410219-01
MRID No.

041402
Shaughnessy No.

Data Evaluation Record

MOLINATE TG, ORDRAM®

Mollusc 48-hour Larvæ Study
Guideline Ref. No. 72-3(b).

1. TEST MATERIAL - Molinate TG

2. STUDY MATERIAL -

S-Ethyl hexahydro-1H-azepine-1-carbothioate 97.6% ai W/W.

3. STUDY TYPE- Mollusc Larvæ Toxicity.

Species tested- Pacific oyster (*Crassostrea gigas*).

4. STUDY IDENTIFICATION:

Tapp, J.F. 1988. Molinate: Determination of acute toxicity of larvæ of the Pacific oyster (*Crassostrea gigas*). ICI PLC, Brixham Laboratory, Freshwater Quarry, Brixham, Devon TQ5 8BA, U.K. Codes BL/B/3422 and FT69/88. Submitted by ICI Americas, Inc., Agricultural Products, Wilmington, Delaware 19897. Registrants Code (?) on the Summary title page- BL/B/3422, RR 90-340B.

5. REVIEWED BY:

James J. Goodyear
Biologist, Section 1
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

Signature: James J. Goodyear
Date: April 11, 1991

6. APPROVED BY:

Leslie W. Touart
Acting Head, Section 1
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

Signature: L. W. Touart
Date: 4/12/91

7. CONCLUSIONS:

The laboratory did not filter the sample of the solution before quantitative analysis. Therefore, the any Molinate that was not in solution would have been measured as dissolved chemical. Therefore, it is "Invalid" and *cannot* be used to for reregistration.

8. RECOMMENDATIONS - N/A.

9. BACKGROUND:

The registrant submitted the study as a "Previously submitted, acceptable study." EEB has no record of having reviewed or even received the study. The records of the Registration Division confirm that the study has never been reviewed.

10. DISCUSSION OF INDIVIDUAL TEST - N/A.

11. MATERIALS AND METHODS:

A. TEST CONDITIONS:

Embryos or Gametes - "The test animals were obtained from Surfside Oyster. . . and assigned Brood stock batch reference number MD 88/2." The experimenters obtained gametes from these adults and mixed them together is seawater. The larvæ were used within 2.3 hours of fertilization.

Inoculum density - "27.9 embryos/ml" (=27,900 embryos/l).

Vessels - 250 ml glass beakers with 200 ml of solution.

Solution - Natural seawater "A stock solution was prepared by dissolving 0.2 g of the test substance in 2 litres of water. Each test solution was prepared by the addition of an appropriate volume of stock solution to dilution water."

Duration - 48-hours.

Temperature - "Nominal test temperature 20±1° C."

pH - 7.90 to 8.10 pH.

Dissolved O_2 - 7.0 to 7.6 mg/l (=78% of saturation).

Salinity -32 ppth.

Photoperiod -Not reported.

B. DOSE:

1.8, 3.2, 5.6, 10, 18, 32, 56, and 100 mg/l nominal (used by ICI for calculation of EC_{50}).
1.6, 3.0, 5.0, 9.7, 16, 29, 54, and 95 mg/l lowest measured (Used by EEB).

C. DESIGN:

Static, not aerated, four replicates of the control, two replicates of each concentration, no solvent reported.

D. STATISTICS:

Stephen, 1977.

12. REPORTED RESULTS:

48-hour EC_{50} = 38 mg/l (CI 35 to 41 mg/l).
NOEL = 31 mg/l.

13. STUDY AUTHORS' CONCLUSIONS/QA MEASURES:

"I, the undersigned, hereby declare that this study was performed under my direction according to the principles of Good Laboratory Practice and that this report represents a true and accurate record of the results obtained. (signed) J F Tapp."

14. REVIEWER'S DISCUSSION AND CONCLUSIONS:

A. TEST PROCEDURES:

To insure that all larvæ were exposed to a given concentration of Molinate, the lowest of the measured levels must be used. Therefore, EEB recalculated the EC_{50} using the lower of the two measured concentrations. The measurement of the concentration of Molinate was done without filtering the solution, therefore, the any undissolved or precipitating Molinate would have been measured as chemical in solution.

B. STATISTICAL ANALYSIS:

Based upon the smallest confidence interval, the moving average method produced the best EC_{50}.

EC_{50} = 36.0 mg/l (CI 33.0 to 39.0 mg/l), NOEL = <1.6 mg/l.

C. DISCUSSION/RESULTS:

Previous study reports submitted by ICI have given the solubility of Molinate at about the same level as this one, but those studies needed acetone to dissolve the Molinate so that it would stay in solution. The Chemical data sheet supplied with the Molinate TG to another laboratory in another study says that acetone should be used as a solvent. Yet this study used no acetone.

D. ADEQUACY OF THE STUDY:

Classification - Invalid.

Rational - The measurement of the concentrations was not done properly.

Repair - Submit original, raw data sheets that show that solution was filtered before it was measured.

15. COMPLETION OF ONE-LINER FOR STUDY- No.

16. CBI APPENDIX - N/A.

LITERATURE CITED

Stephan, C.E. 1977. Methods for calculating an LC_{50}. in, Aquatic Toxicology and Hazard Evaluation. ASTM STP 634. F.L. Mayer and J.L. Hamelink, Eds. American Society for Testing and Materials. pp. 65-84.