UNDATED

420953-04
MRID No.

041402
Shaughnessy No.

Data Evaluation Record

MOLINATE, TG

Addendum to MRID 408357-02
Marine/Estaurine Fish Toxicity
Sheepshead Minnow

Guideline Reg. No. 72-3(a).

1. TEST MATERIAL- Molinate TG.

2. STUDY MATERIAL- S-Ethyl hexahydro-1H-azepine-1-carbothioate 100% ai W/W.

3. STUDY TYPE- Marine/Estaurine Fish Toxicity

4. STUDY IDENTIFICATION:
Hammer, M. 1991. Addendum to MRID No. 408357-02. D171855. S407738. Case no. 818845.

Nicholson, R.B. 1987. Acute toxicity of Ordram© technical to Sheepshead minnow. Springborn Bionomics, Inc., 10307 Gulf Beach Hwy, Pensacola, FL 32507. Final Report No. 87-7-2413. Study No. 723.0287.6106.500. Registrants Code No. (?) on the Summary title page- T-12560, RR 90-342B. MRID 405933-08. Submitted by ICI Americas, Inc., Agricultural Products, Wilmington, Delaware 19897.

5. REVIEWED BY:
James J. Goodyear Signature:
Biologist, Section 1
Ecological Effects Branch Date:
Environmental Fate and Effects Division (H7507C)

6. APPROVED BY:
Leslie W. Touart Signature:
Head, Section 1
Ecological Effects Branch Date:
Environmental Fate and Effects Division (H7507C)

7. CONCLUSIONS- Invalid.

8. RECOMMENDATIONS- N/A.

1/3

9. BACKGROUND:

classification.

10. DISCUSSION OF INDIVIDUAL TEST- N/A.

11. MATERIALS AND METHODS- As before.

12. REPORTED RESULTS:

ICI attributes the difference in our calculated O^2 levels to the difference between its solubility in freshwater and in salt water.

ICI's response to EEB's insistence on measured concentrations was, "In two other static studies where concentrations have been measured, the measured Molinate levels have been shown to be in the ranges of 87-112% of nominal and 89-103% of nominal. Both these studies covered the range used in this study and took samples at the beginning and end of the study, showing no significant change in Molinate concentrations over the test. Therefore, in these static tests it has been shown that nominal concentrations are achieved, maintained and are appropriate for the calculation of the LC_{50}."

13. STUDY AUTHORS' CONCLUSIONS/QA MEASURES:

The study should be upgraded to "Core."

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

A. TEST PROCEDURES:

EEB accepts ICI's explanation of the dissolved O^2 and accepts ICI's original O^2 figures.

In her review of the registrant's study on the American (=Eastern) oyster (*Crassostrea virginica*) Elizabeth Zucker (1985) found that, even though acetone was used, a precipitate had developed at all test concentrations (7.7 to 100 mg/l). In a study on the Sheepshead minnow (*Cyprinodon variegatus*), Zucker (1985) found that, "There was insolubility of test material noted for the two highest test concentrations [60 and 100 mg/l, jg]." This was true even though they used acetone to dissolve the Molinate. The study author did not report the precipitate in the text, Zucker noticed it in the appended raw data. The present study reports do not include original data, just summary tables. Zucker made this study "Supplemental" but with the comment, "Once the registrant explains the solubility situation, the study should be reevaluated as to its acceptability for fulfilling a guideline requirement." The registrant has never attempted to explain the solubility problem.

In their study on the Bluegill sunfish, the measured concentrations were as low as 53% of the nominal concentration. ICI calculated the "percent of nominal" by using the measured figure that was closest to the nominal; EEB used the figure that is furthest from the nominal. Even though they supply the measured concentrations, they calculated the EC_{50} with the nominal figures.

2

The EEB Standard Evaluation Procedures (Zucker, 1985) state, "The test report submitted to the Agency must fully describe the materials and methodology used to perform the study." EEB does not have enough information about the chemistry of Molinate to interpret the tests. EEB has serious questions about the GLP of some studies done by ICI

laboratories. Specifically, it has concerns that Molinate may form a precipitate, or another sign of insolubility, that reduces the true concentration of the test solutions, but ICI has not informed EPA of the problem.

EEB believes that the data on the chemistry of Molinate is insufficient and equivocal. The EEB SEP (Zucker, 1985) states, "It is preferred that solutions be chemically analyzed to determine exact concentrations of pesticides. It is particularly important that residues are measured if: . . . The test material was volatile, insoluble or precipitated out of solution." Because of the history of precipitation of Molinate in aquatic toxicity testing, the history of not reporting that precipitate, and the history of not attempting to explain the solubility situation instead of doing a new test, EEB believes that tests of Molinate must be done with measured concentrations.

B. ADEQUACY OF THE STUDY:

Classification - Invalid.

Rationale - Did not use measured levels.
Repair - None.

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

16. CBI APPENDIX- N/A.