#6321 file

MRID No. 417778-02

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: Bobwhite quail (*Colinus virginianus*).

4. **CITATION:** Long, R.D., K. Hoxter, and G. J. Smith. 1991. Oxytetracycline Calcium Complex: A Dietary LC50 Study with the Northern Bobwhite. Project No. 260-101. Performed by Wildlife International Ltd., Easton, MD. Submitted by Pfizer Incorporated, New York, NY. EPA MRID No. 417778-02.

5. **REVIEWED BY:**

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

Signature: Mark A. Mossler

Date: 4/22/92

Sara R. Ager 8/20/92

6. **APPROVED BY:**

Michael Whitten, M.S.
Wildlife Toxicologist
KBN Engineering and
Applied Sciences, Inc.

Signature: Michael T. Whitten

Date: 4/27/92

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

Signature:

Date:

Henry Craven 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} value of oxytetracycline calcium complex for bobwhite quail was >5620 ppm ai. Therefore, this compound is classified as practically non-toxic to bobwhite quail. The NOEC was 5620 ppm ai.

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

9. **BACKGROUND:**

10. DISCUSSION OF INDIVIDUAL TESTS: N/A.

11. MATERIALS AND METHODS:

A. Test Animals: Bobwhite quail (*Colinus virginianus*) were obtained as eggs from an in-house production flock. 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 from the day of hatch. 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 thermostatically controlled brooding pens. The pen floor measured 72 x 90 cm. The ceiling height was 23 cm. The external walls, ceilings, and the floor were constructed of galvanized wire and sheeting. During the test, the average temperature in the brooding pens was 34 ±2°C and the ambient room temperature was 26 ±1°C. The average relative humidity was 40 ±1%. 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 enough was presented to the birds to last throughout 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 chicks per test level and in each of four 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 groups during the study except for one bird noted to have wing droop on the morning of day 6.

At the 3160 ppm ai level, birds were noted to be ruffled and lethargic beginning on day 3 and diminishing by day 8. Toe- and nostril-picking, limping, and wing droop were also noted. None of these symptoms were noted in the 5620 ppm ai group, so they were not considered treatment-related.

In comparison to the controls, body weight gain appeared to increase in the treatment groups. No reductions in 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 bobwhite 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.

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.

Although the amount of feed consumption during the observation period appeared slightly depressed in the highest treatment group, the body weight data and non-dose related response witnessed indicated that this was an incidental phenomenon.

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} value of oxytetracycline calcium complex for bobwhite quail was >5620 ppm ai. Therefore, this compound is classified as practically non-toxic to bobwhite quail. The no-observed-effect concentration (NOEC) was 5620 ppm ai, based on the lack of mortality or sublethal effects.

D. **Adequacy of the Study:**

(1) **Classification:** Core.

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

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

15. **COMPLETION OF ONE-LINER:** Yes, 4-14-92.

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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:		

8-Day Dietary LC_{50}	60.4%	LC_{50} = 75620 ppm* (95% C.L. N/A) Control Mortality (%) = 0		
Species: Colinus virginianus		Slope = N/A # Animals/Level = 10/trt 40/control Age (Days) = 10 Sex = N/A	M. Mossler 4/14/92	Core
Lab: C.B.I.L. International		8-Day Dose Level ppm* /(% Mortality) 562 (0), 1000 (0), 1780 (0), 3160 (0), 5620 (0)		
MRID # 417778-02		Comments: * based on nominal concentrations of ai. NOEC = 5620 ppm* ai		