3/21/94

MRID No. 429779-02

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# DATA EVALUATION RECORD

1. **CHEMICAL:** MB 46030 (Fipronil).
Shaughnessey No. 129121.

2. **TEST MATERIAL:** M&B 46030; Lot No. PGS963; 100% active ingredient; an off-white powder.

3. **STUDY TYPE:** 72-1. Freshwater Fish Acute Flow-Through Toxicity Test. Species Tested: Rainbow Trout (*Oncorhynchus mykiss*).

4. **CITATION:** Ward, G.S. 1991. M&B 46030: Acute Toxicity to Rainbow Trout, *Oncorhynchus mykiss*, Under Flow-Through Test Conditions. Laboratory Project No. J9005012a. Prepared by Toxikon Environmental Sciences, Jupiter, FL. Submitted by Rhone-Poulenc Ag Company, Research Triangle Park, NC. EPA MRID No. 429779-02.

5. **REVIEWED BY:**

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

**Signature:** Mark A. Mossler
**Date:** 1/13/94

6. **APPROVED BY:**

Rosemary Graham Mora, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

**Signature:** Rosemary Graham Mora
**Date:** 1/13/94

James J. Goodyear, Ph.D.
Project Officer, EEB/EFED
USEPA

**Signature:** Goodyear Ann Stavola
**Date:** 3 28 94

2/16/94
3/10/94

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for a flow-through acute toxicity test using rainbow trout. Based on mean measured concentrations, the 96-hour $LC_{50}$ of 246 µg ai/l classifies MB 46030 as highly toxic to rainbow trout. The NOEC was 34 µg ai/l.

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

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Juvenile rainbow trout (*Oncorhynchus mykiss*) were obtained from a commercial supplier in New Hampshire. The fish were maintained in test dilution water for 16 days prior to test initiation. The temperature during the two days prior to test initiation was 13.9-15.0°C. Commercial feed and newly hatched brine shrimp were offered daily during holding. The fish were not fed for 48 hours prior to test initiation and no mortality was observed in the population during this period. Mean wet weight and standard length of the fish were 0.98 (0.43-1.42) g and 36 (32-40) mm, respectively.

B. **Test System:** A proportional diluter was used to deliver the solutions to the test vessels. The test chambers were 24-l glass tanks containing 15 l of test solution. The test solution depth was 13 cm. The number of volume replacements was approximately 8.5 per day.

The test chambers were randomly positioned in a water bath under a 16-hour light photoperiod with a light intensity of 367-508 lux. Fifteen-minute dawn and dusk simulations were used.

The test dilution water was carbon-treated city water. The water was vigorously aerated prior to use. During the test, the hardness was 68-84 mg/l as $CaCO_3$ and the alkalinity was 16-17 mg/l as $CaCO_3$. The specific conductivity was 342-361 µmhos/cm.

A stock solution of 30 mg active ingredient (ai)/ml was prepared in dimethylformamide (DMF). Approximately 0.981 mg of test material was pumped into the chemical mixing chamber with each diluter cycle (3.27 l of dilution water) providing a nominal concentration of 300 µg ai/l. This solution was proportionally diluted to provide the remaining nominal treatment solutions.

C. **Dosage:** Ninety-six-hour flow-through test. Based on a preliminary test, five nominal concentrations (39, 65, 108, 180, and 300 µg ai/l) were selected for testing. A dilution water and solvent (0.01 ml DMF/l) control were also prepared.

D. **Design:** Twenty trout were impartially distributed (by twos) to each aquarium. One aquarium was used per treatment or control. Fish were not fed during the



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study. Observations of mortality and sublethal responses were made every 24 hours. Dead fish were removed from the containers. The temperature was measured hourly using a data logger. The temperature of the water bath was monitored with a minimum/maximum thermometer. The dissolved oxygen concentration and pH were measured in all test solutions (containing surviving fish) daily.

The concentration of test material in samples collected at test initiation and termination was measured using gas chromatography with electron capture detection.

E. **Statistics:** The 72- and 96-hour median lethal concentration ($LC_{50}$) and associated 95% confidence interval were calculated using a computer program which employed multiple analysis methods (i.e., moving average angle, probit analysis, and binomial probability).

12. **REPORTED RESULTS:** The mean measured concentrations were 33.8, 59.1, 87.6, 160, and 266 µg ai/l (Table 1, attached) and ranged between 81 and 91% of nominal.

Responses of the fish and mortalities are presented in Table 2 (attached). The 96-hour $LC_{50}$, based on mean measured concentrations, was 248 µg ai/l (95% C.I.= 160 µg ai/l - ∞) using binomial probability. The slope of the probit curve was 5.2. The no-observed-effect concentration (NOEC) was 33.8 µg ai/l, based on the lack of mortality or sublethal responses at this level.

During the test, dissolved oxygen concentration remained at or above 77% of saturation and the pH values ranged from 6.8 to 7.7. Based on the results of the hourly monitoring, the temperature was 10.8-12.3°C.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The author presented no conclusions.

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 under FIFRA.

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 biomass loading rate was not reported.

The dilution water was dechlorinated city water. Use of this type water is discouraged; however, since no mortality or sublethal effects were noted in the controls, the use of this water probably did not influence the results of the study.

B. **Statistical Analysis:** The reviewer used EPA's Toxanal program to calculate the 96-hour $LC_{50}$ value and obtained similar results (see attached printout). Since the results of the probit analysis were slightly more conservative, they will be reported. Based on mean measured concentrations, the 96-hour $LC_{50}$ for rainbow trout exposed to MB 46030 was 246 µg ai/l (95% C.I.= 205-342 µg ai/l). The slope of the probit curve (5.2) was the same as the author's.

C. **Discussion/Results:** The author stated that all treatment solutions contained the same amount of solvent (10 µl DMF/l). However, the reviewer does not know how this is possible when a proportional diluter was used to deliver the treatment solutions. Future reports should clarify this issue.

Although the biomass loading rate was not reported, the reviewer determined that this value was 0.153 g/l/day, which is within guideline specifications.

This study is scientifically sound and meets the guideline requirements for a flow-through acute toxicity test using rainbow trout. Based on mean measured concentrations, the 96-hour $LC_{50}$ of 246 µg ai/l classifies MB 46030 as highly toxic to rainbow trout. The NOEC was 34 µg ai/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, 1-10-94.



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Fipronil Review

Page _____ is not included in this copy.

Pages 5 through 7 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.

MOSSLER MB 46030 ONCORHYNCHUS MYKISS 1-10-94

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| CONC. | NUMBER EXPOSED | NUMBER DEAD | PERCENT DEAD | BINOMIAL PROB.(PERCENT) |
|---|---|---|---|---|
| 266 | 20 | 11 | 55 | 41.19014 |
| 160 | 20 | 4 | 20 | .5908966 |
| 87.6 | 20 | 0 | 0 | 9.536742E-05 |
| 59.1 | 20 | 0 | 0 | 9.536742E-05 |
| 33.8 | 20 | 0 | 0 | 9.536742E-05 |

THE BINOMIAL TEST SHOWS THAT 0 AND +INFINITY 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 248.2996

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

| SPAN | G | LC50 | 95 PERCENT CONFIDENCE LIMITS | |
|---|---|---|---|---|
| 1 | .7542481 | 248.2996 | 198.6345 | 968.0013 |

RESULTS CALCULATED USING THE PROBIT METHOD

| ITERATIONS | G | H | GOODNESS OF FIT PROBABILITY |
|---|---|---|---|
| 10 | .2821658 | 1 | .9357709 |

SLOPE = 5.231165

95 PERCENT CONFIDENCE LIMITS = 2.452408 AND 8.009922

LC50 = 245.6389

95 PERCENT CONFIDENCE LIMITS = 205.2173 AND 342.5231

LC10 = 140.4498

95 PERCENT CONFIDENCE LIMITS = 86.33251 AND 171.5213

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