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AB-79-078

DATA EVALUATION RECORD

1. CHEMICAL: Acetochlor.
   Shaughnessey No: 121601.

2. TEST MATERIAL: MON 097; CP 55097 Technical; Acetochlor; lot # XHK-119; 91.3% Active Ingredient; a brown liquid.

3. STUDY TYPE: Freshwater Fish Static Acute Toxicity Test.
   Species Tested: Lepomis macrochirus.

4. CITATION: Griffen, J. and C.M. Thompson. 1979. Acute Toxicity of MON 097 (AB-79-078) to Bluegill Sunfish (Lepomis macrochirus). Static Acute Bioassay Report 24017. Conducted by Analytical Biochemistry Laboratories, Inc. (ABC), Columbia, Missouri. Submitted by Monsanto Chemical Company, St. Louis, Missouri. Monsanto Study No. AB-79-078.

5. REVIEWED BY:

   G. Scott Ward
   Manager
   Aquatic Toxicology Laboratory
   Toxikon Environmental Sciences

   Signature:

   Date:

6. APPROVED BY:

   Michael L. Whitten, M.S.
   Staff Toxicologist
   KBN Engineering and
   Applied Sciences, Inc.

   Signature:

   Date: Cynthia Martin 10.29.90

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

   Signature: Henry T. Craven

   Date: 10/30/90

7. CONCLUSIONS: The study is not scientifically sound and does not meet the guideline requirements.

8. RECOMMENDATIONS: N/A.

9. BACKGROUND:

10. DISCUSSION OF INDIVIDUAL TESTS: N/A.

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11. MATERIALS AND METHODS:

A. Test Animals: Bluegill sunfish used in the test were obtained from Osage Catfisheries, Inc. in Osage Beach, Missouri. Fish were held in culture tanks on a 16-hour day-light photoperiod and observed daily for 14 days prior to testing. Temperature in holding tanks was not mentioned. Bluegill had a mean weight of 0.41 g and a mean standard length of 26.7 mm. Fish were fed a standard commercial fish food daily until 48 hours prior to testing at which time feeding was discontinued.

B. Test System: The test system consisted of 40-liter glass vessels containing 30 liters of soft reconstituted water. The vessels were kept in a water bath at 22 ± 1|C. Test fish were acclimated to dilution water and test temperature without food 48 hours before testing. The photoperiod during the test period was not mentioned.

The dilution water used in the test was soft reconstituted water with the following characteristics: dissolved oxygen: 8.9 mg/L, pH 7.3, total hardness of 45 mg/L as $CaCO_3$; and total alkalinity of 35 mg/L as $CaCO_3$; conductivity was not mentioned.

C. Dosage: This was a 96-hour static, acute toxicity test.

D. Design: Based on a preliminary 48-hour range-finding test, nominal concentrations of the test substance (1.0, 1.8, 3.2, 5.6, 10 mg/L) were selected for the definitive study. Although the text of the report does not mention the use of any control, it is apparent from data in Appendix I that a solvent control (acetone at a concentration of 667 µL/L) was used. There was no untreated control. Each treatment vessel including the control contained 10 fish (treatments were not replicated). All treatments were observed for mortality and behavioral effects at the end of each 24-hour period. Mortality data and water quality parameters are presented in Table 3 (attached). The water quality parameters (temperature, dissolved oxygen, pH) were measured at 0, 48, and 96 hours of testing in the control and lowest concentration (1.0 mg/L). There were no measurements in the other concentrations during the test except in the high

concentration at 0 hour. Ammonia concentrations were measured at 0 hour and at 96 hours in the control and lowest concentration (ammonia was also measured in high concentration at 0 hour).

E. Statistics: LC50 values with their corresponding confidence intervals were calculated according to Litchfield and Wilcoxon (1949) or Stephan (1977).

12. REPORTED RESULTS: During the test the pH ranged from 7.1-7.5 while the temperature ranged from 22-25|C. Ammonia concentrations were higher at the end of the test, but below the toxic limit. Mortality during the test is presented in Table 3 (attached). After 24 hours, there was 100% mortality of bluegill at 5.6 and 10 mg/L; after 48 hours there was 100% mortality of fish at 1.8 and 3.2 mg/L and 20% mortality at 1.0 mg/L, the lowest concentration. After 96 hours of exposure there was no mortality in the solvent (acetone) control and 20% mortality at 1.0 mg/L. The 24-, 48-, and 96-hour LC50 values (based on nominal concentrations) were 2.7 mg/L (95% C.L. = 2.1-3.5 mg/L), 1.3 mg/L (95% C.L. = 1.0-1.7 mg/L) and 1.3 mg/L (95% C.L. = 1.0-1.7 mg/L), respectively.

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

No conclusions were presented by the authors.

The daily mortality rate of organisms was inspected prior to study initiation by the Quality Assurance Unit of ABC Laboratories. The data and records were also inspected once and the final report was inspected once. A Study Compliance Statement was included in the report, indicating that the study was conducted in compliance with Good Laboratory Practice Regulations.

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

A. Test Procedure: The test procedures were in accordance with protocols recommended by the SEP, except for the following deviations:

- Each designated treatment group was exposed to a concentration that is approximately 56 percent of the next highest concentration. The SEP recommends 60 percent of the next highest concentration.

- o A concurrent, untreated (dilution water only) control was not used.
- o The solvent concentration in the solvent control and the highest test concentration (667 µL/L) exceeded the maximum solvent concentration recommended in the SEP (500 µL/L).
- o The test temperature deviated from the 22 ± 1°C guideline recommendation by 2°C on day 2; no indication of the length of the deviation was reported.
- o Due to the mortality pattern, there was no NOEC and no slope for the concentration-response line.
- o Test solutions were aerated after 72 hours but the concentrations of the test substance were not confirmed by chemical analyses.
- o No photoperiod or light/dark transition period were reported.
- o Water quality measurements should have been taken from the control, high, medium, and low concentrations. In this study, measurements were not taken at initiation in the medium (3.2 mg/L) concentration.

B. Statistical Analysis: The reviewer recalculated the 96-hour LC50 using EEB's Toxanal computer program. The result (attached) was similar to that performed by the author.

C. Discussion/Results: The study is scientifically sound but deviates substantially from guideline requirements. Specifically, aeration was initiated at 48 hours in all aquaria, but test concentrations were not measured. Test solutions must be analyzed to determine the exact concentration of test material if the test solutions are aerated, since aeration may cause volatilization of the pesticide. Additionally, a dilution water control was not maintained. *

D. Adequacy of the Study:

(1) Classification: Invalid.

(2) **Rationale:** Deviations from SEP (see Sections 14.A and 14.C).

(3) **Repairability:** No.

15. **COMPLETION OF ONE-LINER:** Yes, June 11, 1990.

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ACETOCHLOR

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Pages _____ through _____ 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.

X FIFRA registration data.

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____ 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.

SCOTT WARD ACETOCHLOR LEPOMIS MACROCHIRUS 06-11-90

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
10	10	10	100	9.765625E-02
5.6	10	10	100	9.765625E-02
3.2	10	10	100	9.765625E-02
1.8	10	10	100	9.765625E-02
1	10	2	20	5.46875

THE BINOMIAL TEST SHOWS THAT 0 AND 1.8 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 1.203225

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.

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