UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

December 20, 1989

MEMORANDUM

SUBJECT: Addendum to Fenethanil (RH-7592) review #1, dated 12-1-89 (record # 244519)

FROM: James W. Ackerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H-7507C)

TO: S. Lewis (PM 21)
Herbicide/Fungicide Branch
Registration Division (H-7505C)

Review #1 for Fenethanil (RH-7592) dated 12-1-89, stated that prior to Section 3 registration EEB would require data regarding avian reproduction, fish early life stage, and invertebrate life cycle. Upon reconsideration of the submitted data and label use instructions it has been decided that the fish early life stage and invertebrate life cycle data will not be required at this time. Prior to Section 3 registration EEB will still require data for avian reproduction. If you have any question regarding this memorandum please contact Harry Winnik, Biologist, EFED/EEB at 557-7463.

CONCURRENCES								
SYMBOL	H7507C	H7507C						
SURNAME	WINNIK	Caven						
DATE	12-20-89	12/20/89						

EPA Form 1320-1 (12-70) OFFICIAL FILE COPY

244519
RECORD NO.

129011
SHAUGHNESSEY NO

1
REVIEW NO.

EEB REVIEW

DATE: IN 5-3-89 OUT 12-1-89

FILE OR REG. NO. 707-EUP-RER

PETITION OR EXP. NO. 9G3746

DATE OF SUBMISSION 3-1-89

DATE RECEIVED BY EFED 4-28-89

RD REQUESTED COMPLETION DATE 7-28-89

EEB ESTIMATED COMPLETION DATE 7-28-89

RD ACTION CODE/TYPE OF REVIEW 711

TYPE PRODUCT(S) Fungicide

DATA ACCESSION NO(S) 410735-06 and -07, 410312-31 thru -38

PRODUCT MANAGER, NO. S. Lewis (21)

PRODUCT NAME(S) RH-7592 Fungicide

COMPANY NAME Rohm & Haas Company

SUBMISSION PURPOSE Proposed EUP for new chemical for use on stone fruit.

SHAUGHNESSEY NO.	CHEMICAL	% A.I.
129011	Fenethanil	22.8

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EEB Review

RH-7592

100.0 Submission Purpose and Label Information

100.1 Submission Purpose and Pesticide Use

Proposed experimental use permit (EUP) for RH-7592 Fungicide use on stone fruit.

100.2 Formulation Information

Active Ingredient:
Fenethanil (2-[2-(4-chlorophenyl)ethyl]-2-phenyl-3-(1H- 1,2,4-triazole)-1-propanenitrile) 22.8%
Inert Ingredients 77.2%

*Equivalent to 2 lbs. active ingredient per gallon

100.3 Application Methods, Directions, Rates

Refer to attached label

100.4 Target Organisms

Blossom Blight (Monilinia spp.)
Fruit Brown Rot (Monilinia spp.)
Scab
Rust (Tranzschelia sp.)

100.5 Precautionary labeling

Environmental Hazards

This pesticide is toxic to fish. Do not apply directly to water or wetlands. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not apply when weather conditions favor drift or runoff from areas treated.

101.0 Hazard Assessment

101.1 Discussion

The objectives of the proposed program as described by the registrant is to:

1. To confirm product performance when applied in standard grower spray schedules and equipment.

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2. To define optimum use rates, application timings and number of applications required for disease control and maximum fruit quality and marketable yield.

3. Generate field residue data, on representative crops in the stone fruit crop grouping, to support a Section 3 registration application.

4. To provide opportunities to define and demonstrate product performance characteristics for Rohm and Haas Company Sales and Marketing personnel, agricultural chemical dealers and distributors, University and Cooperative Extension Service personnel.

The EUP has been requested for a 22-month period in the following states:

Region	State	No. Trials	No. Acres	Total Lbs.Active
Western	California	100	250	188
	Idaho	10	25	18
	Montana	4	10	8
	Oregon	16	40	30
	Utah	8	20	16
	Washington	16	40	30
	Total	154	385	290
Central	Alabama	2	5	4
	Arkansas	4	10	8
	Colorado	4	10	8
	Illinois	2	5	4
	Indiana	2	5	4
	Louisiana	4	10	8
	Michigan	16	40	30
	Missouri	2	5	4
	Ohio	2	5	4
	Oklahoma	2	5	4
	Texas	8	20	16
	Wisconsin	8	20	16
	Total	56	140	110

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Region	State	No. Trials	No. Acres	Total Lbs.Active
Eastern	Georgia	16	40	30
	Maryland	6	15	12
	New Jersey	12	30	24
	New York	4	10	8
	North Carolina	8	20	16
	Pennsylvania	8	20	16
	South Carolina	16	40	30
	Virginia	8	20	16
	West Virginia	4	10	8
	Total	82	205	158
	Grand Total	292	730	558

101.2 Likelihood of Adverse Effects to Nontarget Organisms

Environmental Fate Data

The following data was obtained from the Environmental Fate and Groundwater Branch review of EUP to test RH-7592 on stone fruit, submitted by Clinton Fletcher, Chemist, Review Section 1, EFGWD/EFED:

. RH-7592 will be stable to hydrolysis at pH levels found in the environment.

. RH-7592 will degrade in soil under aerobic conditions with a half-life of 285 and 367 days in Lawrenceville silty clay loam and Pasquotank sandy loam soils, respectively.

. RH-7592 will degrade in soil under anaerobic conditions with a half-life of 451 and 655 days in the Lawrenceville silty clay loam and the Pasquotank sandy loam soils, respectively.

. RH-7592 will be only slightly mobile to immobile in soils. Adsorption appears to be associated with percent organic matter present. RH-7592 will be slightly mobile in soils containing a low percent organic material (≤1%) and relatively immobile in soils with higher levels of organic material.

. RH-7592 residues have only a slight potential to leach in the soil environment.

. RH-7592 will not bioaccumulate in fish and any residues that are taken up will be depurated when fish are no longer exposed to RH-7592 residues.

The above data indicate that RH-7592 is quite stable and may be persistant in the environment (under aerobic conditions up to 367 days and under anaerobic conditions up to 655 days).

Terrestrial Hazard

RH-7592 may be characterized as practically non-toxic on an acute basis to avian species (Bobwhite quail Colinus virginianus, LD_{50}>2150 mg a.i./kg).

RH-7592 may be characterized as slightly toxic on a subacute basis to avian species (Mallard duck Anas platyrhynchos, LC_{50} of 2013 ppm, and Bobwhite quail Colinus virginianus, LC_{50} of 4050 ppm).

RH-7592 may be characterized as relatively non-toxic to nontarget insects (Honey bee Apis melifera, LD_{50}>292.18 ug a.i./bee).

At a maximum application rate of 7.5 oz/A RH-7592 (equivalent to 0.125 lbs a.i./A) the maximum residue expected on such food items as insects and forage would be 1.5 ppm and 7.25 ppm respectively. These levels are significantly below the LC_{50} values for Bobwhite Quail and Mallard Ducks with respect to RH-7592.

On the basis of these data, the proposed EUP does not pose a significant threat to birds or insects.

At the time of this review there was no mammalian toxicity data available. Therefore, a hazard assessment to mammals was not possible.

Aquatic Hazard

Rh-7592, with a 96-hour LC_{50} or 1.5 mg a.i./L for Rainbow trout Salmo gairdneri, is considered moderately toxic to coldwater fish. Data for the Bluegill sunfish (Lepomis macrochirus), 96-hour LC_{50} of 0.68 mg a.i./L, indicate that RH-7592 is highly toxic to warmwater fish.

The 48-hour EC_{50} for Daphnia magna of 2.3 mg a.i./L indicates that RH-7592 is moderately toxic to freshwater invertebrates.

Assuming a direct application to a pond 6 ft. deep and a maximum application rate of 0.125 lbs a.i./A, the resulting residue level in the water would be approximately 7.7 ppb. This concentration is less than one-tenth the LC_{50} values for coldwater fish, warmwater fish and freshwater invertebrates. As such, RH-7592

does not pose a significant hazard to aquatic organisms as a result of single applications. However, according to the label instructions the potential exists for multiple applications of RH-7592. Subsequently, the EPA Pesticide Residue Fate Simulation computer program was used to estimate the maximum and average residues expected from drift and runoff from a 10 acre treated area into a 1 acre pond, 6 ft. deep as a result of multiple applications of RH-7592. The application rate was assumed to be 0.125 lb. a.i./acre. Since the solubility of RH-7592 is 3.8 ppm the runoff rate was assumed to be 2%. Using EEC calculation formulas for Aerial Application or Mist Blower (see attached), an EEC of 1.96 ppb was obtained. Assuming half life figures of 285 days and 655 days, application intervals of 14 day and 10 days respectively, number of applications of 6 and 8 respectively, and lengths of simulation of 84 days and 80 days respectively, maximum and average residues were calculated (see attached). The table below lists the values obtained for each data set:

	Set 1	Set 2
EEC/Application	1.96 ppb	1.96 ppb
Half Life	285 days	655 days
# of Applications	6	8
Application Interval	14 days	10 days
Length of Simulation	84 days	80 days
Maximum Residue	10.8 ppb	15.1 ppb
Average Residue	6.4 ppb	8.6 ppb

The average residues calculated for data sets 1 and 2 approach and exceed respectively 0.01 LC_{50} of warmwater fish of 0.68 mg. a.i./L (6.8 ppb). These results combined with the fact that the LC_{50} of warmwater fish is less than 1 mg. a.i./L, trigger the need for Fish Early Life Stage and Invertebrate Life Cycle studies prior to Section 3 registration.

Plant Hazard

Due to the low water solubility of RH-7592 (3.8 ppm) the hazard to aquatic plants should be minimal and aquatic plant growth testing on the freshwater green alga Selenastrum capricornutum will not be required at this time.

101.3 Endangered Species Consideration

RH-7592 Fungicide will be tested in 27 states on approximately 730 acres (see section 101.1). Because of the limited acreage treated and the low application

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rates proposed, this EUP does not pose a significant hazard to endangered species.

101.4 **Adequacy of Toxicity Data**

Seven studies were submitted with the EUP. The following is a brief summary of the results of the EEB reviews of these studies:

- Fletcher, D. W., (1988), 21-Day Acute Oral LD_{50} Study with RH-7592 Technical in Bobwhite Quail, prepared by Bio-Life Associates, Ltd., Neillsville, Wisconsin, Report No. 88RC-0021, Submitted by

Rohm and Haas Company, Spring House, Pennsylvania. EPA Accession No. 410312-31

This study is scientifically sound and fulfills the guideline requirements for an avian single-dose oral toxicity test.

The oral LD_{50} of RH-7592 Technical for Bobwhite quail Colinus virginianus was greater than 2,150 mg a.i./kg of body weight as determined by this study. RH-7592 is considered practically non-toxic to Bobwhite Quail.

- Fletcher, D. W., (1988), 8-Day Acute Dietary Study with RH-7592 Technical in Mallard Ducklings, prepared by Bio-Life Associates, Ltd., Neilsville, Wisconsin, Report No. 88RC-0019, submitted by

Rohm and Haas Company, Spring House, Pennsylvania, EPA Accession No. 410312-32

This study is scientifically sound and fulfills the guideline requirements for an avian dietary LC_{50} test.

The dietary LC_{50} of RH-7592 Technical for Mallard duck Anas platyrhynchos was 2,013 ppm active ingredient as determined by this study. RH-7592 Technical is considered slightly toxic to Mallards. The NOEC was 312 ppm active ingredient.

- Fletcher, D. W., (1988), 8-Day Acute Dietary Study with RH-7592 Technical in Bobwhite Quail, prepared by Bio-Life Associates, Ltd., Neilsville, Wisconsin, Report No. 88RC-0020, submitted by

Rohm and Haas Company, Spring House, Pennsylvania, EPA Accession No. 410312-33

This study is scientifically sound and fulfills the guideline requirements for an avian dietary LC_{50} test.

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The dietary LC_{50} of RH-7592 Technical for Bobwhite quail Colinus virginianus was 4,500 ppm active ingredient as determined by this study. RH-7592 Technical is considered slightly toxic to Bobwhite Quail. The NOEC was 625 ppm active ingredient.

- Swigert, J.P., (1988), Acute Flow-Through Toxicity of RH-7592 Technical to Bluegill sunfish (Lepomis macrochirus), prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, Missouri, Report No. 88RC-0024, submitted by

Rohm and Haas Company, Spring House, Pennsylvania, Accession No. 410735-06.

This study appears a scientifically sound and fulfills the guideline requirements for an acute 96-hour flow-through toxicity test using a warmwater fish species.

The 96-hour LC_{50} of RH-7592 Technical to Bluegill sunfish (Lepomis macrochirus) was 0.68 mg a.i./L based on mean measured concentrations as determined by this study. RH-7592 Technical is classified as highly toxic to Bluegill. The NOEC was 0.42 mg a.i./L after 96 hours.

- Swigert, J.P., (1988), Acute Flow-Through Toxicity of RH-7592 Technical to Rainbow trout Salmo gairdneri, prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, Missouri, Report No. 88RC-0025, submitted by

Rohm and Haas Company, Spring House, Pennsylvania, Accession No. 410312-35.

This study appears a scientifically sound and fulfills the guideline requirements for an acute 96-hour flow-through toxicity test using a coldwater fish species.

The 96-hour LC_{50} of RH-7592 Technical to Rainbow trout Salmo gairdneri was 1.5 mg a.i./L based on mean measured concentration as determined by this study. RH-7592 Technical is classified as moderately toxic to Rainbow Trout. The NOEC was 0.70 mg a.i./L after 96 hours.

- Burges, D., (1988), Acute Flow-Through Toxicity of RH-7592 Technical to Daphnia magna, prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, Missouri, Report No. 88RC-022, submitted by

Rohm and Haas Company, Spring House, Pennsylvania
Accession No. 410735-07.

This study appears scientifically sound and fulfills the guideline requirements for an acute 48-hour flow-through toxicity test for freshwater invertebrates.

The 48-hour EC_{50} of RH-7592 Technical to Daphnia magna was 2.3 mg a.i./L based on mean measured concentrations as determined by this study. RH-7592 Technical is classified as moderately toxic to Daphnia magna. The NOEC was determined to be 0.78 mg a.i./L after 48 hours.

- Atkins, E.L., (1988), RH-7592 Technical: Bee Adult Toxicity Dusting Test, conducted by Department of Entomology, University of California, Report No. 88RC-0066, submitted by

Rohm and Haas Company, Spring House, Pennsylvania
Accession No. 410312-38

This study is scientifically sound and fulfills the guideline requirements for an acute contact LD_{50} test using honeybees.

The 96-hour LD_{50} of RH-7592 Technical to Honey bee Apis melifera was greater then 292.18 ug a.i./bee as determined by this study. RH-7592 Technical is considered relatively non-toxic to honeybees when administered as a dusting powder. The NOEL for this study was 292.18 ug a.i./bee, the only dosage tested.

Prior to section 3 registration the following data will be required:

- Mammalian toxicity
- Avian reproduction (preferably Mallard and Bobwhite)
- Fish early life stage
- Invertebrate life cycle

Following review of required EEB data, submission of additional toxicity data may be necessary.

101.5 Adequacy of Labeling

The following statements should appear on the product label:

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Drift or runoff from treated areas may be hazardous to aquatic organisms in adjacent aquatic sites. Do not contaminate water when disposing of equipment washwaters and rinsate.

102.0 Classification

Not classified

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103.0 **Conclusions**

EEB has reviewed the proposed EUP for RH-7592 Fungicide on stone fruits. Environmental fate data indicate that RH-7592 is quite stable and may be persistant in the environment (under aerobic conditions up to 367 days and under anaerobic conditions up to 655 days).

Based on data available, the proposed EUP will not pose significant adverse effects to avian, insect, and fish or invertebrate species.

Due to the low water solubility of RH-7592, the proposed EUP will not pose significant adverse effects to aquatic plants.

In light of the apparent persistance of RH-7592 and the label use recommendations the following acute and chronic study data will be required prior to section 3 registration:

- Avian reproduction (preferably Mallard and Bobwhite)
- Fish early life stage
- Invertebrate life cycle

Following review of required EEB data, submission of additional toxicity data may be necessary.

Attachment

Harry A. Winnik 11-30-89
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

Henry Craven, Head, Section IV 11/30/89
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

James W. Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C) 11/30/89

RIN 3477-95

EEB FENETHANIL REVIEW

Page____ is not included in this copy.

Pages 13 through 14 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.

Attachment A

EEC CALCULATION SHEET

I. For un-incorporated ground application

A. Runoff

___lb(s) x 0.0_ (_% runoff) x 10 (A) (from 10 A. drainage basin) = _____lb(s) (tot.runoff)

EEC of 1 lb a.i. direct application to 1 A. pond 6-foot deep = 61 ppb

Therefore, EEC = 61 ppb x ____(lb) = _____ ppb

II. For incorporated ground application

A. Runoff

___lb(s) ÷ _____ (cm) (depth of incorporation) x 0.0_ (_% runoff) x 10 (A) (10 A d.basin) = _____lb(s) (tot.runoff)

Therefore, EEC = 61 ppb x _____(lbs) = _____ppb

III. For aerial application (or mist blower)

A. Runoff

____ lb(s) x 0.6 (appl. efficiency) x 0.0 (_% runoff) x 10 (A) (10 A. d.basin) = _____lb(s) (tot.runoff)

B. Drift

_____ lb(s) x 0.05 (5 % drift) = _____ lb(s) (tot. drift)

Tot. loading = _____ lb(s) (tot. runoff) + _____ lb(s) (tot. drift) = _____lb(s)

Therefore, EEC = 61 ppb x _____(lbs) = _____ppb

ILY ACCUMULATED PESTICIDE RESIDUES---MULTP. APPL.

emical name	RH-7592 (Fenethanil)
itial concentration (PPB)	1.96
lf-life	285
number of application	6
plication interval	14
ngth of simulation (day)	84

AY	RESIDUE (PPB)
	1.96
	1.955239
	1.950489
	1.945751
	1.941025
	1.93631
	1.931606
	1.926914
	1.922233
	1.917564
0	1.912906
1	1.908259
2	1.903624
3	1.899
4	3.854387
5	3.845024
6	3.835684
7	3.826367
8	3.817072
9	3.807799
0	3.79855
1	3.789323
2	3.780118
3	3.770935
4	3.761775
5	3.752637
6	3.743522
7	3.734428
8	5.685357
9	5.671546
0	5.657769
1	5.644026
2	5.630316
3	5.616639
4	5.602995
5	5.589385
6	5.575808
7	5.562263
8	5.548751
9	5.535273
0	5.521827
1	5.508414
42	7.455033

POINT AT WHICH RESIDUE EXCEEDS 1/100 LC_{50} OF WARMWATER FISH

5	7.400837
6	7.382859
7	7.364925
8	7.347035
9	7.329188
0	7.311384
1	7.293624
2	7.275907
3	7.258232
4	7.240601
5	7.223013
6	9.165466
7	9.143202
8	9.120992
9	9.098836
0	9.076734
1	9.054686
2	9.03269
3	9.010749
4	8.98886
5	8.967025
6	8.945243
7	8.923513
8	8.901836
9	8.880212
0	10.81864
1	10.79236
2	10.76615
3	10.73999
4	10.7139
5	10.68788
6	10.66192
7	10.63602
8	10.61018
9	10.58441
0	10.5587
1	10.53305
2	10.50746
3	10.48194
4	10.45648
ximum residue	10.81864
erage residue	6.436193

ILY ACCUMULATED PESTICIDE RESIDUES---MULTP. APPL.

emical name	RH-7592 (Fenethanil)
itial concentration (PPB)	1.96
lf-life	655
number of application	8
plication interval	10
ngth of simulation (day)	80

+Y	RESIDUE (PPB)
	1.96
	1.957927
	1.955856
	1.953788
	1.951721
	1.949657
	1.947595
	1.945535
	1.943477
	1.941421
0	3.899368
1	3.895244
2	3.891124
3	3.887008
4	3.882897
5	3.87879
6	3.874688
7	3.870589
8	3.866495
9	3.862406
0	5.818321
1	5.812167
2	5.80602
3	5.799879
4	5.793744
5	5.787617
6	5.781495
7	5.77538
8	5.769271
9	5.76317
30	7.717074
1	7.708912
2	7.700758
3	7.692614
4	7.684477
5	7.676349
6	7.66823
7	7.660119
8	7.652017
9	7.643924
0	9.595839
1	9.585689
2	9.575551
3	9.565424

POINT AT WHICH RESIDUE EXCEEDS 1/100 LC_{50} OF WARMWATER FISH

5	9.545201
6	9.535105
7	9.525019
8	9.514944
9	9.50488
0	11.45483
1	11.44271
2	11.43061
3	11.41852
4	11.40644
5	11.39438
6	11.38233
7	11.37029
8	11.35826
9	11.34625
0	13.29425
1	13.28019
2	13.26614
3	13.25211
4	13.23809
5	13.22409
6	13.2101
7	13.19613
8	13.18217
9	13.16823
0	15.11431
1	15.09832
2	15.08235
3	15.0664
4	15.05046
5	15.03454
6	15.01864
7	15.00276
8	14.98689
9	14.97104
0	14.9552

ximum residue ----------	15.11431
erage residue ----------	8.64478