3-5-90

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: Early Life Stage Toxicity of MON-7200 to Rainbow Trout (Salmo gairdneri) in a Flow-Through System

4. Study ID: MRID NO. 410015-15
McAllister, W.A. 1988. Early life stage toxicity of MON-7200 to rainbow trout (Salmo gairdneri) in a flow-through system. An unpublished study by Analytical Bio-Chemistry Laboratories, Inc. 7200 E. ABC Lane, Columbia, Missouri 65205.

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

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

7. Conclusion:The study is scientifically sound and meets the guideline requirements for a fish early life stage test. Based on significant adverse effects on survival and growth, the no observed effect concentration was 0.056 mg/l and the lowest observed effect concentration was 0.12 mg/l. The maximum allowable toxic concentration (MATC) of MON 7200 (90.7% a.i.) for rainbow trout was estimated to be >0.056 mg/l and <0.12 mg/l.

8. Recommendations: N/A

9. Background: Proposed registration of new chemical

10. Discussion of Individual Tests: N/A.

11. Materials and Methods:

a. Test Animals - Trout eggs used for the initiation of the definitive test were obtained from Mt. Lassen Trout Farm (U.S. D.I. disease free cert.) in Red Bluff, California. Unfertilized eggs were shipped by air freight under refrigerated conditions. Eggs were slowly acclimated from approx 6.5 C to 10 C, then thoroughly mixed. They were then rinsed with control water 4 times then covered again with water and allowed to water harden before distribution to the test system incubation cups.

b. Test System - A two-liter proportional diluter system described by Mount and Brungs (1967) with a Hamilton Model 420 Syringe dispenser, was used for the intermittent introduction of a dimethylformamide solution of MON7200 to four replicate test chambers per concentration. The test system dilution water was obtained from uncontaminated deep well water part of which was passed through a reverse osmosis system then blended back to a total hardness of 40 to 50 mg/l (as CaCO3) and a pH of approximately 8.0.

The inside dimensions of the glass test aquaria measured 15.6 x 30.7 cm with a water depth of 25 cm. This yields an approximate replicate chamber volume of 12 liter. Water was delivered to the replicated chambers at an average rate of 81.5 replicate/day, an amount sufficient to replace the replicate volume 6.8 times per day. The test aquaria was immersed in a water bath held at approximately 10 C and the light intensity at the surface was 147 +29.8 foot candles.

c. Dosing - The study included the following five concentrations; 0.06, 0.12, 0.23, 0.46, 0.96, plus a control and solvent control. The average measured concentration for each treatment group was 0.024, 0.056, 0.12, 0.20, 0.41, respectively. The solvent used in the study was DMF.

d. Design - The definitive study was initiated by distributing several impartially selected newly fertilized rainbow trout eggs at a time into successive incubator cups in each of the 4 replicate exposure aquaria (note: 30 eggs/cup; 120 eggs/concentration). In addition, 50 eggs were placed in each of the 4 control replicates. Egg mortality was recorded daily. After 11 days, 200 eggs were set aside for viability (fertility success). When hatching commenced, the number of eggs hatched in each incubation cup was recorded daily until hatching was completed. The 60 day post-hatch growth period began on study day 38 (study length = 98 days). On day 40, the number of fry per replicate was reduced to 15; on day 45 they were released into the growth chambers. Feeding began on day 49, initially the fry were fed live brine shrimp nauplii and ground salmon starter was added to the diet on day 57. On study day 74, standard length of the fry was determined by the photographic method of McKim and Benoit (1971).

At test termination, all surviving fish were sacrificed and measured for standard length, blotted, and weighed.

Water quality parameters of temperature, dissolved oxygen, conductivity, and pH were measured on days 0, 1, 7, and every 7th day thereafter.

e. Statistics - Continuous data were assessed by ANOVA techniques for nested design experiments in a manner similar to that described by McClave, et. al. (1981). If significant effects due to concentration were determined by the ANOVA calculations, Tukey's HSD comparison test was used to determine those treatment levels having responses significantly different from control response.

12. Reported Results:

The significant effects that occurred in the treatment test concentrations when compared to the control were reduced survival in test levels 4 and 5 and a reduction in both weight and length in levels 3 and 4. The behavior/physical effects that were noted in the lower test levels did not indicate enough of an effect for a sufficient duration to be judged affected. Therefore, based on the data for this 60-day post-hatch rainbow trout early life stage toxicity study, the Maximum Acceptable Toxicant Concentration (MATC) is 0.082 mg/l MON7200.

13. Study Authors Conclusion:

"... limits for MON7200 were estimated to be the mean measured concentrations of 0.056 mg/l and 0.12 mg/l. The MATC, defined as the geometric mean of the lowest observed effect concentration (LOEC) and the no observed effect concentration (NOEC) is 0.082 mg/l MON7200."

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 test system dilution water was not sterilized or tested for pesticides, heavy metal, or other contaminants before the initiation of the study.

- The pH of the dilution water was approximately 8.0 (not fluctuating more than + 10%), recommended pH is 7.2 - 7.6.

b. Statistical Analysis - The statistical analysis conducted by the study author was appropriate.

c. Discussion/ Results - The most sensitive indicator of MON 7200 toxicity (among the toxic endpoints used in the study) were fry survival and growth. Larval survival was reduced significantly at 0.20 mg/l and adverse growth effects were significant at 0.012 mg/l. Sublethal behavior/physical effects occurred at all treatment levels.

The study author reports the maximum allowable toxic concentration (MATC) to be the geometric mean of the no observed effect level (NOEL) and the lowest observed effect level (LOEL). EEB considers the range of these two values to be a more adequate representation of the MATC. Therefore, based on these data, the MATC for MON 7200 (at 90.7 % a.i.) is estimated to be >0.056 mg/l and <0.12 mg/l. The no observed effect level is 0.056 mg/l.

d. Adequacy of Study

1) Classification: Core

2) Rationale: The discrepancies noted in the reviewers discussion do not significantly detract from the study.

3) Repairability: N/A

15. Completion of One-Liner:

February 26, 1990

LITERATURE CITED

McClave, J.T., J.H. Sullivan, and J.G. Pearson. 1981. Statistical analysis of fish chronic toxicity data. IN Aquatic Toxicology and Hazard Assessment: Fourth Conference. ASTM STP 737. American Society for Testing and Materials.

McKim, J.M. and D. A. Benoit. 1971. Effect of long-term exposure to copper on survival, reproduction and growth of brook trout (Salvelinus fontinalis). J. Fish. Res. Bd. Canada 28:655-662.

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