DATA EVALUATION RECORD

1. Chemical: MON-7200 (Dithiopyr)

2. Test Material: 90.7 % a.i.
3,5,-Pyridine-dicarbothioic acid, 2-(diflouromethyl) -4-(2-methylpropyl)-6-(triflouromethyl)-S,S-dimethyl ester.

3. Study Type: Acute Toxicity Study of Mon-7200 to Daphnia magna

4. Study ID: MRID NO. 410015-14
Forbis, Alan D. 1988. The acute toxicity of Mon-7200 to Daphnia magna. Unpublished study by Analytical Biochemistry Laboratories, Inc. 7200 E. ABC Lane, Columbia, Missouri 65205.

5. Reviewed by: Cynthia Moulton
Biologist
EEB/EFED
Cynthia Moulton 3.5.90

6. Approved by: Norman Cook
Head Section II
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Norman J. Cook 3.5.90

7. Conclusion: The study is classified as invalid and does not satisfy guideline requirements. See reviewers discussion of the test procedure for the discrepancies of the study.

8. Recommendations: This study needs to be redone using an appropriate solvent (and a solvent control) to obtain an adequate dose response curve.

9. Background: Proposed registration of new chemical

10. Discussion of Individual Tests: N/A.

11. Materials and Methods:

a. Test Animals - First instar Daphnia magna from an in-house ABC Laboratories culture.

b. Test System - 250 ml beakers were used as test chambers, each with 200 ml of daphnid culture/test water. The vessels were kept at 20 + 2 C in a 16 hour daylight photoperiod. An initial range finding experiment was conducted using 10 Daphnia each in nominal concentrations of 0.01, 1.0, 5.0, and 10 mg/l. From the results of this study, five treatment concentrations plus a control in duplicate with ten Daphnia per beaker were used for the definitive bioassay.

The temperature, dissolved oxygen, and ph were measured in the control, and the low, middle, and high concentrations at 0 and 48 hours.

c. Dosing - Static bioassay using nominal concentrations, no solvents were used. Analysis of test levels was made at 0-hour and 48 hours; x ± s.d. recovery was 12 ± 0.89%.

d. Design - A control and five nominal concentrations (in duplicate) were used; 1.3, 2.2, 3.6, 6.0, and 10 mg/l. Mean measured values for these levels were: 0.17, 0.29, 0.45, 0.72 and 1.1 mg/l, respectively.

e. Statistics - The LC50 value was determined by transferring percent mortality into probit values.

12. Reported Results:

The 48-hour LC50 >1.1 mg/l for 90.7% ai. MON 7200 and first instar D. magna.

13. Study Authors Conclusion:

"The 24- and 48-hour LC50 values were both > 1.1 mg/l."

The study was conducted following the intent of the Good Laboratory Practice Regulations and the final report was reviewed by ABC Laboratories Quality Assurance Unit.

14. Reviewers Discussion and Interpretation of the Study:

a. Test Procedures - The following discrepancies in the study were noted:

- The recommended test temperature for Daphnia is 20 C. The temperature reported by study authors was 20 + 2 C (cited also in previous review 7-25-88).

- Temperature should be measured continuously (hourly) in at least one test vessel during the entire study period. If temperature is controlled by a waterbath, measurements can be recorded every six hours. In this study test vessels were kept in a "controlled area"; however, temperature was recorded only at 0 and 48 hours (cited also in previous review on 7-25-88).

- The percent recovery of the spiked samples was 96 + 4.0%, the percent recovery of the test samples was 12 + 0.89%. According to the ASTM Standard Practice for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians, " if measured concentrations of toxicant is more than 30% higher or lower than the concentration calculated from the composition of the stock solution and the calibration of the metering system, identification of the cause may provide useful information about the operation of the metering system or the properties of the toxicant". There was no explanation given in the study report as to the cause of the deviation of 84% between the spiked and test samples. However, since a solvent was not used in preparing the definitive test levels, but acetone was used on the spiked samples, we conclude this accounts for the percent recovery differences.

- The authors of the study conclude that the LC50 for MON 7200 to Daphnia magna is > 1.1 mg/l. However there was no mortality in 3 of 5 treatment levels and 10 % mortality in the 2 highest concentrations. A dose response curve can not be determined from these data. The study authors conclude that the LC50 is greater than its water solubility of 1.1 mg/l (as calculated by study authors; Monsanto specifies solubility as 0.7 mg/l), based on nominal concentrations. First, an LC50 value of > 1.1 mg/l is unacceptable because this estimate includes the moderately toxic to practically nontoxic range. Second, a solvent may have been used to dissolve appropriate amounts of the test substance, up to 10 mg/l, as established by the initial range finding experiment, to show a valid dose response. Previous studies involving MON 7200 reviewed on 7-25-88; Salmo gairdneri and Lepomis macrochirus acute static tests utilized the solvent dimethylformamide (DMF). Also the supplemental Daphnia magna study used Acetone as a solvent.

b. Statistical Analysis - Because the reviewer considers the study invalid, a statistical analysis was not performed on the data.

c. Discussion/ Results - The study was inconclusive and did not provide a valid LC50 value of MON 7200 on Daphnia magna.

d. Adequacy of Study

1) Classification: Invalid

2) Rationale: Major discrepancies (see reviewers discussion of test procedures) detract from the validity of the study.

3) Repairability: none

15. Completion of One-Liner:

February 26, 1990