DATA EVALUATION RECORD

1. CHEMICAL: Avermectin B_1

2. FORMULATION: Technical Avermectin B_1 (91.43% purity)

3. CITATION: Fink, Robert and Joann Beavers. 1981. Eight-day dietary LC_{50} of L-676, 863-00V50 to mallard duck (Anas platyrhynchos). Final report by Wildlife International LTD to Merck Sharp & Dohme. Rahway, N.J. Accession No. 246358 in 618-EUP-10.

4. REVIEWED BY: Mary L. Gessner
   Fishery Biologist
   HED/EEB

5. DATE REVIEWED: 12/22/81

6. TEST TYPE: Avian 8-day dietary LC_{50}
   Test species - mallard duck

7. REPORTED RESULTS: The subacute LC_{50} (and 95% C.I.) of L-676, 863-00V50 in mallard duck is 899 (691-1600) ppm.

8. REVIEWER'S CONCLUSIONS: This study is not adequate to fulfill the guideline requirement regarding an avian dietary test on waterfowl. Testing, at the initial dose levels, did not produce 50% mortality, therefore an LC_{50} could not be calculated. Additional testing at a higher dose resulted in over 50% mortality, but it was conducted after the other dose levels. Also, no control was run with the second phase of testing.

Materials/Methods

Test Procedure

Mallard ducks were obtained from the production flock at Wildlife International. During brooding and throughout the study, the ducklings received no antibiotic medication. Starter ration and water were available ad libitum throughout the study. A photoperiod of 14 hours daylight was maintained. At 14 days of age the birds were randomly assigned to treatment groups (10/pen) without regard to sex. Six treatment levels were tested. The experimental material was dispersed in corn oil and added to the starter ration. The birds were exposed to the test material for five days, and then maintained on the basal diet for three days. Control birds received the basal diet, only, throughout the study. Body weights were recorded by pen at initiation and termination of the study. Food consumption was recorded by pen during the five-day exposure period. Symptoms of toxicity and mortality were recorded daily throughout the study.

Statistical Analysis

Mortality was analyzed statistically by probit analysis.

Discussion/Results

There were no mortalities in either negative control group. All birds were normal in appearance and behavior throughout the test period. The initial study tested five treatment levels: 56.2, 100, 178, 316, and 562 ppm. At the 56.2 , 100, 178, 316, and 562 ppm. At the 56.2 ppm level lethargy was observed on days 1,2,3, and 5. All birds appeared normal from Day 6 through the termination of the study. At the 100 ppm level, lethargy and lower limb weaknesses were observed on Day 1 and lethargy continued to be displayed through Day 5. One bird remained lethargic on Day 6, but all birds were asymptomatic by Day 7. At the 178 ppm level lethargy became apparent on Day 1, with reduced reaction to external stimuli (sound and movement) also observed on Days 2 and 3. Toxic symptoms continued to be observed on Days 4 and 5, but all birds were asymptomatic on Day 6. At the 316 ppm level lethargy was observed beginning on Day 1, with reduced reaction to external stimuli, which was observed through Day 5. A few birds remained lethargic on Day 6, but all birds were asymptomatic by Day 7. At the 562 ppm level lethargy continued through Day 7. One mortality occurred at this dose level. There was a dose-related reduction in both food consumption and body weight at the 100 ppm through 562 ppm concentration levels.

A study utilizing a single dose level of 1000 ppm was then initiated. Six of 10 birds died at this dosage. Symptoms of toxicity observed included reduced reaction to external stimuli, wing droop, loss of coordination, prostrate posture, loss of righting reflex and lower limb rigidity. All mortalities occurred during Days 1 and 2. The surviving birds continued to exhibit lethargy, reduced reaction to external stimuli and loss of coordination through Day 5, and remained Lethargic until termination of the study. There was a marked reductin in food consumption and an actual loss in average body weight for the test period.

Reviewer's Evaluation

A. Test Procedure

Testing generally followed EPA-recommended protocol. However, the calculated LC_{50} is based on information from two separate testing periods. Apparently no range-finding test was conducted, which led to a definitive test that produced no dose-response line. Both EPA and ASTM say that for a test to be acceptable, at least three concentrations must produce between 0 and 100% mortality and at least one concentration must kill more than 50% and at least one less than 50% of the birds in a pen. Since only one mortality occurred, at the highest level, a test utilizing a single higher dose was initiated. No concurrent control was reported for the second test. The LC_{50} was then calculated by combining data collected in the two separate tests. It is statistically unsound to calculate the LC_{50} in this manner. There is an inconsistency in the report as to how many control animals were utilized. The test indicates that 50 control birds were used, but only 20 are mentioned in the results tables. More control mortality may have occurred than is shown in the report.

B. Statistical Analysis

The 1000 ppm level cannot be included in the LC_{50} calculations because it was not run concurrently with the other test levels. None of the initial concentrations caused 50% mortality so an accurate LC_{50} cannot be determined from the data.

C. Discussion/Results

The data generated from this study cannot be used to calculate an LC_{50} for waterfowl. The initial toxicant levels tested did not produce 50% mortality. The additional dose tested (1000 ppm) was not run concurrently nor was it accompanied by controls. Variation in test animals and conditions is not controlled when dose levels are run at different times. Initial testing indicates that the LC_{50} is greater than 562 ppm. Subsequent testing suggests that the LC_{50} may be less than 1000 ppm, but an accurate LC_{50} cannot be calculated from these data.

D. Conclusions:

1. Category: Invalid

2. Rationale: The initial testing did not produce 50% mortality, therefore, an LC_{50} cannot be calculated. Data from two separate tests may not be combined for purposes of calculating an LC_{50}. No concurrent control was run with the 1000 ppm level.