S406678
SUBMISSION #

129011
SHAUGHNESSY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 11-26-91 DATE: OUT 3-29-93

FILE OR ID NO. MRID 418750-09

PETITION OR EXP. NO.

DATE OF SUBMISSION 10-28-91

DATE RECEIVED BY EFED 11-26-91

RD REQUESTED COMPLETION DATE 5-5-92

EEB ESTIMATED COMPLETION DATE 03-15-93

RD ACTION CODE/TYPE OF REVIEW Data Evaluation Record
Growth and Reproduction
of Aquatic Plants - Tier 2
Selenastrum capriconutum

TYPE OF PRODUCT(S) : I,D,H,F,N,R,S Fungicide

DATA ACCESSION NO(S).

PRODUCT MANAGER (NO.) Cynthia Giles-Parker

PRODUCT NAME(S) Fenbuconazole, RH7592, Fenethanil, Indar, RH-57,592

COMPANY NAME Rohm and Haas

SUBMISSION PURPOSE Meet EEB Study requirements

SHAUGHNESSY NO.	CHEMICAL & FORMULATION(S)	% A.I.
129011	Fenbuconazole	98.3
	Inert	1.7

DATA EVALUATION RECORD

1. **CHEMICAL:** RH-7592.
Shaughnessey No. 129011.

2. **TEST MATERIAL:** RH-7592 technical; Lot No. BPP-3-1786R; TD No. 90-045; 96.7% active ingredient; a white powder.

3. **STUDY TYPE:** 123-2. Growth and Reproduction of Aquatic Plants - Tier 2. Species Tested: *Selenastrum capricornutum*.

4. **CITATION:** Burgess, D. and J.W. Blasberg. 1991. Acute Toxicity of RH-7592 to *Selenastrum capricornutum* Printz. Laboratory Project ID No. 38928. Rohm and Haas Report No. 90RC-0110. Conducted by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO. Submitted by Rohm and Haas, Spring House, PA. EPA MRID No. 418750-09.

5. **REVIEWED BY:**

Mark A. Mossler, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Mark A. Mossler
Date: 12/4/92

6. **APPROVED BY:**

Louis M. Rifici, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Louis M Rifici
Date: 12/4/92

Henry T. Craven, M.S.
Supervisor, EEB/EFED
USEPA

Signature: Regina Hirsch 3/22/93
Date: Henry T. Craven 4/14/93

7. **CONCLUSIONS:** This study is scientifically sound but does not meet the requirements for a Tier 2 aquatic plant growth and reproduction study. A precise NOEC was not determined. Based on mean measured concentrations, the 120-hour LOEC and EC_{50} for *S. capricornutum* exposed to RH-7592 were 0.09 and 0.41 mg ai/l, respectively.

8. **RECOMMENDATIONS:** N/A.

9. **BACKGROUND:**

S.25

V

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

11. **MATERIALS AND METHODS:**

A. **Test Species:** The alga used in the test, *Selenastrum capricornutum*, came from laboratory stock cultures originally obtained from The University of Texas. Stock cultures were maintained in algal medium (p. 12, attached). The culture used as the inoculum for the test was transferred to fresh medium three days before test initiation.

B. **Test System:** Test vessels used were sterile 250-ml Erlenmeyer flasks fitted with foam plugs. The test medium was the same as that used for culturing with the pH adjusted to 7.5 ±0.1 and filtered (0.45 µm). Test vessels were randomly placed and maintained on a shaker (shaking rate of 90-100 rpm) under continuous cool-white illumination (4.3 klux) in a growth chamber. The temperature of the chamber was maintained at 24 ±1°C.

C. **Dosage:** Five-day growth and reproduction test. Based on the results of a preliminary test, five nominal concentrations of 0.10, 0.20, 0.40, 0.80, and 1.6 mg active ingredient (ai)/l were selected for the definitive test.

A 16 mg/ml primary stock solution was prepared by dissolving the test material in acetone. A 1.6 mg ai/l working stock was created in nutrient medium from the primary stock and was used to prepare the lower concentration solutions. A medium control and a solvent control (0.1 ml of acetone/l of algal medium) were also prepared.

D. **Test Design:** Three replicate flasks (3 per treatment level and the controls) were used for the definitive test. One-hundred ml of the appropriate test or control solution were placed into each flask.

An inoculum of *Selenastrum capricornutum* cells calculated to provide 3,000 cells/ml (1.0 ml) was introduced into each flask. At test initiation, average cell density in the controls was 3,300 cells/ml. At each 24-hour interval, cell counts were conducted on each replicate vessel using a hemacytometer and microscope.

The pH and temperature were measured in parent solutions at test initiation and in one replicate at

shaking rate within the growth chamber were measured daily.

At test initiation (initial solutions) and termination (composited solutions), samples were removed from each test solution and the controls for analysis by high performance liquid chromatography.

E. **Statistics:** The EC_{50} and 95% confidence interval (C.I.) were determined by quadratic regression of response (percent reduction of cell density as compared with the controls) vs. mean measured concentration over the range of test concentrations. The data were subjected to analysis of variance (ANOVA) coupled with Dunnett's test ($p \leq 0.05$), but the no-observed-effect concentration (NOEC) was determined to be the EC_{10}. Replicate cell counts were square root transformed before analysis.

12. **REPORTED RESULTS:** The mean measured concentrations were 0.091, 0.18, 0.34, 0.68, and 1.3 mg ai/l and averaged 86% of nominal (Table 3, attached).

Cell densities determined at each observation time are presented in Table 4 (attached). Based on mean measured concentrations, the 120-hour EC_{50} was calculated to be 0.47 mg ai/l (95% C.I. = 0.39-0.57 mg ai/l) and the NOEC was 0.026 mg ai/l (calculated using the fitted quadratic equation).

The pH was between 7.3 and 7.4 in all test solutions and the controls at test initiation and between 7.4 and 7.8 at termination. The temperature was 24°C during the study. Illuminance ranged between 3.9 and 4.7 klux.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** No conclusions were made by the study authors.

Good Laboratory Practice and Quality Assurance Unit statements were included in the report indicating compliance to EPA Good Laboratory Practices Regulations (40 CFR Part 160).

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:**

A. **Test Procedure:** The test procedure and the report were generally in accordance with the SEP and Subdivision J guidelines, except for the following deviations:

Three-day old cultures were used to initiate the test. Six to eight-day old cultures are recommended.

The NOEC was not reached in the exposure solutions.

B. **Statistical Analysis:** The reviewer used EPA's Toxanal program to determine the EC_{50} (using mean measured concentrations). The NOEC was verified using ANOVA coupled with Dunnett's test. The reviewer obtained a slightly more conservative value for the EC_{50}. Using the moving average angle method, the EC_{50} and 95% C.I. were 0.41 mg ai/l and 0.34-0.51 mg ai/l, respectively. The results of Dunnett's test indicated that significant effects occurred at all test levels, Therefore, the NOEC could not be determined and the lowest-observed-effect concentration (LOEC) was 0.091 mg ai/l (see attached printouts).

C. **Discussion/Results:** This study is scientifically sound but does not meet the requirements for a Tier 2 aquatic plant growth and reproduction study. Based on mean measured concentrations, the 120-hour LOEC and EC_{50} for *S. capricornutum* exposed to RH-7592 were 0.09 and 0.41 mg ai/l, respectively.

D. **Adequacy of the Study:**

(1) **Classification:** Supplemental.

(2) **Rationale:** The NOEC was not determined.

(3) **Repairability:** No.

15. **COMPLETION OF ONE-LINER:** Yes, 11-30-92.

5

RIN 3477-95

EEB FENBUCONAZOLE REVIEW

Page____ is not included in this copy.

Pages 6 through 8 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.

V 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.

Selenastrum cell density

Summary Statistics and ANOVA

Transformation = None

Group	n	Mean	s.d.	cv%
Concentration (mg ai/l*)				
1 = control	6	289.5000	13.7804	4.8
2* 0.091	3	218.6667	3.7859	1.7
3* 0.18	3	221.3333	15.6950	7.1
4* 0.34	3	176.0000	27.8388	15.8
5* 0.68	3	94.0000	22.7156	24.2
6* 1.30	3	52.0000	1.0000	1.9

NOEC = ≤ 0.091 mg ai/l*

LOEC = 0.091 mg ai/l*

*) the mean for this group is significantly less than the control mean at alpha = 0.05 (1-sided) by a t - test with Bonferroni adjustment of alpha level

* - mean measured concentrations

Minumum detectable difference for
t-tests with Bonferroni adjustment = -24.709539
This difference corresponds to -8.54 percent of control

```
**************************************************
*                                                *
* Note - the above value for the minimum         *
* detectable difference is approximate as        *
* the sample sizes are not the same for all of   *
* the groups.                                    *
*                                                *
**************************************************
```

Between groups sum of squares = 150128.309524 with 5 degrees of freedom.

Error mean square = 270.322222 with 15 degrees of freedom.

Bartlett's test p-value for equality of variances = .020

MOSSLER RH-7592 SELENASTRUM CAPRICORNUTUM 11-30-92

****

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
1.3	100	81	81	0
.68	100	68	68	0
.34	100	40	40	0
.18	100	24	24	0
.091	100	24	24	0

BECAUSE THE NUMBER OF ORGANISMS USED WAS SO LARGE, THE 95 PERCENT CONFIDENCE INTERVALS CALCULATED FROM THE BINOMIAL PROBABILITY ARE UNRELIABLE. USE THE INTERVALS CALCULATED BY THE OTHER TESTS.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS .4344233

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
4	5.292434E-02	.4118839	.3364052	.5142363

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
3	.287498	2.713061	4.322112E-02

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

SLOPE = 1.513602

95 PERCENT CONFIDENCE LIMITS = .7020262 AND 2.325178

LC50 = .3859899

95 PERCENT CONFIDENCE LIMITS = .2254994 AND .7058533

LC10 = 5.591368E-02

95 PERCENT CONFIDENCE LIMITS = 5.893845E-03 AND .1191838

****

DATABASE ENTRY FORM
FOR ACUTE OR CHRONIC TOXICITY STUDIES

1. **Chemical** RH-7592 **Shaughnessy** ~~129000~~ 129011

2. **Common Name Of Organism Tested** green algae

3. **Scientific Name** Selenastrum capricornutum

4. **Age Of Organisms** 3-days

5. **Guideline No.** 123-2

6. **Type Of Dosing Method Or Study (Circle One)**

   1. Oral 2. Dietary 3. Reproduction (4. Static)
   5. Static Renewal 6. Flowthrough 7. Acute Contact
   8. Other _____

7. **% AI Of Test Substance** 96.7

8. **Study Duration (Hrs Or Days)** 120 hr

9. **Dose Type (Circle One)** A. LD50 B. LC50 (C. EC50) D. MATC

10. **Toxicity Level** A. mg/kg B. ppm (C. mg/l)* D. µg/l E. ng/l
    F. µg/bee G. Other *ai

11. **95% C.L.s** 0.34-0.51 mg ai/l EC50 = 0.41 mg ai/l

12. **Curve Slope** n/a

13. **NOEL** could not be determined

14. **Study Date (YEAR)** 1991

15. **Study Review Date (YEAR)** 1992

16. **Category (Circle One)** CORE (SUPPLEMENTAL) INVALID

17. **MRID Or Accession Number** 418750-09

18. **Laboratory** Analytical Bio-Chemistry Laboratories

19. **Reviewer** M. Mossler

20. **For Reproductive Studies (avian or aquatic) Indicate Which Parameter Affected At What Toxicity Level.**

    Eggs Laid _____ % Cracked _____ % Viable _____
    % Live Embryos _____ % Eggs hatched _____ 14D Survivors _____
    Growth Effected at _____ Other Effects _____