#6321

MRID No. 417778-03

DATA EVALUATION RECORD

8/20/1992

1. **CHEMICAL:** Oxytetracycline.
Shaughnessey No. 006304.

2. **TEST MATERIAL:** Calcium oxytetracycline; 60.4% purity; a tan powder.

3. **STUDY TYPE:** Avian Dietary LC_{50} Test. Species Tested: Mallard duck (*Anas platyrhynchos*).

4. **CITATION:** Long, R.D., K.A. Hoxter, and G.J. Smith. 1991. Oxytetracycline Calcium Complex: A Dietary LC50 Study with the Mallard. Project No. 260-102. Performed by Wildlife International Ltd., Easton, MD. Submitted by Pfizer Incorporated, New York, NY. EPA MRID No. 417778-03.

5. **REVIEWED BY:**

Mark A. Mossler, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Mark L Mossler
Date: 4/27/92

Sara R Ager 8/20/92

6. **APPROVED BY:**

Michael Whitten, M.S.
Wildlife Toxicologist
KBN Engineering and
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Signature: Michael L Whitten
Date: 4/27/92

Henry T. Craven, M.S.
Supervisor, EEB/EFED
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Signature:
Date:

Anne Stavola 8/26/92

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for an avian dietary LC_{50} toxicity test. Based on nominal concentrations, the LC_{50} of oxytetracycline calcium complex for mallard ducklings was >5620 ppm ai. Therefore, this compound is classified as practically non-toxic to the mallard duck. The NOEC was 5620 ppm ai.

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

9. **BACKGROUND:**

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

.5 hrs

11. MATERIALS AND METHODS:

A. Test Animals: Mallard ducklings (*Anas platyrhynchos*) were obtained at one day of age from a supplier in Hanover, IL. The birds were from the same hatch, pen-reared and were phenotypically indistinguishable from wild birds. All birds were acclimated to the caging and facilities for 9 days. The birds were 10 days of age at test initiation. During acclimation, the birds were observed daily.

B. Test System: The birds were housed indoors in brooding pens. The pen floor measured 62 x 92 cm. The ceiling height was 25.5 cm. The external walls, ceilings, and the floor were constructed of vinyl-coated wire mesh. During the test, the average temperature in the brooding pens was 34 ±2°C and the ambient room temperature was 25 ±1°C. The average relative humidity was 77 ±13%. A 16-hour photoperiod was used throughout the study. The light intensity was approximately 130 lux.

The test diets were prepared by mixing the test substance in corn oil and blending into the diet. The concentration of corn oil in the treated and control diets was 2%. The diets were prepared at test initiation with a blender and additional diet was added as needed during the exposure period.

The birds were offered water and feed *ad libitum* throughout the study. A list of the ingredients in the feed was given in the report and it appeared to be free of unfamiliar ingredients and medications.

C. Dosage: Acute dietary LC_{50} test. Dosage levels selected for the study were 562, 1000, 1780, 3160, and 5620 ppm active ingredient (ai). The dose levels were corrected for the percent active ingredient of the test material.

D. Design: Ten ducklings per test level and in each of three controls were randomly assigned to pens. Signs of toxicity, abnormal behavior, and mortality were assessed at least twice daily. Body weights by group were measured at initiation, day 5, and day 8 (termination) of the test. Average feed consumption was determined by group for days 0-5 (the exposure period) and 6-8 (the observation period). Feed consumption was determined by measuring the change in the weight of the feed presented

to the birds over a given period of time. However, this is an estimate due to wastage by birds.

Samples were taken to determine the homogeneity and concentration of the test material. The samples were frozen and sent to Hazleton Laboratories America, Inc., for analysis by microbial zone inhibition.

E. **Statistics:** The LC_{50} value was estimated by visual assessment of the data due to the mortality pattern in this study.

12. **REPORTED RESULTS:** No mortality or abnormal effects were observed in the control or treatment groups during the study.

No reductions in body weight gain or feed consumption were observed in any treatment group (Tables 3 & 4, attached).

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The dietary LC_{50} for mallard ducklings exposed to oxytetracycline calcium complex was greater than 5620 ppm ai, the highest concentration tested. The no mortality and no-observed-effect level (NOEL) was 5620 ppm ai.

Statements of adherence to Quality Assurance resulting in conformance to Good Laboratory Practice standards (40 CFR Part 160) were included in the biological and analytical reports.

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

A. **Test Procedure:** The test procedures were in accordance with Subdivision E, ASTM, and SEP guidelines with the following exceptions:

Group weights were used during the study. Individual body weights of the birds are recommended for monitoring weight gain or loss.

Necropsies were not conducted. These are recommended, but not required, by the guidelines.

The humidity during the test (77 $\pm$13%) was occasionally higher than recommended (80%).

The pen dimensions (62 x 92 cm = 5704 cm^2) were smaller than recommended (70 x 100 cm = 7000 cm^2).

B. **Statistical Analysis:** Since a dose response was not evident by the end of the testing period, an LC_{50} value and 95% confidence limits could not be obtained. Upon review of the data, the LC_{50} reported by the authors (>5620 ppm ai) appears correct.

C. **Discussion/Results:** The report stated that the test material was added to the diet with corn oil. However, Appendix II stated that 100 ml of acetone was used in the diet preparation. If acetone was used, it should have been noted in the report.

The results from the residue analyses (included as a separate report) indicated that the test material was homogeneous and present in the diets at the proper concentrations.

Body weight gain and feed consumption were generally less in the treatment groups than in the control groups. However, mean initial body weights in treatment groups were 12-26 g less than mean initial values in control groups. When the percent weight change is examined (Tables 3 & 4), treatment group values fall in the range of control values. In consideration of this, no treatment-effect on body weight or food consumption is indicated.

This study is scientifically sound and meets the guideline requirements for an avian dietary LC_{50} toxicity test. Based on nominal concentrations, the LC_{50} of oxytetracycline calcium complex for mallard ducklings was >5620 ppm ai. Therefore, this compound is classified as practically non-toxic to the mallard duck. The no-observed-effect concentration (NOEC) was 5620 ppm ai.

D. **Adequacy of the Study:**

(1) **Classification:** Core.

(2) **Rationale:** N/A.

(3) **Repairability:** N/A.

15. **COMPLETION OF ONE-LINER:** Yes, 4-15-92.

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Shaughnessey # 006304 Chemical Name Oxytetracycline calcium complex Chemical Class _____ Page 1 of 1

Study/Species/Lab/ MRID #	Chemical % a.i.	Results	Reviewer/ Date	Validation Status
14-Day Single Oral LD_{50}		LD_{50} = mg/kg (95% C.L.) Control Mortality (%) =		
Species		Slope = # Animals/Level = Age (Days) =		
		Sex =		
Lab				
		14-Day Dose Level mg/kg/(% Mortality)		
		( ), ( ), ( ), ( ), ( )		
MRID #		Comments:		
0				
8-Day Dietary LC_{50}	60.4	LC_{50} = >5620 ppm (95% C.L.*) Control Mortality (%) = 0		
Species		Slope = n/a # Animals/Level = 10/rep 30/control Age (Days) = 10		
Anas platyrhynchos		Sex = n/a		
Lab			M. Mossler 4/15/92	Core
Wildlife International		8-Day Dose Level ppm* /(% Mortality)		
		562 (0), 1000 (0), 1780 (0), 3160 (0), 5620 (0)		
MRID #		Comments:		
417778-03		*- based on nominal concentrations of ai		
		NOEC = 5620 ppm ai*		