11-12-92

MRID No. 88947

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: Salmo gairdneri.

4. **CITATION:** Hill, R.W. 1981. Cypermethrin: Determination of the Acute Toxicity of Formulation GFU 070 to Rainbow trout (Salmo gairdneri). Prepared and submitted by Imperial Chemical Industries PLC, Brixham, Devon, United Kingdom. Brixham Study Number: G 244/B / Brixham Report Number: BL/B/2093. EPA MRID No. 88947.

5. **REVIEWED BY:**

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

Signature: Kimberly Rhodes
Date: March 20, 1991
Renee Lam 10/18/92

6. **APPROVED BY:**

Pim Kosalwat, Ph.D.
Senior Scientist
KBN Engineering and
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Signature: P. Kosalwat
Date: 3/28/91

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

Signature: Arm Stavola 10/19/92
Date: Henry T. Craven 11/12/92

7. **CONCLUSIONS:** This study appears scientifically sound but ~~does not~~ fulfills the guideline requirements for an acute flow-through toxicity test for freshwater fish only for GFU 070. Several discrepancies were observed in the study report. The 96-hour LC50, based upon mean measured concentrations, of GFU 070 to rainbow trout (Salmo gairdneri) was 13.0 µg/L. Therefore, GFU 070 is classified as very highly toxic to rainbow trout. The NOEC could not be determined due to adverse effects at all treatment levels.

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

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Rainbow trout (Salmo gairdneri) were obtained from a commercial supplier in Zeals, Wiltshire. The fish were maintained at the testing facility for at least 6 weeks prior to testing. The fish were acclimated in the test vessels to test conditions for a minimum of 2 days. The rainbow trout used in this study ranged in weight from 2.00 to 5.40 grams (g) with a mean weight of 3.38 g. The rainbow trout ranged in length from 51 to 74 millimeters (mm) with a mean length of 61.2 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. The test solutions were transported to a glass mixing chamber where a magnetic stirrer was used to ensure mixing before entering the test vessels. A 95% exchange of the test solutions was calculated to occur within 4.5 hours. The test temperature was maintained at 12 ± 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 1.8, 3.2, 5.6, 10, 18, 32, and 56 µg ~~a.i.~~/L as GFU 070. QS 10/9/92

D. **Design:** Twenty juvenile rainbow trout were placed within each of seven nominal GFU 070 test concentrations (See Section 11.C) 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 were conducted throughout the 96-hour test period for pH, dissolved oxygen concentration, temperature, water hardness, and conductivity. Analytical determination of GFU 070 was performed daily on the control and each GFU 070 concentration using gas chromatography.

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

12. **REPORTED RESULTS:** The mean measured GFU 070 concentrations during the exposure were 1.15, 2.24, 4.75, 7.69, 18.0, 34.9, and 64.7 µg/L (Table 3, attached). The mean measured test concentrations ranged from 63.9 to 115.4% of the nominal concentrations.

Mortality and behavioral observations during the 96-hour flow-through toxicity test are shown in Tables 1 and 2 (attached). There were no mortalities observed in the 1.15, 2.24, and 4.75 µg/L mean measured concentrations. The general toxic symptoms noted in this study were loss of equilibrium, quiescence, surfacing, darkening in color, and coughing. The no-observed-effect concentration (NOEC) was determined to be <1.15 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 38 (31.7-45.4), 20 (16.6-23.2), 15 (12.7-17.6), and 13 (10.9-15.3) µg/L, respectively.

During the study, the temperature ranged from 11.5 to 12.4°C, dissolved oxygen concentration ranged from 9.9 to 11.4 mg/L, and pH ranged from 7.1 to 7.9. The total hardness and conductivity of the dilution water ranged from 25 to 28 mg/L as $CaCO_3$ and 65 to 70 microsiemens/cm, respectively.

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 three 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, instead of the whole product

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. QS 10/9/96

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. QS 10/9/96

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. This report states that the rainbow trout were acclimated for a minimum of two days. The actual acclimation time was not reported.

o The report did not state whether the rainbow trout 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. The report did not mention how the temperature was regulated and how often the temperature measurements were recorded.

o The SEP states that the dissolved oxygen concentration must be measured at the beginning of the test and every 48 hours thereafter to the end of the test. Measurements should be taken from the control, and the high, medium, and low concentrations as long as animals are present at those levels. The report did not mention how often the dissolved oxygen concentrations were measured.

o Loading was not given. AS 10/9/92.

o The SEP states that the pH should be measured at the beginning and end of the test in the control and the high, medium, and low toxicant concentration. The report did not mention how often the pH was measured.

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. This wasn't a requirement for this type of study AS 10/9/92

B. **Statistical Analysis:** The reviewer used EPA's Toxanal computer program to calculate the LC50 values. These calculations are attached. The 96-hour LC50 value, based on mean measured concentrations, was determined to be 13.0 µg/L with a 95% confidence interval of 10.7-15.5 µg/L which is similar to that reported by the author. The slope of the concentration-response curve was determined by probit analysis to be 7.4. The NOEC could not be determined due to adverse effects at all treatment levels.

C. **Discussion/Results:** This study is scientifically sound but does not fulfill the guideline requirements for a flow-through acute toxicity test for freshwater fish. The test design for a formulated product study should include a control where organisms are exposed to just the inert ingredients. Furthermore, the NOEC could not be determined due to adverse effects at all treatment levels. The report did not adequately describe the source of the dilution water and the time-intervals in which the water quality parameters were measured, however, the ranges reported were within the guideline requirements and there was no control mortality.

See my comments previous page AS 10/9/92.

The probit method provides a 96-hour LC50 value of 13.0 µg/L with a 95% confidence interval of 10.7-15.5 µg/L. Therefore, GFU 070 is classified as very highly toxic to rainbow trout (Salmo gairdneri).

D. **Adequacy of the Study:** QS 10/9/92

(1) **Classification:** Supplemental.

(2) **Rationale:** ~~Several discrepancies were observed as listed in Section 14.A.~~ ~~or~~ Labeled Product tested. However, the Study Satisfies the requirement for testing w/CFU 02

(3) **Repairability:** ~~Pending the registrant's responses on the above discrepancies.~~

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

Cypermethrin Review

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.

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.

96-Hour LC50
Cypermethrin

KIMBERLY RHODES CYPERMETHRIN SALMO GAIRDNERI 3-4-91

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
64.7	20	20	100	9.536742E-05
34.9	20	20	100	9.536742E-05
18	20	17	85	.1288414
7.69	20	1	5	2.002716E-03
4.75	20	0	0	9.536742E-05
2.24	20	0	0	9.536742E-05
1.15	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 7.69 AND 18 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 12.66192

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
5	5.135019E-02	13.22192	10.49127	16.8011

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
7	.1559574	1	.9999894

SLOPE = 7.366907
95 PERCENT CONFIDENCE LIMITS = 4.457609 AND 10.2762

* LC50 = 12.96198
95 PERCENT CONFIDENCE LIMITS = (10.69062 AND 15.48327)

LC10 = 8.715229
95 PERCENT CONFIDENCE LIMITS = 6.103981 AND 10.58669