DP Barcode : D198211
PC Code No : 129011
EEB Out : / / 1-14-94

To: Cynthia Giles-Parker
Product Manager 22
Registration Division (7505C)

From: Anthony F. Maciorowski, Chief
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 000707-EGN
Chemical Name : Fenbuconazole
Type Product : fungicide
Product Name : Indar
Company Name : Rohm & Haas
Purpose : Review eco-effects data.

Action Code: 101 Date Due: 5/11/94
Reviewer: Regina Hirsch

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)	43590-D		122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur
P=Partial (Study partially fulfilled Guideline but additional information is needed
S=Supplemental (Study provided useful information but Guideline was not satisfied)
N=Unacceptable (Study was rejected)/Nonconcur

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DATA EVALUATION RECORD

1. CHEMICAL: Fenbuconazole (RH-57,592)

2. TEST MATERIAL: 98% TGAI, white powder, Lot Number BPP-3-1786R.

3. STUDY TYPE: §72-3

4. CITATION:

Author:	Emily Dionne
Title:	RH-57,592 technical - acute toxicity to Eastern Oyster (*Crassostrea virginica*) under flow-through conditions.
Date:	29 November 1993
Laboratory Report #:	93-10-4971
Any Other Study #:	86.0493.6168.504
Sponsor:	Rohm and Haas Company
Sponsor #:	93RC-0073
Laboratory:	Springborn Laboratories, Inc.
MRID No.:	430580-03

5. REVIEWED BY:

Regina M. Hirsch, Wildlife Biologist Signature: R. Hirsch
Ecological Effects Branch
Environmental Fate and Effects Division (7507 C) Date: 7/13/94

6. APPROVED BY:

Les Touart, Chief, Section 1 Signature:
Ecological Effects Branch
Environmental Fate and Effects Division (7507C) Date: 7/14/94

7. CONCLUSION

This study is scientifically sound and fulfills the guideline requirements for an acute toxicity test using the Eastern oyster. Under the conditions of the test, the 96-hour low effect level was 0.69 mg/L and the no effect level was 0.53 mg/L, which classifies Fenbuconazole as highly toxic to Eastern oysters.

8. RECOMMENDATIONS

9. BACKGROUND

10. MATERIALS AND METHODS

V

A. Test Organisms: Eastern Oysters

Guideline Criteria	Reported Information
Species (Scientific Name)	*Crassostrea virginica*
Mean valve height (25 - 50 mm -- the long axis)	32 mm (sd 3 mm)
Supplier	P. Cummins Oyster Company, Pasedena, MD
All oysters from same source (yes or no)	yes
All oysters from the same year class (yes or no)	yes
Other Comments	

B. Source/Acclimation

Guideline Criteria	Reported Information
Acclimation Period (minimum 10 days)	16 days
Wild caught 7 day quarantine (yes or no)	no
Check for signs of disease or injury (yes or no, if yes describe)	yes, checked for mortality and after the shell growth was grinded off, checked for stress.
If diseased it can be treated in 48-hr pretest no sign of the disease remains (Report hours prior to test in which no sign of disease or N/A)	N/A
Was peripheral shell growth removed prior to testing? If so how much.	yes, 3-5 mm
Feeding during the acclimation	Fed a supplemental algal diet of Isochrysis galbana Parke, clone T-ISO and Tetraselmis maculata.
<3% mortality 48 hours prior to testing (% mortality, if any)	yes

C. Test System:

Guideline Criteria	Reported Information
Describe source of dilution water (natural unfiltered seawater)	Natural unfiltered seawater from Cape Cod Canal, Bourne, MA
Does water support test animals without observable signs of stress?	yes
What was the salinity of the test water?	32‰ ppt
Water Temperature (between 15°C and 30°C -- but must be consistent)	20 ± 2°C
pH	8.0
Dissolved Oxygen (Static 1st 48 hrs 40%; 2nd 48 hrs 60%; Flow-through 60%) (% of lowest conc. & hour)	See Table 1
Total Organic Carbon	1.3 mg/L
Test Aquaria 1. Material (glass or stainless steel) - 2. a. Static volume (18.9 L (5 gal or 19000 cc) with 15 L solution) b. Static or flow-through volume (300x600x300 = 54000 cc.)	glass 18 L 49.5 X 25.5 X 29 cm
Type of Dilution System (Reproducible supply of toxicant)	Harvard Apparatus peristaltic pump was calibrated to deliver 0.1875 ml/min of the 4.0 mg ai/ml stock solution.
Flow rate Consistent flow rate-meter systems calibrated before study and checked 2*24 hours - 5 to 10 vol/24 hours	6 solution volume replacements per 24 hours
Biomass Loading Rate (all oysters should be able to sit on the bottom with water flowing freely around them)	yes

Photoperiod (16 L & 8 D)	16 hours light and 8 hours dark
Solvents (Do not exceed 0.5 ml/L for flow-through)	0.5 ml/L acetone
Other Comments	

D. Test Design:

Guideline Criteria	Reported Information
Range Finding Test (LC_{50} >100 mg/L with 30 shrimp, no definitive test required.)	tested nominal concentrations of 0.032 to 4.0 mg/L. After 96-hours growth reduction of 63-100% was observed in oysters in 1.2 and 4.0 mg ai/L. No reduction in shell growth at 0.032, 0.11 and 0.36 mg ai/L.
Definitive Test	
Nominal Concentrations (control+5 treatment levels; dosage should be 60% of the next highest concentration; concentrations should be geometric series)	0.26, 0.43, 0.72, 1.20, 2.00 mg ai/L
Controls (Minimum control mortality; static 10%; flow-through 5%	no mortality observed
Number of Test Organisms; (Minimum 10/level can be divided among containers)	20 oysters in each test aquarium (40 per treatment level)
All organisms must be randomly assigned to test vessels. (yes or no, describe if no)	yes
Biological Observations (yes or no)	yes, every 24 hours
Water Parameter Measurements 1. Temperature - record every 6 hrs;>1°C. 2. D.O. beginning,48 hrs,end for control high, medium, and low dose. 3. pH beginning,48 hrs, end for control, high, medium, and low dose.	21-22°C See Table 1 See Table 1

Chemical Analysis (needed if aeration, volatile, insoluble, precipitate, not steel or glass, known to adsorb, and flow-through) (yes or no)	No precipitate observed
Other Comments	

11. REPORTED RESULTS:

Guideline Criteria	Reported Information
Mean Measured Concentrations (report conc.)	0.18, 0.28, 0.53, 0.69, 1.60 mg ai/L
Recovery of Chemical (% recovery)	
Mortality & Observations (Describe observations & attach mortality tables)	No mortality at any treatment level; however reduced feeding and reduced fecal and pseudofecal production were observed at 1.6 mg/L
Measurements of shell increments per control and test concentration.	See Table 3
Ratio of mean growth of test concentration to mean growth of controls. (provides percentage index of the response of the molluscs to toxicant)	See Table 4
EC_{50} = reduced shell deposition by 50% compared to the controls	EC_{50} = 1.2 mg/L using the mean measured concentrations EC_{50} = 0.69 mg/L
Author's Comments	

12. STUDY AUTHOR'S CONCLUSIONS / QUALITY ASSURANCE MEASURES:

Based on the test data, the 96-hour EC_{50} was calculated by linear regression to be 1.2 mg ai/L (95% CI of 0.65 to 1.9 mg ai/L). Based on these results and criteria established be the U.S. Environmental Protection Agency (1985), RH-57,592 Technical would be classified as moderately toxic to *Crassostrea virginica*.

Quality assurance and good laboratory practice statements were included in the report, indicating that the study was conducted in accordance with U.S. EPA Good Laboratory

Practices Regulations set forth in FIFRA 40 CFR Part 160.

13. REVIEWER'S DISCUSSION AND INTERPRETATION

A. Test Procedure:

The following items did not meet the guideline criteria:

1. Mean measured concentrations were > 60% of the next highest concentration (range 43%-76%).

B. Statistical Analysis

Guideline Criteria	Reported Information
Binomial (yes, no, or not reported)	
Moving Average Angle (yes, no, or not reported)	
Probit (yes, no, or not reported)	yes, Probit concentrations transformed to log concentration therefore 4 linear regression curves were computed
Williams Test	yes (EEB used this), LOEC = 0.69 mg/L and NOEC = 0.53

C. Discussion/Results:

This study is scientifically sound and fulfills the guideline requirements for an acute toxicity test using the Eastern oyster. Under the conditions of the test, the 96-hour LOEC was 0.69 mg/L and the NOEC 0.53 mg/L which classifies Fenbuconazole as highly toxic to Eastern oysters.

D. Adequacy of the Study:

1. Classification: Core

2. Rational:

3. Reparability:

14. COMPLETION DATE OF ONE-LINER FOR STUDY:

RIN 3477-95

EEB FENBUCONAZOLE REVIEW

Page_____ is not included in this copy.

Pages 8 through 11 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.

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✓ FIFRA registration data.

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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.

Acute Oyster Study for Fenbuconazole
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WILLIAMS TEST (Isotonic regression model) TABLE 2 OF 2

IDENTIFICATION	ISOTONIZED MEAN	CALC. WILLIAMS	SIG P=.05	TABLE WILLIAMS	DEGREES OF FREEDOM
control	2.620				
solvent control	2.539	0.421		1.66	k= 1, v=273
0.18	2.539	0.421		1.73	k= 2, v=273
0.28	2.460	0.829		1.75	k= 3, v=273
0.53	2.419	1.038		1.77	k= 4, v=273
0.69	1.645	5.049	*	1.77	k= 5, v=273
1.6	0.552	10.707	*	1.78	k= 6, v=273

s = 0.864
Note: df used for table values are approximate when v > 20.

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WILLIAMS TEST (Isotonic regression model) TABLE 1 OF 2

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	control	40	2.620	2.620	2.620
2	solvent control	40	2.355	2.355	2.539
3	0.18	40	2.722	2.722	2.539
4	0.28	40	2.460	2.460	2.460
5	0.53	40	2.419	2.419	2.419
6	0.69	40	1.645	1.645	1.645
7	1.6	40	0.552	0.552	0.552

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5	0.53	40	2.419	2.419	2.419
6	0.69	40	1.645	1.645	1.645
7	1.6	40	0.552	0.552	0.552