

US EPA ARCHIVE DOCUMENT

DP Barcode : D183291
 PC Code No : 060101
 EEB Out : 3/19/93

To: Barbara Briscoe
 Product Manager 51
 Special Review and Reregistration Division (H7508W)

From: Douglas J. Urban, Acting Chief
 Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 060101-000618
 Chemical Name : Thiabendazole
 Type Product :
 Product Name :
 Company Name : Merck & Co.
 Purpose : Review acute fish test.

Action Code: 603
 Reviewer: Greg Susanke

Date Due: 02/04/93

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)			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)	424777-01	Y	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



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 18 1993

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Review of data submission for Thiabendazole
FROM: Anthony F. Maciorowski, Chief *Anthony F. Maciorowski*
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)
TO: Barbara Briscoe, Product Manager 51
Franklin Rubis, Team Reviewer
Special Review and Reregistration Division (H7508W)

The Freshwater Toxicity Study with Bluegill, MRID No. 424777-01 satisfies guideline data requirement 72-1(a).



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

J

DATA EVALUATION RECORD

- 1. **CHEMICAL:** Thiabendazole.
Shaughnessey No. 060101.
- 2. **TEST MATERIAL:** Thiabendazole; I.D. No. L-585216-000S159;
Lot No. PRM-295; 98.5% active ingredient; a white powder.
- 3. **STUDY TYPE:** 72-1. Freshwater Fish Static Acute Toxicity
Test. Species Tested: Bluegill Sunfish (*Lepomis
macrochirus*).
- 4. **CITATION:** Holmes, C.M., J.P. Swigert, and G.J. Smith.
1992. Thiabendazole: A 96-Hour Static Acute Toxicity Test
with the Bluegill *Lepomis macrochirus*. Project No. 105A-
118A. Prepared by Wildlife International Ltd., Easton, MD.
Submitted by Merck Research Laboratories, Three Bridges, NJ.
EPA MRID No. 424777-01.

5. **REVIEWED BY:**

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

Signature: *Louis M Rifici*
Date: 3/11/93

6. **APPROVED BY:**

Pim Kosalwat, Ph.D.
Senior Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: *P. Kosalwat*
Date: 3/11/93

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

Signature: *Henry T. Craven* 3/18/93
Date: *Henry T. Craven* 3/18/93

7. **CONCLUSIONS:** This study is scientifically sound and meets
the guideline requirements for an acute toxicity test using
bluegill sunfish. The 96-hour LC₅₀ value was 19 mg a.i./l
mean measured concentration. Therefore, thiabendazole is
classified as slightly toxic to bluegill sunfish. The NOEC
was 5.4 mg a.i./l.

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

9. **BACKGROUND:**

3

10. DISCUSSION OF INDIVIDUAL TESTS: N/A.**11. MATERIALS AND METHODS:**

- A. **Test Animals:** Juvenile bluegill sunfish (*Lepomis macrochirus*) from the same year class were obtained from a commercial supplier in Middletown, DE. The fish were held in the laboratory for at least 14 days prior to test initiation and were acclimated to the test conditions for approximately 50 hours. During holding, the fish were fed a commercially-available flaked food and frozen brine shrimp nauplii until 50 hours before the test. The temperature during the 14-day period immediately preceding the acclimation period was 18.4-22.6°C. The holding water had a pH of 8.3 to 8.5, a conductivity of 330-340 $\mu\text{mhos/cm}$, an alkalinity of 190 mg/l as CaCO_3 , and a hardness of 140-144 mg/l as CaCO_3 .

Mean weight and length of 10 control fish were 0.47 (0.22-0.62) g and 27 (24-32) mm.

- B. **Test System:** The test chambers were Teflon[®]-lined, 25-l polyethylene aquaria filled with 20 l of test solution. The solution depth was approximately 24-25 cm. The aquaria were indiscriminately positioned in a temperature-controlled water bath (22 \pm 1°C). The chamber was maintained on a 16-hour light photoperiod with 30-minute dawn and dusk simulations. Light intensity was 280 lux at the solution surface.

Medium-hard well water, obtained on-site, was aerated and filtered before use as dilution water. During the four-week period immediately prior to test initiation, the water had a hardness of 136-168 mg/l as CaCO_3 , an alkalinity of 184-192 mg/l as CaCO_3 , a conductivity of 330-370 $\mu\text{mhos/cm}$, and a pH of 8.0-8.3.

A stock solution (0.051 g a.i./ml) was prepared by dissolving the test material in dimethylformamide (DMF). The test solutions were prepared by mixing aliquots of the stock with well water.

- C. **Dosage:** Ninety-six-hour static test. Based on a preliminary study, five nominal concentrations (3.3, 5.4, 9.0, 15, and 25 mg a.i./l), a dilution water control, and a solvent control were tested. The solvent concentration in all treatment groups and the solvent control group was 0.5 ml/l.

- D. **Design:** Bluegill were impartially removed from holding tanks in groups of two and equally distributed to each aquarium, two aquaria per concentration, for a total of 20 fish per concentration. Biomass loading rate was 0.24 g/l. The fish were not fed during the test. Observations of mortality and sublethal responses were made at 4, 24, 48, 72 and 96 hours.

The dissolved oxygen concentration and pH were measured in alternating replicates of each treatment and the controls every 24 hours. The temperature of one control aquarium was monitored continuously and each replicate aquarium was measured at the beginning and end of the test. Dilution water hardness, alkalinity, and conductivity were measured at test initiation.

Test solution samples were collected daily for analysis and determination of mean measured concentrations. The concentration of thiabendazole in solution was determined using fluorescence detection.

- E. **Statistics:** The LC_{50} values and 95% confidence intervals were calculated using the computer program developed by Stephan (binomial method).

12. **REPORTED RESULTS:** The mean measured concentrations were 3.2, 5.4, 9.5, 16, and 26 mg a.i./l (Table 1, attached).

No mortality or treatment-related effects were observed in the dilution water control or the 5.4 mg a.i./l test concentration. In both the solvent control and the 3.2 mg a.i./l treatment groups, one of the twenty fish appeared lethargic and discolored by test termination. Since all other fish in those groups appeared healthy and normal and there were no clinical signs of toxicity in the 5.4 mg a.i./l treatment group, the effects noted at 3.2 mg a.i./l were not considered to be treatment related.

Dissolved oxygen ranged from 6.3 to 8.4 mg/l. The pH values ranged from 8.1 to 8.6. The temperature was 21.1-22.2°C.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:**

The 96-hour LC_{50} value was 19 mg a.i./l with a 95% confidence interval of 16-26 mg a.i./l mean measured concentration. The no mortality was 9.5 mg a.i./l.

Quality Assurance and Good Laboratory Practice statements were included in the report, indicating that the study was conducted in accordance with USEPA Good Laboratory Practice Standards set forth in 40 CFR Part 160. However, the

5

screening of contaminants in the dilution water was not conducted under GLP standards and the test substance characterization was the responsibility of the sponsor. The dates and types of quality assurance audits performed were presented.

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

A. Test Procedure: The test procedures were generally in accordance with the SEP, except for the following:

The fish were acclimated to the test conditions for approximately 50 hours. The recommended acclimation period for bluegill is at least two weeks.

The report states that the hardness, alkalinity, and conductivity of the dilution water were measured at test initiation. The results were not reported.

The period between test solution preparation and the initiation of the test was not stated in the report. Tests should be initiated within 30 minutes of solution preparation.

B. Statistical Analysis: The reviewer used EPA's Toxanal program to calculate the 96-hour LC_{50} and 95% confidence interval and obtained the same results (see attached printout). The no-observed-effect concentration (NOEC) was 5.4 mg a.i./l.

C. Discussion/Results: This study is scientifically sound and meets the guideline requirements for an acute toxicity test using bluegill sunfish. The 96-hour LC_{50} value was 19 mg a.i./l mean measured concentration. Therefore, thiabendazole is classified as slightly toxic to bluegill sunfish. The NOEC was 5.4 mg a.i./l.

D. Adequacy of the Study:

- (1) **Classification:** Core.
- (2) **Rationale:** N/A.
- (3) **Repairability:** N/A.

15. COMPLETION OF ONE-LINER FOR STUDY: Yes, 03-05-93.

Page ___ is not included in this copy.

Pages 7 through 9 are not included in this copy.

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.

RIFICI THIABENDAZOLE BLUEGILL SUNFISH 03-05-93

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
26	20	20	100	9.536742E-05
16	20	3	15	.1288414
9.5	20	0	0	9.536742E-05
5.4	20	0	0	9.536742E-05
3.2	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 16 AND 26 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 18.9756

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.
