

408341-01
MRID No.

041402
Shaughnessy No.

Data Evaluation Record

MOLINATE TG, ORDRAM®

Invertebrate Acute Toxicity Test
Guideline Ref. No. 72-2(a).

1. TEST MATERIAL - Molinate TG, Ordram®

2. STUDY MATERIAL:

S-Ethyl hexahydro-1H-azepine-1-carbothioate 98.3 % ai W/W.

3. STUDY TYPE:

Invertebrate Acute Toxicity.

Species tested-

Water fleas

Daphnia magna

4. STUDY IDENTIFICATION:

Hamer, M.J and E. Farrelly. 1988. Acute toxicity test of Ordram® technical to freshwater invertebrates. ICI Agrochemical Research Station, Bracknell, Berkshire, U.K. Laboratory Project No. RJ 0687B. Submitted by ICI Americas, Inc., Agricultural Products, Wilmington, Delaware 19897. Registrants Code No. (?) on the Summary title page- RJ067B, RR 90-280B.

5. REVIEWED BY:

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

Signature: James 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 study *cannot* be used to fulfil reregistration requirements at this time.

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:

Animals - *Daphnia magna*, >24 hours old, first instar larvae.

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

Solution - reconstituted water.

Temperature - $20 \pm 0.5^\circ \text{C}$.

Duration - 48 hours.

pH - 8.2 to 8.3 pH.

Dissolved O₂ - >8.5 mg/l ($\approx 90\%$ of saturation).

B. DOSE:

"Test I 167, 100, 60, 36, 22, 13 + untreated control."

"Test II 167, 100, 60, 36, 22, 13, 7.8, 4.7 2.8 + untreated control."

"The control used reconstituted water only."

C. DESIGN:

Ten daphnids per replicate, 3 replicates per dose level (i.e., 30 daphnids per dose level), static, not aerated, two separate tests were conducted and their results were combined, toxicity was assessed at 3, 9, 24, and 48 hours.

D. STATISTICS:

"A combined EC_{50} was calculated by taking a weighted mean of the individual log EC_{50} 's with weight being a given by the inverse of the estimated variance of the log EC_{50} ."

12. REPORTED RESULTS:

$EC_{50} = 14.9 \text{ mg/l}$ (CI not given)

13. STUDY AUTHORS' CONCLUSIONS/QA MEASURES:

"In accordance with ICI Agrochemicals policies and procedures for Good Laboratory Practice, the conduct of this study has been inspected/audited by the Quality Assurance Unit at Jealotts Hill Research Station, Bracknell, Berks., RG12 6EY. England."

"The 24 and 48 hour EC_{50} values were 67 and 15 $mg\ l^{-1}$ respectively, based nominal concentrations. Mean measured concentrations were in the range 87-106% nominal, measured at 0 and 48 hours. The No Observed Effects Level was 4.7 l^{-1} ."

14. REVIEWER'S DISCUSSION AND CONCLUSIONS:

A. TEST PROCEDURES:

The practice of doing separate experiments (as opposed to having multiple replicates that are subjected to identical conditions) and calculating an EC_{50} based upon their combined data set is not acceptable statistically. To insure that the daphnids were exposed to a given concentration of Molinate, the lowest of the two measured levels must be used. Therefore, EEB recalculated the EC_{50} using the lower of the two measured concentrations and treated the data sets as separate experiments.

The levels were measured with a Gas Liquid Chromatography but the description of the methods (p.11) does not state that the sample solutions were filtered before they were analyzed. Therefore, the solution may have had undissolved Molinate in it.

B. STATISTICAL ANALYSIS:

Based upon the lowest confidence interval, the "best" EC_{50} is produced by the moving average method analysis of Test I. The $EC_{50} = 14.5\ mg/l$. (CI 12.9 to 15.9 mg/l).

C. DISCUSSION/RESULTS:

Previous study reports on Molinate (reviewed by Elizabeth Zucker (1985) have given the solubility of Molinate at about the same level as this one, but those studies needed acetone to dissolve the Molinate. Even so, it precipitated in some or all of the levels. In one case the registrant did not report the precipitate in the narrative. The Chemical data sheet supplied with the sample of Molinate TG says that acetone should be used as a solvent. Yet this study used no acetone and has no acetone control.

If this test had been accepted (or if it is later upgraded to "Core"), Molinate would be categorized as "Slightly toxic" to daphnids.

D. ADEQUACY OF THE STUDY:

Classification - Invalid.

Rational - The measured levels cannot be considered accurate.