days 14 through 362. The highest concentration of RH-6467 detected was at day 29 when it was 0.059 ppm in one 0-3 inch sample. Small quantities of degradates were detected at 3-6 inches in the high application rate experiment. In the low rate study at 0-3 inches, the highest concentrations of RH-9130, RH-9129, and RH-6467 in individual samples were 0.022 ppm (day 29), 0.018 ppm (day 60), and 0.012 (day 362), respectively. There were no detections of any monitored degradate at the 3-6 inch depth at any sampling interval in the low application rate experiment.

Fortification recoveries were: RH-7592 (parent fenbuconazole) - 88.5 ± 9.9%; RH-9130 - 90.6 ± 8.0%; RH-9129 - 82.2 ± 10.1%; and RH-6467 - 91.5 ± 8.3%. Based on fortification recoveries, respective correction factors of 0.85, 0.85, 0.8, and 0.9 were used.

DISCUSSION:

1. The data confirm the results of earlier field dissipation studies, i.e., fenbuconazole is a moderately persistent to persistent compound under actual use conditions. For both high and low use rate studies, fenbuconazole residues were still present in soil at study termination (day 362). Residues of fenbuconazole may accumulate in soil following repeated applications over multiple growing seasons. When used on field crops (EFGWB reviewed a proposed new use for foliar and seed treatment for wheat on 09/01/93) fenbuconazole residues are likely to persist in soil and be available for rotational crop uptake. Also, the residues may be transported with sediment in runoff from treated fields.

2. The author states that "The study run at the higher application rate produced a curve which is smoother, probably because the higher overall residues can be measured with higher precision. This study serves as the best model for RH-7592 dissipation in soil." EFGWB does not necessarily agree with this conclusion. The experiment used a single application at an exaggerated rate (1 lb a.i./A) which is not typical of field use. The label indicates that the maximum rate for a single application is 0.125 lb

a.i./A; multiple applications up to a seasonal limit of 1 lb a.i./A are allowed. EFGWB believes that the best assessment of fenbuconazole dissipation from soil under typical use conditions would be derived from studies conducted at multiple locations using multiple applications of the fungicide.

3. The study reports a half-life of approximately 55 days for the first 60 days of the study. Early dissipation of residues in the high application rate experiment is proposed with a 27% decline in residues (from 0.72 to 0.52 ppm) from day 0 to day 14. Although the registrant suspected early dissipation of residues, no soil samples were taken between days 0 and 14. More sampling should have been carried out between days 0 and 14 to better assess the reported early dissipation. From days 60 to 362, the reviewer-calculated half-lives were 256 and 269 days for the 0-6 inch and 0-3 inch soil segments, respectively. Regardless of the early decline in residues, the laboratory and field data are consistent and indicate that parent fenbuconazole will be moderately persistent to persistent in soil.

4. Very little water (approximately 13.4 inches) was applied to plots during the study. Plots were intended to receive irrigation and rainfall amounting to 120% of the 30-yr monthly average. But protocol deviations submitted indicate that during much of the study water was not applied as scheduled and that the irrigation system malfunctioned resulting in uneven water distribution over the subplots. This normally would be a significant problem, but the purpose and results of this particular study do not appear to be comprised as a result of the irrigation problem.

5. The study reports that field spike, tank mix, and day zero spray card samples were taken but not analyzed. Field spikes from the previous field dissipation study (MRID 42053503) were run and reported in MRID 41875025. Zero day spray cards and tank mix samples were not analyzed because the time zero soil residue levels were 70-90% of the theoretical. EFGWB concurs that the time zero soil residues adequately confirmed the application rate.

6. The study was conducted using a single application of fenbuconazole. In the previous study (MRID 42053503) where multiple applications were made, a half-life of 407 days was reported for vegetated plots of sandy loam soil in Madera, CA.

7. Assessing degradate dissipation is difficult due to the lack of apparent trends in decline and the presentation of the data. Also, in some cases, the concentrations of degradates reported for control samples exceeded those of the treated plots.

Fenbuconazole

Page_____ is not included in this copy.

Pages 29 through 33 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.