

US EPA ARCHIVE DOCUMENT

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 PC Code No : 129011
 EEB Out : / / 7-20-94

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
 Reviewer: Regina Hirsch

Date Due: 5/11/94

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) | 430590-02 | | 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 | | |

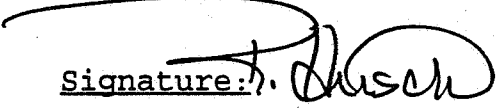
Y=Acceptable (Study satisfied Guideline)/Concur
 P=Partial (Study partially fulfilled Guideline but additional information is needed)
 S=Supplemental (Study provided useful information but Guideline was not satisfied)
 N=Unacceptable (Study was rejected)/Nonconcur

DATA EVALUATION RECORD

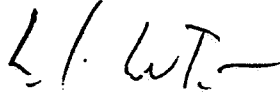
1. CHEMICAL: Fenbuconazole (RH-57,592)
2. TEST MATERIAL: 98% TGAI, white powder, Lot Number BPP-3-1786R.
3. STUDY TYPE: S72-3
4. CITATION:

Author: Mark W. Machado
Title: RH-57,592 technical - acute toxicity to mysid shrimp (*Mysidopsis bahia*)
Date: 10 December 1993
Laboratory Report #: 93-11-5012
Any Other Study #: 86.0493.6167.515
Sponsor: Rohm and Haas
Sponsor #: 93RC-0072
Laboratory: Springborn Laboratories, Inc. Wareham, MA
MRID No.: 430580-02

5. REVIEWED BY:

Regina M. Hirsch, Wildlife Biologist
Ecological Effects Branch
Environmental Fate and Effects Division (7507 C) Signature:  Date: 7/20/94

6. APPROVED BY:

Les Touart, Chief, Section 1
Ecological Effects Branch
Environmental Fate and Effects Division (7507C) Signature:  Date: 7/20/94

7. CONCLUSION

This study appears to be scientifically sound and fulfills the guideline requirements for an acute toxicity test on mysids. The 96-hour EC₅₀ was 0.63 mg ai/L, which classifies Fenbuconazole as being highly toxic to mysid shrimp.

8. RECOMMENDATIONS

9. BACKGROUND

10. MATERIALS AND METHODS

A. Test Organisms: Mysid Shrimp

| Guideline Criteria | Reported Information |
|--|---|
| Species (Scientific Name) | <i>Mysidopsis bahia</i> |
| Mean Weight (> 0.5 grams) | ≤ 24 hours old |
| Supplier | Springborn Laboratories. SLI Lot Number 93Ab |
| All shrimp from same source (yes or no) | yes |
| All shrimp from the same year class (yes or no) | yes |
| Other Comments | |

B. Source/Acclimation

| Guideline Criteria | Reported Information |
|---|---------------------------|
| Acclimation Period (minimum 10 days) | N/A |
| Wild caught 7 day quarantine (yes or no) | no |
| Check for signs of disease or injury (yes or no, if yes describe) | N/A |
| 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) | |
| <3% mortality 48 hours prior to testing (% mortality, if any) | Information not available |

C. Test System:

| Guideline Criteria | Reported Information |
|---|---|
| Describe source of dilution water | Seawater collected from Cape Cod Canal, Bourne, MA |
| Does water support test animals without observable signs of stress? | yes |

| | |
|---|---|
| What was the salinity of the water used? (30-34% ppt for marine (stenohaline) shrimp and 10-17% ppt for estuarine (euryhaline) shrimp. | 31-33% |
| Water Temperature (22°C) | 25 ± 1°C |
| pH 8.0-8.3 marine (stenohaline) shrimp 7.7-8.0 estuarine (euryhaline) shrimp | 7.9-8.0 |
| Dissolved Oxygen (Static 1 st 48 hrs 40%; 2 nd 48 hrs 60%; Flow-through 60%) (% of lowest conc. & hour) | |
| Total Organic Carbon | 1.2 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.) | 19.5 glass aquaria 7-11 L fluctuation 39 X 20 X 25 cm |
| Type of Dilution System (Reproducible supply of toxicant) | yes |
| Flow rate Consistent flow rate-meter systems calibrated before study and checked 2*24 hours - 5 to 10 vol/24 hours | 7 volume replacements per 24 hours |
| Biomass Loading Rate (Static no > 0.8 g/L ≤ 17°C; >17°C 0.5 g/L; Flow-through 1 g/L/24) | 0.00013 g biomass/L |
| Photoperiod (16 L & 8 D) | 16 light and 8 dark |

| | |
|--|------------|
| Solvents 1. (Do not exceed 0.5 ml/L for static tests) 2. (Do not exceed 0.1 ml/L for flow-through) | 0.093 ml/L |
| Other Comments | |

D. Test Design:

| Guideline Criteria | Reported Information |
|---|--|
| <u>Range Finding Test</u> (LC ₅₀ >100 mg/L with 30 shrimp, no definitive test required.) | 0.25, 0.41, 0.68, 1.1, 1.9 mg ai/L 100% mortality @ 1.1 and 1.9 |
| <u>Definitive Test</u> | |
| Nominal Concentrations (control+5 treatment levels; dosage should be 60% of the next highest concentration; concentrations should be geometric series) | 0.14, 0.24, 0.40, 0.66, 1.10 mg ai/L |
| Controls (Minimum control mortality; static 10%; flow-through 5%) | 0% |
| Number of Test Organisms; (Minimum 20/level can be divided among containers) | 20 /test concentration and control |
| All organisms must be randomly assigned to test vessels. (yes or no, describe if no) | yes |
| Biological Observations (yes or no) | yes |
| 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. | Temp. continuously measured in 1 control replicate. Temp. measured in all other test and control vessels daily. For DO and pH see Table 1 |

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| | |
|--|---|
| Chemical Analysis (needed if aeration, volatile, insoluble, precipitate, not steel or glass, known to adsorb, and flow-through) (yes or no) | No visible signs of undissolved test material |
| Other Comments | |

11. REPORTED RESULTS:

| Guideline Criteria | Reported Information |
|---|---|
| Mean Measured Concentrations (report conc.) | 0.16, 0.21, 0.33, 0.53, 0.94 mg ai/L |
| Recovery of Chemical (% recovery) | |
| Mortality & Observations (Describe observations & attach mortality tables) | See Table 3 |
| Author's Comments | |

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

No conclusions were made.

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:

Test complied with guidelines.

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B. Statistical Analysis

| Guideline Criteria | Reported Information |
|--|---|
| Binomial (yes, no, or not reported) | yes, confidence intervals were calculated. 95% CI 0.53-0.94 mg ai/L |
| Moving Average Angle (yes, no, or not reported) | |
| Probit (yes, no, or not reported) | |
| Other Comments -- study used nonlinear interpolation | EC ₅₀ = 0.63 mg ai/L |

C. Discussion/Results:

This study appears to be scientifically sound and fulfills the guideline requirements for an acute toxicity test on mysids. The 96-hour EC₅₀ was 0.63 mg ai/L, which classifies Fenbuconazole as being highly toxic to mysid shrimp.

D. Adequacy of the Study:

1. Classification: Core
2. Rational:
3. Reparability:

14. COMPLETION DATE OF ONE-LINER FOR STUDY:

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Regina Hirsch Fenbuconazole Acute Toxicity to Mysid Shrimp

| CONC. | NUMBER EXPOSED | NUMBER DEAD | PERCENT DEAD | BINOMIAL PROB. (PERCENT) |
|-------|----------------|-------------|--------------|--------------------------|
| .94 | 20 | 20 | 100 | 9.536742E-05 |
| .53 | 20 | 4 | 20 | .5908966 |
| .33 | 20 | 0 | 0 | 9.536742E-05 |
| .21 | 20 | 1 | 5 | 2.002716E-03 |
| .16 | 20 | 0 | 0 | 9.536742E-05 |

THE BINOMIAL TEST SHOWS THAT .53 AND .94 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS .6333479

THE MOVING AVERAGE METHOD CANNOT BE USED WITH THIS DATA SET BECAUSE NO SPAN WHICH PRODUCES MOVING AVERAGE ANGLES THAT BRACKET 45 DEGREES ALSO USES TWO PERCENT DEAD BETWEEN 0 AND 100 PERCENT.

RESULTS CALCULATED USING THE PROBIT METHOD

| ITERATIONS | G | H |
|------------|----------|----------|
| 7 | 5.985625 | 15.93358 |

GOODNESS OF FIT PROBABILITY

0 A PROBABILITY OF 0 MEANS THAT IT IS LESS THAN 0.001.

SINCE THE PROBABILITY IS LESS THAN 0.05, RESULTS CALCULATED USING THE PROBIT METHOD PROBABLY SHOULD NOT BE USED.

SLOPE = 6.70461
 95 PERCENT CONFIDENCE LIMITS = -9.698579 AND 23.1078

LC50 = .5997951
 95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

LC10 = .3877761
 95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

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RIN 3477-95

EEB FENBUCONAZOLE REVIEW

Page _____ is not included in this copy.

Pages 9 through 12 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.
