5-17-89

Accession No. 407009-07

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
   Applied Sciences, Inc.

   Signature: James R Newman
   Date: 11/11/88

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

   Signature:
   Date: 5/17/89
   Henry T. Craven 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 CO_2 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 cm^3) was smaller than the recommended size of 70 x 100 x 24 (= 168,000) cm^3.

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.

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No. _____ Chemical Name Ethyltriaol Chemical Class ____ Page 1 of 1

(CHWG-1608 Technical)

Study/Species/Lab/ Accession	Chemical % a.i.	Results	Reviewer/ Date	Validati Status
4-Day Single Dose Oral LD_{50}		LD50 = mg/kg (95% C.L.) Contr. Mort.(%)=		
pecies	____	Slope= # Animals/Level= Age(Days)= Sex =	_____	____
ab		14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( )		
cc.		Comments:		
4-Day Single Dose Oral LD_{50}		LD50 = mg/kg. (95% C.L) Contr. Mort.(%)=		
pecies	____	Slope= # Animals/Level= Age(Days)= Sex =	_____	____
ab		14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( )		
cc.		Comments:		
-Day Dietary LC_{50}		LC50 = >4816 ppm* (95% C.L. —) Contr. Mort.(%) = 0		
pecies Anas platyrhynchos		Slope= — # Animals/Level= 10 Age(Days)= 9 Sex = not determined	PK/11-1-88	Core
ab Mobay Corporation 96-28		8-Day Dose Level ppm*/(%Mortality) 4816(0), ( ), ( ), ( ), ( )		
cc. A07009-07		Comments: *mean measured concentration (nominal conc. = 5000 ppm		
-Day Dietary LC_{50}		LC50 = ppm (95% C.L) Contr. Mort.(%)=		
pecies		Slope= # Animals/Level= Age(Days)= Sex =	_____	____
ab	____	8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( )		
cc.		Comments:		
-8-Hour LC_{50}		LC50 = pp__ (95% C.L.) Contr. Mort.(%)= Sol. Contr. Mort.(%)=		
pecies		Slope= # Animals/Level= Temperature =	_____	____
ab	____	48-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )		
cc.		Comments:		
6-Hour LC_{50}		LC50 = pp__ (95% C.L.) Con. Mor.(%)= Sol. Con. Mor.(%)=		
pecies		Slope= # Animals/Level= Temp.=	_____	____
ab	____	96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )		
cc.		Comments:		
6-Hour LC_{50}		LC50 = pp__ (95% C.L.) Con. Mort.(%)= Sol. Con. Mort.(%)=		
pecies		Slope= # Animals/Level= Temp.=	_____	____
ab	____	96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )		
cc.		Comments:		

8