

US EPA ARCHIVE DOCUMENT

DATA EVALUATION RECORD

- 1. **CHEMICAL:** Ethyltrianol.
Shaughnessey No.
- 2. **TEST MATERIAL:** HWG 1608 (technical grade), Batch No. 86R0082I, CAS Registry No. 107534-96-3, 96.28% purity, Common name: FOLICUR, a crystalline solid.
- 3. **STUDY TYPE:** Avian Dietary LC50 Test.
Species Tested: Anas platyrhynchos.
- 4. **CITATION:** Toll, P.A. 1988. HWG 1608: Subacute Dietary LC50 to Mallard Ducks. Study No. 87-175-01. Prepared and Submitted by Mobay Corporation, Stilwell, KS. EPA Accession No. 407009-07.

5. **REVIEWED BY:**

Prapimpan Kosalwat, Ph.D.
Staff Toxicologist
KBN Engineering and
Applied Sciences, Inc.

Signature: P. Kosalwat
Date: 11/8/88

6. **APPROVED BY:**

James R. Newman, Ph.D.
Project Manager/
Principal Scientist
KBN Engineering and
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Signature: James R. Newman
Date: 11/11/88

Henry T. Craven, M.S.
Supervisor, EEB/HED
USEPA

Signature: Henry T. Craven
Date: 5/17/89

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements for an avian dietary LC50 test. With an LC50 value of greater than 4816 ppm a.i. mean measured concentration, HWG 1608 is considered practically non-toxic to mallard ducks (Anas platyrhynchos). The NOEC was less than 4816 ppm a.i. A more precise NOEL could not be determined due to the test material-related effect found at 4816 ppm, the only dietary concentration tested.

8. **RECOMMENDATIONS:** N/A.

9. BACKGROUND:

10. DISCUSSION OF INDIVIDUAL TESTS: N/A.

11. MATERIALS AND METHODS:

A. Test Animals: Day old mallard ducks (Anas platyrhynchos) were obtained from Whistling Wings, Hanover, Illinois. The ducks were placed into galvanized steel brooders (60 x 90 x 25.5 cm) maintained at a heater temperature of approximately 100°F with a temperature gradient to ambient temperature (approximately 72°F), with relative humidity of 45-70%. Room lighting was maintained under a 16/8-hour light/dark cycle. Brooder bedding (pelletized wood) was changed five times during the course of the study.

Food (Teklad DU-11 Duck Starter) and water (Kansas City Municipal water) were available ad libitum prior to and throughout the 9-day laboratory acclimation period. Less than 5% mortality was noted during the three days prior to test initiation and all unsuitable birds were eliminated from inclusion in the test prior to assignment to test groups.

B. Test System: The test system was assumed to be the same as the system used to acclimate the birds described above.

C. Dosage: 8-day Dietary LC50 test. Based on results of a range-finding study, the HWG 1608 nominal dietary concentration was set at 5000 ppm. Appropriate amounts of technical grade HWG 1608, corn oil, and acetone were combined in an Erlenmeyer flask, then added to the feed while mixing in a Hobart mixer. Compensation was made for the HWG 1608 purity in calculating diet concentrations. Samples from all prepared diets were taken for HWG 1608 (a.i.) concentration analysis prior to study initiation.

D. Design: At nine days of age, ten birds of unknown sex weighing 104 to 142 g were randomly allocated to the treatment group and two control groups. Treatment birds were given feed containing HWG 1608 for five days, then given control feed for a three-day observation period.

Observations for mortality and toxic signs were made twice daily except on weekends when only one observation per day was made. Body weights were recorded at test

initiation and termination and on Day 5. Feed consumption for each group was recorded daily. At the end of the study, all surviving birds were sacrificed by CO₂ asphyxiation. Necropsy examinations were conducted on all surviving surviving ducks.

- E. **Statistics:** The control group means were compared using a t-test. If no significant differences were noted ($p \leq 0.05$), control groups were combined for all additional analyses. Body weight, growth (weight change) and feed consumption data for the 5000-ppm dietary level was then compared to control also using a t-test. If a treatment mean was significantly different from controls ($p \leq 0.05$), that was considered a toxicant effect level. All statistical analyses were conducted using software supplied by SAS Institute Inc.

12. **REPORTED RESULTS:** Mean measured concentration of HWG 1608 in the 5000-ppm dietary level was 4816 ppm, representing 96% of the nominal concentration. Chemical analyses also showed that diet preparations containing HWG 1608 from the range-finding study were homogeneous and stable throughout the five-day exposure period.

No mortalities occurred in birds given 4816 ppm HWG 1608 in the feed. The treated birds showed depressed body weight gain compared to controls (Table 3, attached). However, during the three-day observation period, the treated birds gained more weight than controls indicating recovery. There were no significant differences in feed consumption (Table 4, attached), though the treated birds ate less than controls which could indicate a palatability problem.

Results from postmortem examinations revealed incidental occurrences of multiple pinpoint depressed red zones in the mucosa of the gizzard in both control and treated birds (Table 5, attached).

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The subacute dietary LC50 of HWG 1608 to mallard ducks was >4816 ppm a.i. The no-observed-effect-concentration (NOEC) was <4816 ppm a.i., based on body weight depression.

The study had been audited periodically at all phases by the quality assurance unit in compliance with the Good Laboratory Practice regulations. The final report was reviewed and signed by the quality assurance unit of Mobay Corporation.

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

A. Test Procedure: The test procedures and the report were in accordance with the SEP guidelines, except for the following deviations:

o A no-observed-effect level (NOEL) of HWG 1608 was not included in the test.

o The brooder was reported as being "maintained at a heater temperature of approximately 100°F (38°C) with a temperature gradient to ambient temperature (approximately 72°F or 22°C)." The SEP recommends the brooder temperature of approximately 35°C.

o The size of brooders used in the test (60 x 90 x 25.5 = 137,700 cm³) was smaller than the recommended size of 70 x 100 x 24 (= 168,000) cm³.

B. Statistical Analysis: The statistical analysis performed by the author was appropriate and the results appeared to be valid. Since there was no mortality in any test birds, statistical analysis was not needed to calculate the LC50 value.

C. Discussion/Results: With an LC50 value of greater than 4816 ppm a.i. mean measured concentration, HWG 1608 is considered practically non-toxic to mallard ducks, when administered through a diet for five days. The NOEL was <4816 ppm a.i. A more precise NOEC could not be determined due to test material-related effect found at 4816 ppm, the only dietary concentration tested.

D. Adequacy of the Study:

(1) Classification: Core.

(2) Rationale: Although the test procedures deviated from the guidelines, the reviewer does not believe they significantly affected the validity of the test results.

(3) Repairability: N/A.

15. COMPLETION OF ONE-LINER: Yes, November 1, 1988.

Page _____ is not included in this copy.

Pages 5 through 7 are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
 - Description of the product manufacturing process.
 - Description of quality control procedures.
 - Identity of the source of product ingredients.
 - Sales or other commercial/financial information.
 - A draft product label.
 - The product confidential statement of formula.
 - Information about a pending registration action.
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No. _____

Chemical Name Ethyltriato Chemical Class _____

Page 1 of 1

(HWG-1608 Technical)

Study/Species/Lab/
Accession _____
Chemical
& a.i.

Results

Reviewer/
Date _____
Validati
Status _____

4-Day Single Dose Oral LD50

LD50 = mg/kg (95% C.L.) Contr. Mort.(%) = _____

Species _____

Slope = _____ # Animals/Level = _____ Age(Days) = _____
Sex = _____

Lab _____

14-Day Dose Level mg/kg/(% Mortality)
() , () , () , () , ()

acc. _____

Comments: _____

4-Day Single Dose Oral LD50

LD50 = mg/kg (95% C.L.) Contr. Mort.(%) = _____

Species _____

Slope = _____ # Animals/Level = _____ Age(Days) = _____
Sex = _____

Lab _____

14-Day Dose Level mg/kg/(% Mortality)
() , () , () , () , ()

acc. _____

Comments: _____

8-Day Dietary LC50

LC50 = >4816 ppm * (95% C.L.) Contr. Mort.(%) = 0

Species Anas platyrhynchos

Slope = _____ # Animals/Level = 10 Age(Days) = 9
Sex = not determined

Lab Mobay Corporation
96-28

8-Day Dose Level ppm/(% Mortality)
4816 (0) , () , () , () , ()

acc. 407009-07

Comments: * Mean measured concentration (nominal conc. = 5000 ppm)

PK/11-1-88 Core

8-Day Dietary LC50

LC50 = ppm (95% C.L.) Contr. Mort.(%) = _____

Species _____

Slope = _____ # Animals/Level = _____ Age(Days) = _____
Sex = _____

Lab _____

8-Day Dose Level ppm/(% Mortality)
() , () , () , () , ()

acc. _____

Comments: _____

48-Hour LC50

LC50 = pp (95% C.L.) Contr. Mort.(%) = _____
Sol. Contr. Mort.(%) = _____

Species _____

Slope = _____ # Animals/Level = _____ Temperature = _____

Lab _____

48-Hour Dose Level pp/(% Mortality)
() , () , () , () , ()

acc. _____

Comments: _____

96-Hour LC50

LC50 = pp (95% C.L.) Con. Mor.(%) = _____
Sol. Con. Mor.(%) = _____

Species _____

Slope = _____ # Animals/Level = _____ Temp. = _____

Lab _____

96-Hour Dose Level pp/(% Mortality)
() , () , () , () , ()

acc. _____

Comments: _____

96-Hour LC50

LC50 = pp (95% C.L.) Con. Mort.(%) = _____
Sol. Con. Mort.(%) = _____

Species _____

Slope = _____ # Animals/Level = _____ Temp. = _____

Lab _____

96-Hour Dose Level pp/(% Mortality)
() , () , () , () , ()

acc. _____

Comments: _____

8