

US EPA ARCHIVE DOCUMENT

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DEC - 3 1992

TO: Cynthia Giles-Parker
Product Manager 22
Registration Division (H7505C)

FROM: Paul J. Mastradone, Ph.D., Chief *PJM*
Environmental Chemistry Review Section #1
Environmental Fate & Ground Water Branch/EFED (H7507C)

THRU: Henry Jacoby, Chief *H. Jacoby*
Environmental Fate & Ground Water Branch/EFED (H7507C)

Attached, please find the EFGWB review of...

Reg./File # : 000707-EUP-121 & 000707-EUP-REL

Common Name : Fenbuconazole (RH-7592, Fenethanil)

Product Name : _____

Company Name : Rohm and Haas

Purpose : Review request for extension of EUP on stone fruit and request for new EUP on pecans.

Type Product : Fungicide Action Code: 710 EFGWB nos: 92-0007, 92-0307

Review Time : 2.0 days

EFGWB Guideline/MRID/Status Summary Table: The review in this package contains...

161-1	162-4	164-4	166-1
161-2	163-1	164-5	166-2
161-3	163-2	165-1	166-3
161-4	163-3	165-2	167-1
162-1	164-1	165-3	167-2
162-2	164-2	165-4	201-1
162-3	164-3	165-5	202-1

Y = Acceptable (Study satisfied the Guideline)/Concur P = Partial (Study partially satisfied the Guideline, but additional information is still needed)
S = Supplemental (Study provided useful information, but Guideline was not satisfied) N = Unacceptable (Study was rejected)/Non-Concur

1.0 CHEMICAL:

Common Name: Fenbuconazole, RH-7592, Fenethanil

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

2.0 TEST MATERIAL: NA

3.0 STUDY/ACTION TYPE:

Review request for extension of the existing experimental use permit (EUP) for stone fruit and review request for new EUP for pecans.

4.0 STUDY IDENTIFICATION:

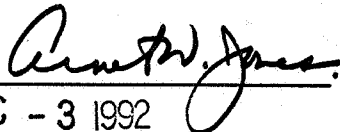
Letter of 08/28/91 from R. Costlow, Rohm and Haas, to C. Giles-Parker, OPP/RD, requesting extension of an existing EUP (permit no. 707-EUP-121) for use on stone fruit. No MRID number.

Letter of 09/26/91 from R. Costlow, Rohm and Haas, to C. Giles-Parker, OPP/RD, requesting an EUP for use on pecans. No MRID number.

5.0 REVIEWED BY:

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

Signature:

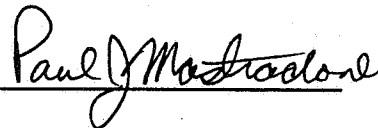

DEC - 3 1992

Date:

6.0 APPROVED BY:

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

Signature:


DEC - 3 1992

Date:

7.0 CONCLUSIONS:

7.1 The environmental fate data requirements necessary to support an extension of the EUP on stone fruit have been satisfied.

7.2 The environmental fate data requirements necessary to support a new EUP for pecans have been satisfied. See Background for details.

8.0 RECOMMENDATIONS: See Conclusions.

9.0 BACKGROUND:

9.1 Extension of EUP for Fenbuconazole Use on Stone Fruit

In previous reviews (EFGWB nos. 90546 [10/12/89] & 90770 [10/18/89]), EFGWB concluded that the data requirements necessary to support EUPs on stone fruit and almonds were satisfied. The following data requirements have been satisfied:

- hydrolysis (161-1)
- aerobic soil metabolism (162-1)
- anaerobic soil metabolism (162-2)
- leaching and adsorption/desorption (163-1)

The fish accumulation study presented was satisfactory to support EUPs, but the data requirement (165-4) is only partially satisfied pending identification of an unknown degradate.

In their letter of 08/28/91 (copy attached), the registrant (Rohm and Haas) requested an extension for the current EUP on stone fruit (and temporary tolerances on stone fruit crop group). The extension was requested in order to collect additional efficacy and residue data in certain (unspecified) states. They wish to collect data on air versus ground applications and submitted a revised label which does not prohibit aerial application. According to Rohm and Haas, the EUP currently in effect (707-EUP-121) was granted on 02/15/90 for 279 gal of RH-7592 2F (558 lb a.i.) for use on 730 A/yr. On 02/22/91 the initial agreement was amended and approved for the EUP to be continued to 10/31/91 for 234.4 gal of RH-7592 2F (468.5 lb a.i.) for use on 625 A/yr. The extension request would continue these limits to 10/31/93.

9.2 Application for EUP for Fenbuconazole Use on Pecans

In its letter of 09/26/91 (copy attached), the registrant requested an EUP for fenbuconazole use on pecans along with a temporary tolerance of 0.1 ppm for fenbuconazole and its metabolites in raw pecans.

The stated objectives of the experimental program (copy attached) are to: 1) confirm product performance using standard spray schedules and equipment; 2) define optimum use rates, application timings, and number of applications required for disease control, nut quality, and yield; and 3) define and demonstrate product performance for registrant marketing personnel, agricultural chemical dealers, and other parties. The program will include 40 grower trials conducted on 200 A in AL, GA, LA, MS, OK, and TX. RH-7592 2F will be evaluated against standard grower treatments in varied climatic conditions and application methods. The maximum amount of a.i. used during the 2-yr program will be 400 lb.

9.3 Environmental Fate Summary

At present there is insufficient information to assess fully the environmental fate of fenbuconazole. However, based upon previously reviewed acceptable laboratory studies, fenbuconazole is stable. The compound does not hydrolyze at pH values found in the environment. It 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). 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 related to soil organic matter content. It does not bioaccumulate in fish (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.

9.4 Status of Environmental Fate Data Requirements

The status of the environmental fate data requirements for fenbuconazole is shown below:

<u>Data Requirement</u>	<u>Status</u>	<u>MRID No.</u>
<u>Degradation</u>		
Hydrolysis (161-1)	Fulfilled ¹	41031246
Photodegradation water (161-2)	In review ²	41875023
Photodegradation soil (161-3)	In review ²	41875024
<u>Metabolism</u>		
Aerobic soil metab. (162-1)	Fulfilled ¹	41031247
Anaerobic soil metab. (162-2)	Fulfilled ¹	41031247
<u>Mobility</u>		
Leaching/ads./des. (163-1)	Fulfilled ¹	41031248
<u>Dissipation</u>		
Soil Dissipation (164-1)	In review ²	42053503 41875029
Soil Dissip.- Long-term (164-5)	Reserved	
<u>Accumulation</u>		
Confined rotational crop (165-1)	NA ³	41875027
Bioaccumulation in fish (165-4)	In review ⁴	41073509
<u>Spray Drift</u>		
Droplet size spectrum (201-1) and Drift field eval. (202-1)	Reserved ⁵	

¹ These data requirements are fulfilled. See EFGWB No. 90546, 10/12/89.

² Studies in support of these data requirements have been submitted and are in review.

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 The original bioaccumulation in fish study submitted, which partially fulfills this data requirement, failed to identify some of the metabolites of the parent compound. Data pertaining to identification of these metabolites are in review.

⁵ 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 EEB.

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10.0 DISCUSSION:

The extension of the EUP for RH-7592 use on stone fruits would involve aerial application. No details are provided concerning aerial application of this fungicide.

Spray drift from aerial or air blast application, or runoff may result in fenbuconazole contamination of surface water and could pose a hazard to fish and other aquatic organisms. The proposed labels indicate that RH-7592 is toxic to fish and aquatic organisms.

11.0 COMPLETION OF ONE-LINER: NA

12.0 CBI APPENDIX: NA



August 28, 1991

Ms. Cynthia Giles-Parker
Product Manager
Registration Division
Fungicide-Herbicide Branch
U.S. Environmental Protection Agency
Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Ms. Giles-Parker:

SUBJECT: RH-7592 (fenbuconazole) Experimental Fungicide -
EPA Registration Number 707-EUP-121:
Request for EUP Extension
Pesticide Petition 9G3746 for Temporary Tolerances for
Fenbuconazole on the Stone Fruit Crop Group

The Rohm and Haas Company requests an extension for its experimental program for RH-7592 fungicide (fenbuconazole) on stone fruit (707-EUP-121) and an extension of the temporary tolerances on the stone fruit crop group (Pesticide Petition 9G3746). The initial approval of the EUP and temporary tolerance was granted by EPA 15 February 1990. The approval was for 279 gallons of RH-7592 2F (558 pounds of active ingredient) per year and 730 acres per year. The approval was amended and approved 22 February 1991 and continued to 31 October 1991. This approval was for 234.4 gallons of RH-7592 2F (468.5 pounds of active ingredient) per year and 625 acres per year. An extension of these limits to 31 October 1993 would adequately support our research program.

There are no residue data supporting the initial EUP request which were from Craven Laboratories.

We request this extension because we wish to collect additional efficacy and residue data in certain states. Because we wish to collect data on air versus ground applications a revised label is submitted which does not prohibit aerial application. The lack of a temporary tolerance would prohibit use of RH-7592 in the coming use season on certain stone fruit crops and this would prevent Rohm and Haas from continuing field research on this crop protectant while the Petition for Permanent Tolerances is being reviewed by EPA. It is important that a tolerance exist continuously to prevent any inadvertent and unintentional violations of FIFRA resulting from previously approved programs.

Ms. Cynthia Giles-Parker
RH-7592 2F Experimental Fungicide
707-EUP-121 (PP 9G3746 Stone Fruit)

-Page 2-

It is our hope that the permanent tolerance petition for fenbuconazole on stone fruits will be approved prior to the 1993 use season, in which case portions of the research program could continue without the need for an EUP.

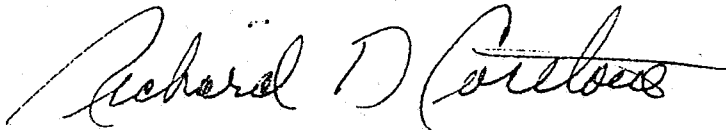
Attached to this letter is Form 8570-17, an application to amend the original application and five copies of the revised label.

All other sections of the FEB91 approval, the certification with respect to citation of data in support of the registration, and the data reference list are unaffected by this amendment. We note that Rohm and Haas has filed a petition for a permanent tolerance on this crop group.

A copy of the letter to Headquarters Accounting Operations Branch and the certified check in the amount of \$2,950.00 to the EPA are included.

If you have any questions regarding this letter or comments regarding its impact I ask that you call me at (215) 592-3581 to discuss them.

Best Regards,



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

Attachments

Please read the instructions on the reverse before completing.

US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (TS-767)
Washington, DC 20460



Application for an Experimental Use Permit To Ship and Use a Pesticide for Experimental Purposes Only

Form Approved
OMB No. 2070-0001
Approval expires 7-31-87

1. Type of Application

New Extension (Give Permit Number below)

2. EPA Company Number
707

3. Date of Application
August 28, 1991

Permit Number
707-EUP-121

4. Name and Address of Firm/Person to Whom the Experimental Use Permit Is To Be Issued (Include ZIP Code)

Rohm and Haas Company
Independence Mall West
Philadelphia, PA 19105

5. Name and Address of Shipper (If shipment is intended and if different from applicant's name and address)(Include ZIP Code)

Rohm and Haas Company
Independence Mall West
Philadelphia, PA 19105

6. Name of Product

RH-7592 Experimental Fungicide

7. Is Product Registered with EPA

Yes (Give Registration Number below) No

EPA Registration Number

8. Total Quantity Proposed for Shipment/Use Product

Active Equivalent (in pounds)

9. Proposed Period of Shipment/Use

October 31, 1991

October 31, 1993 -

10. Places from which Shipped

Rohm and Haas Company
Rtes. 13 and 413
Bristol, PA

11. Will Technical Material Be Imported?

Yes (Give total quantity below) No

Gallons

234.4 gals./year

Pounds

468.5 lbs./year

12. Place Where Directions for Use Appear

On container label

In printed matter accompanying product

Certification

This is to certify that food or feed derived from the experimental program will not be used or offered for consumption or sale for consumption except by laboratory or experimental animals if illegal residues are present in or on such food or feed.

13. Specify the name & telephone no. of the individual most familiar with this application who can be contacted directly, if necessary to process this application

Richard D. Costlow, Ph.D., D.A.B.T.
215-592-3581

14. Signature of Applicant or Authorized Firm Representative

15. Title

Product Registration Manager

16. Date Signed

8/28/91

Below for EPA Use Only

In any correspondence on this application, refer to this number

Received by EPA OPP Registration Division,
Washington, DC 20460

Normal review time indicates that processing of this application should be completed by (date)

Name of EPA Contact

Telephone No.

8

Fenbutonazole

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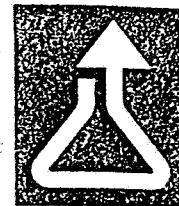
The material not included contains the following type of information:

- 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.
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

L. Trainor

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**

September 26, 1991

Ms. Cynthia Giles-Parker,
Product Manager (PM22)
Registration Division (H7505C)
Office of Pesticide Programs
Document Distribution Desk (EUP / PETN)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Ms. Giles-Parker:

SUBJECT: Fenbuconazole

RH-7592 (Indar®) 2F Experimental Fungicide

EPA File Symbols 707-EGN and 707-EGR

Application for Experimental Use Permit and ¹²⁵707-EUP-REL

Petition for a Temporary Tolerance on Pecans 26438

Submitted with this letter is an application from the Rohm and Haas Company for a registration action under FIFRA §5 for the active ingredient fenbuconazole.

We wish to register an end use product (EP) RH-7592 2F ~~Experimental Fungicide~~ for experimental use on pecans. The chemical nomenclature for fenbuconazole is

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

Concurrent with this application we submit a petition for a Temporary Tolerance of 0.1 ppm for fenbuconazole and its metabolites on the raw agricultural commodity pecans. A ~~Temporary Tolerance~~ of 1.0 ppm is currently established for fenbuconazole on the stone fruit crop group (55 FR 17488; 707-EUP-121; Pesticide Petition Number 9G3746) and Permanent Tolerances are currently pending for fenbuconazole on the Stone Fruit Crop Group (PP 1F3989) and Pecans (PP 1F3995).

(1)

The following items are included to support the application for registration for RH-7592 2F Experimental Fungicide:

1. Application for Experimental Use Permit - EPA Form 8570-17,
2. Five copies of the proposed labeling,
3. Certification with Respect to Citation of Data, and
4. Three (3) copies of a binder containing summaries for Section A (Product Chemistry), Section B (Proposed Labeling), Section C (Mammalian Toxicology), Section D (Nature and Magnitude of the Residue), Section E (practical methods for removing residues in excess of the proposed tolerances), Section F (Proposed Temporary Tolerance), Section G (Proposed Experimental Program), Section I (Ecological Toxicology), Section J (Environmental Fate), and a bibliography of the studies submitted, indicating which study fulfills each of the guideline requirements for a Terrestrial Food Crop Registration.

Data to fulfill all guideline requirements have been previously submitted to EPA in connection with Experimental Use Permits, Temporary Tolerances, registration of the TGAI/MP, registration of the EP, or requests for Permanent Tolerances. These studies are cited in "Reference List of Studies Submitted (Revised September 1991)" in each binder (NOTE: The submission date for a study and the EPA MRID Number, if available, are provided for each study.)

The following items are included in support of the Temporary Tolerance Petition for Pecans:

1. Three copies of a data binder containing summaries for Section A (Product Chemistry), Section B (Proposed Labeling), Section C (Mammalian Toxicology), Section D (Nature and Magnitude of the Residue), Section E (practical methods for removing residues in excess of the proposed tolerances), Section F (Proposed Permanent Tolerances), Section G (reasonable grounds in support of the petition), Section I (Ecological Toxicology), and Section J (Environmental Fate).
2. Copies of the cover letter and the certified check for \$11,200.00 sent to the Headquarters Accounting Operations Branch to cover the processing fees for the tolerance petition. This fee is correct as noted in 40 CFR § 180.33 (56 FR 4946-4947).

Ms. Cynthia Giles-Parker
Fenbuconazole - EUP and Pecan Temporary Tolerance
RH-7592 2F Experimental Fungicide

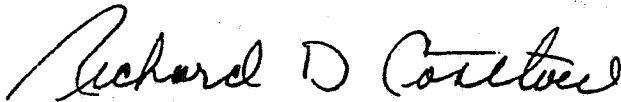
-Page 3-

We respectfully request that this registration application and temporary tolerance petition be reviewed and approved in compliance with the timing guidelines established under FIFRA so that use of fenbuconazole will be available for experimental use in pecan production regions for disease control during the use season which begins in February, 1992.

Please notify the Rohm and Haas Company of the dates by which the reviews from each of the Science Branches are expected.

If you have any questions regarding this application I ask that you call me at (215) 592-3581 to discuss them prior to any regulatory action.

Best Regards,



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

RH-7592 2F Experimental Fungicide
Application for U.S. EPA Experimental Use Permit

Petition for a Temporary Tolerance for Fenbuconazole
Pecans

Section B

Proposed Labeling

RH-7592 2F Experimental Fungicide
Application for U.S. EPA Experimental Use Permit

Petition for a Temporary Tolerance for Fenbuconazole
Pecans

Section B

Proposed Labeling

RH-7592 2F Experimental Fungicide

This section contains a proposed label for RH-7592 2F Experimental Fungicide. The formulated product is intended for use on pecans.

The labelling included in this section is sufficient to support an application under FIFRA §5 for registration of the use of RH-7592 2F Experimental Fungicide on a Raw Agricultural Commodity (RAC) crop, Pecans. It also supports the petition for a Temporary Tolerance under FFDC A §408 on Pecans.

Fenbutaconazole

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The material not included contains the following type of information:

- Identity of product inert ingredients.
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ROHM AND HAAS COMPANY

INDEPENDENCE MALL WEST

PHILADELPHIA, PENNSYLVANIA 19105



RH-7592 2F Experimental Fungicide
Application for Experimental Use Permit
Use on Pecans
EPA Experimental Use Permit No. 707-EUP-_____

SECTION G

Proposed Experimental Program

September, 1991

RH-7592 2F Experimental Fungicide
Application for U.S. EPA Experimental Use Permit

Petition for a Temporary Tolerance for Fenbuconazole
Pecans



Section G

Proposed Experimental Program for
RH-7592 Use on Pecans

Fenbuticorazole

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Pages 22 through 31 are not included.

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