11-12-92

MRID No. 88948

DATA EVALUATION RECORD

1. **CHEMICAL:** Cypermethrin.
Shaughnessey Number: 109702.

2. **TEST MATERIAL:** Cypermethrin formulation GFU 070; emulsifiable concentrate; 25.1% active ingredient; prepared from technical material batch P22; a brown liquid.

3. **STUDY TYPE:** Freshwater Fish Flow-through Acute Toxicity Test. Species Tested: Lepomis macrochirus.

4. **CITATION:** Hill, R.W. 1981. Cypermethrin: Determination of the Acute Toxicity of Formulation GFU 070 to Bluegill (Lepomis macrochirus). Prepared and submitted by Imperial Chemical Industries PLC, Brixham, Devon, United Kingdom. Brixham Study Number: G244/C / Brixham Report Number: BL/B/2099. EPA MRID No. 88948.

5. **REVIEWED BY:**

Kimberly Rhodes
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Kimberly Rhodes
Date: March 28, 1991

Renee Lamb 10/8/92

6. **APPROVED BY:**

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

Signature: P. Kosalwat
Date: 3/28/91

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

Signature: Drew Stavola 10/9/92
Date: Henry T. Craven 11/12/92

7. **CONCLUSIONS:** This study is not scientifically sound and does not fulfill the guideline requirements for an acute flow-through toxicity test for freshwater fish since a precise LC50 and NOEC could not be determined. Excessive mortality (>5%) occurred in Test Series I and random mortality occurred in Test Series II indicating that the test organisms were in poor physical condition.

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

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Bluegill (Lepomis macrochirus) were obtained from a commercial supplier in Missouri. The fish were maintained at the testing facility for at least 18 days prior to testing. The fish were acclimated to the test temperature for at least five days. Prior to test initiation, the fish were transferred to the test vessels and acclimated to testing conditions for two days. The bluegill used in this study ranged in weight from 0.13 to 0.71 grams (g) with a mean weight of 0.33 g. The bluegill ranged in length from 21 to 32 millimeters (mm) with a mean length of 25.0 mm.

B. **Test System:** The test was conducted in a continuous diluter system utilizing a series of peristaltic pumps which delivered the test solutions to 20-L glass vessels at a rate of 200 mL/minute. A 95% exchange of the test solutions was calculated to occur within 4.5 hours. The test temperature was maintained at 22 ± 1°C. The dilution water was supplied from a 20,000-gallon reservoir.

C. **Dosage:** 96-hour flow-through acute test. The nominal test concentrations were as follows: Series I - 10, 13.5, 18, 24, 32, 42, and 56 µg ~~a.i.~~/L. Series II - 1.0, 1.35, 1.8, 2.4, 3.2, 4.2, 5.6, and 7.5 µg ~~a.i.~~/L. as GFU 070 as lb/gal

D. **Design:** Two separate definitive tests were conducted. Test Series I consisted of seven nominal GFU 070 concentrations and a control. Test Series II consisted of eight nominal GFU concentrations and a control. Twenty juvenile bluegill were placed within each GFU 070 test concentration and the control. Observations for mortality and sublethal symptoms were made at least once every 24 hours during the 96-hour test period.

Water quality measurements (pH, dissolved oxygen concentration, and temperature) were conducted at test initiation and every 24 hours of the exposure on each test concentration containing surviving fish. The water hardness of the dilution water was measured every 24 hours of the exposure. Analytical determination of

GFU 070 was performed every 24 hours of the exposure on each test concentration containing surviving fish using gas chromatography.

E. **Statistics:** Statistical analysis of the concentration vs. effect data (mortality) was obtained by combining the data for Test Series I and II and employing a computerized LC50 program identified as 150, 150 - Toxic, Probit Analysis.

12. **REPORTED RESULTS:** Test Series I mean measured GFU 070 concentrations during the exposure were 7.9, 11.0, 15.4, 20.8, 27.4, 39.7, and 48.9 µg/L (Table 8, attached). Test Series II mean measured GFU 070 concentrations during the exposure were 0.50, 0.72, 1.04, 1.40, 1.91, 2.62, 3.52, and 5.03 µg/L (Table 8, attached). The mean measured test concentrations for Series I and II ranged from 79.0 to 94.5% and 50.0 to 67.1% of the nominal concentrations, respectively.

Mortality and behavioral observations during the 96-hour flow-through toxicity test are shown in Tables 1 and 6 (attached). Random mortalities occurred in all exposure concentrations and controls during the 96 hour exposure. The state of health of the fish may have been lower than normal. The general toxic symptoms noted in this study were quiescence, darkening, loss of balance, and an increase in respiration rate. The no-observed-effect concentration (NOEC) was determined to be <0.5 µg/L, the lowest mean measured concentration tested.

The 24-, 48-, 72-, and 96-hour LC50 values and 95% confidence intervals, based on mean measured GFU 070 concentrations, were determined to be 7.6 (2.76-20.67), 5.2 (2.28-11.91), 4.6 (2.80-8.30), and 4.1 (2.28-8.72) µg/L, respectively.

During Test Series I, the temperature ranged from 21.1 to 22.4°C, dissolved oxygen concentration ranged from 7.8 to 8.4 mg/L, pH ranged from 7.7 to 8.0, and total hardness of the dilution water ranged from 35 to 49 mg/L as $CaCO_3$. During Test Series II, the temperature ranged from 22.2 to 23.1°C, dissolved oxygen concentration ranged from 8.0 to 8.8 mg/L, pH ranged from 7.5 to 7.9, and total hardness of the dilution water ranged from 32 to 36 mg/L as $CaCO_3$.

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

A GLP compliance statement was included in the report and the study was audited by ICI's QA unit on numerous occasions. A statement of quality assurance was included in the report, indicating that the study was conducted in accordance with U.S. EPA Good Laboratory Practice Standards.

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

A. **Test Procedure:** The test procedures were in accordance with protocols recommended by the guidelines, but deviated from the SEP as follows:

This is not critical unless we need to determine the toxicity of the inerts alone, and NOT the whole product. GS 10/5/92

o The SEP states that the test design for a formulated product study should include a control where organisms are exposed to just the inert ingredients. During this test, inert ingredients were not tested as a control.

o The SEP states that flow rates should be five to ten volume additions per day. During this study a flow rate of 288 liters per day into each 20 liter test vessel was used which provided a flow rate of approximately 14.4 volume additions per day.

This is not critical as concentrations were measured. GS 10/5/92

o The ASTM states that measured concentration of test material in any chamber should be no more than 30% higher or lower than the nominal concentration. If the concentration of the test chamber is too low, the stock solutions may have been prepared incorrectly or volatility or degradation of the test material may have occurred. During Test Series II, all measured concentrations were considerably low. The mean measured concentrations ranged from 50.0% to 67.1% of the nominal concentrations.

o The procedures used to prepare toxicant stock solutions were not thoroughly described as required by the SEP.

o The report did not provide complete descriptions of holding conditions such as the percent of mortality 48 hours prior to test initiation and feeding prior to and during testing.

o The SEP recommends that fish be acclimated to study conditions for at least two weeks prior to testing. During this study, the fish were acclimated to the test temperature for a minimum of five days and were further transferred to test vessels and acclimated to test conditions for only two days prior to test initiation.

o The report did not state whether the bluegill were randomly assigned to each test vessel as required by the SEP.

o The report did not fully describe the source of the dilution water and a description of any pretreatment.

o The SEP states that temperature should be measured continuously (hourly) in at least one test vessel during the entire study period. If the temperature is controlled by a water bath, measurements can be recorded every six hours. During Test Series I and II, the temperature was measured and recorded every 24 hours for each test concentration containing surviving fish.

o The SEP recommends a 16-hour light and an 8-hour dark photoperiod with 15- to 30-minute transition periods between light and dark. The photoperiod of this test was not reported.

o NOEC could not be determined due to adverse effects at all treatment levels.

o The ASTM states that one treatment other than the control should have killed or affected less than 37% of the organisms exposed to it, and one treatment should have killed or affected more than 63% of the organisms. During Test Series I, ≥95% mortality occurred. During Test Series II, ≤50% mortality occurred. Therefore, a precise LC50 value could not be determined.

o The SEP states that a test is not acceptable if more than 5% of the control organisms die during a flow-through test. During Series I, 10% mortality occurred in the control.

B. **Statistical Analysis:** The reviewer could not obtain an LC50 from Test Series I or II since ≥95% mortality occurred in Test Series I and ≤50% mortality occurred in Test Series II. The NOEC could not be determined due to adverse effects at all treatment levels.

C. **Discussion/Results:** This study is not scientifically sound and does not fulfill the guideline requirements for a flow-through acute toxicity test for freshwater fish since a precise LC50 value could not be determined. Test Series I and II were not performed concurrently. Therefore, it is unacceptable to combine the study results in order to calculate a precise LC50 value. Furthermore, an NOEC could not be determined due to adverse effects at all treatment levels.

The author states that the state of health of the fish may have been lower than normal. The report, however, did not provide the percent of mortality 48 hours prior to test initiation. Test Series I had excessive control mortality (i.e., >5%) and Test Series II consisted of random mortalities throughout the exposure concentrations. Therefore, it appears that the test organisms were in poor physical condition during the tests.

The ASTM states that measured concentration of test material in any chamber should be no more than 30% higher or lower than the nominal concentration. If the concentration of the test chamber is too low, the stock solutions may have been prepared incorrectly or volatility or degradation of the test material may have occurred. During Test Series II, all measured concentrations were considerably low. The mean measured concentrations ranged from 50.0% to 67.1% of the nominal concentrations. If the cause is degradation, the test organisms are probably being exposed to significant concentrations of degradation products and measurements of the degradation product(s) may be desirable. Furthermore, the test design for a formulated product study should include a control where organisms are exposed to just the inert ingredients.

D. **Adequacy of the Study:**

(1) Classification: Invalid.

(2) Rationale: See Section 14.A and 14.C.

(3) Repairability: No.

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, 03-04-91.

Cypermethrin Review

Page _____ is not included in this copy.

Pages 9 through 14 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.

X 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.