

US EPA ARCHIVE DOCUMENT

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

- A. **Test Animals:** The birds used in the study were 10-day old bobwhite quail (*Colinus virginianus*) obtained from the Wildlife International Ltd. production flock. All birds were from the same hatch, pen-reared and phenotypically indistinguishable from wild birds. The birds could not be differentiated by sex. The birds were acclimated to the facilities from the day of hatch until test initiation. Birds exhibiting abnormal behavior were not used in the test.
- B. **Test System:** During acclimation and testing, birds were housed indoors in pens constructed of galvanized steel wire mesh and sheeting. Pen dimensions were 72 cm x 90 cm x 23 cm. Fluorescent lights provided 16 hours of light per day. The average temperature in the brooding compartment of the pens was $38 \pm 1^{\circ}\text{C}$. The average ambient room temperature was $26.0 \pm 1.8^{\circ}\text{C}$, with an average relative humidity of $42 \pm 8\%$.
- C. **Dosage:** Eight-day dietary LC_{50} test. Nominal dietary concentrations were 562, 1000, 1780, 3160, and 5620 parts per million (ppm). The dietary concentrations were not adjusted for purity of the test substance. Therefore, the dietary concentrations and the LC_{50} are reported as ppm of the test substance as received.
- D. **Design:** Groups of ten birds were assigned, by indiscriminate draw, to each of four control groups and five treatment groups. All birds were fed Wildlife International Ltd.'s game bird ration. Food and water were supplied *ad libitum* during acclimation and during the test.

The test diets were prepared by mixing the test substance first into acetone and then blending into the diet with corn oil. The concentration of corn oil in the treatment and control diets was 2%. Acetone was volatilized from the diets during the mixing procedure. Diets were prepared on the day of test initiation. The birds were fed the appropriate dietary concentrations for five days, and then given untreated food during a three-day recovery period. Samples of the diets were taken to verify the test concentrations and to confirm the stability and homogeneity of the test substance in

the diets. The samples were frozen and sent to ESE Laboratories, Gainesville, Florida, for analysis. Diets were analyzed for silver and zinc by ICP, and quantitation of the test substance was based on silver concentrations due to background concentrations of zinc in the avian diet.

Observations were made at least twice daily for mortalities, signs of toxicity, and abnormal behavior. Birds were weighed individually at test initiation, on day 5, and at test termination (day 8). Group food consumption was determined for the five-day exposure period and the three-day recovery period. Consumption was measured by calculating the change in the weight of the feed presented to the birds over time.

E. Statistics: Due to the absence of mortality in all treatment groups, the LC₅₀ was not calculated. An estimation of the LC₅₀ was made by a visual inspection of the mortality data.

12. REPORTED RESULTS: Results of diet samples analyzed for dose verification, homogeneity, and test substance stability show that measured values were similar to nominal values (Tables 1 - 3, attached).

There were no mortalities in the control groups nor in any treatment group during the study. All birds in the control and treatment groups were normal in appearance and behavior throughout the test period.

When compared to the control groups, there was no reduction in body weight or feed consumption in any treatment group during days 0-5.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES: The dietary LC₅₀ was greater than 5620 ppm, the highest concentration tested. The no mortality concentration was 5620 ppm. The no-observed-effect concentration was 5620 ppm.

Quality Assurance and Good Laboratory Practice statements were included in the report and analytical appendix, indicating conformance with GLP regulations as set forth in 40 CFR Part 160, with the following exceptions:

Periodic analyses of basal ration and water for background organic and inorganic concentrations were not fully conducted under Good Laboratory Practice Standards.

Test substance characterization was not audited by Wildlife International Ltd. for compliance with Good Laboratory Practice Standards. These data were reportedly the responsibility of the sponsor for separate submittal to EPA.

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 except for the following deviations:

The temperature in the brooding compartment of the pens was approximately 38°C; guidelines state that the brooder temperature should be approximately 35°C.

The birds were not randomly assigned to pens. Instead, they were assigned by "indiscriminate draw."

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

- B. Statistical Analysis:** Due to the absence of mortality during the test, the LC₅₀ could not be calculated. Based on nominal concentrations, the LC₅₀ was greater than 5620 ppm.

- C. Discussion/Results:** The report stated that the birds were assigned to groups by indiscriminate draw. Strictly speaking, "indiscriminate draw" is not the same as "random" assignments. However, this method of assignment probably did not affect the results of the test.

Other deviations mentioned in paragraph 14.A (above) were relatively minor and probably did not affect the results of the test.

Using nominal concentrations, the LC₅₀ was greater than 5620 ppm. The NOEC was 5620 ppm.

The study is scientifically sound and meets the requirements of an LC₅₀ study using a formulated product.

- D. Adequacy of the Study:**

(1) **Classification:** Core for a formulated product.

(2) **Rationale:** The deviations noted in 14 A probably did not affect the vailidity of the study.

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

15. **COMPLETION OF ONE-LINER:** Yes; September 13, 1993.

Silver Lestite DER

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