2/4/1994

DATA EVALUATION RECORD

1. **CHEMICAL:** Silver-Copper Zeolite. Shaughnessey Number: 129057.

2. **TEST MATERIAL:** Silver-copper zeolite; CAS # 130328-19-7; Batch # TZ 156; % a.i.: silver 3.4% anhydrous weight basis, copper 6.1% anhydrous weight basis; purity: anhydrous silver-copper zeolite > 99% in total anhydrous weight; a light blue powder.

3. **STUDY TYPE:** 71-1A. Avian Single Dose Oral LD_{50} Test. Species Tested: Bobwhite Quail (*Colinus virginianus*).

4. **CITATION:** Campbell, S.M. and J.B. Beavers. 1993. Silver-Copper Zeolite: An Acute Oral Toxicity Study with the Northern Bobwhite. Project No. 363-101. Performed by Wildlife International Ltd., Easton, MD. Submitted by Kanebo Zeolite, USA., Inc., New York, New York. EPA MRID No. 428710-01.

5. **REVIEWED BY:**

Nancy M. Gourlie, M.S.
Staff Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Nancy M Gourlie
Date: 9-23-93

6. **APPROVED BY:**

Michael L. Whitten, M.S.
Wildlife Toxicologist
KBN Engineering and
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Signature: Michael L. Whitten
Date: 9/23/93

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

Signature: Heather Mansfield 1/8/94
Date: 2 14 94

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the requirements for an avian oral LD_{50} test using a formulated product. The LD_{50} of greater than 2250 mg/kg classifies the test material as practically non-toxic to northern bobwhite. The NOEL was established at 810 mg/kg, based on loss in body weight noted among birds at the 1350 and 2250 mg/kg dosage levels.

6 hrs

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

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** The birds used in the study were 22-week-old northern bobwhite quail (*Colinus virginianus*) obtained from Top Flight Quail Farm, Belvidere, New Jersey. The birds were from the same hatch, pen-reared, and phenotypically indistinguishable from wild birds. They were acclimated to the laboratory for 8 weeks prior to dosing.

B. **Test System:** The birds were housed indoors in pens constructed of galvanized wire grid and sheeting. The pens measured 78 x 51 x 20-25 cm high. The photoperiod was 8 hours of light (369 lux) per day. The average temperature was 22.1 ± 2.8°C and the average relative humidity was 51 ± 10%.

C. **Dosage:** Fourteen-day single dose oral LD_{50} test. Based on known toxicity data, five nominal dosages (292, 486, 810, 1350, and 2250 mg/kg of body weight) were selected for the test. Dosages were not corrected for purity of the test substance.

D. **Design:** Ten birds (five males and five females) were assigned to each treatment and control group by indiscriminate draw. Each group was assigned two pens in which the birds were separated by sex.

Except for a 15-hour fasting period immediately prior to dosing, water and a game bird ration were offered *ad libitum* during acclimation and testing.

The test substance was dispersed in 0.5% carboxymethyl cellulose. Each bird was individually weighed and dosed on the basis of milligrams of test substance per kilogram of body weight. A single dose was orally intubated directly into the crop or proventriculus of each bird using a stainless steel cannula. The control birds received diluent only.

All birds were observed daily during acclimation and during testing for mortality, signs of toxicity, and abnormal behavior. The birds were individually weighed at test initiation and on days 3, 7, and 14. Group food

consumption was determined for days 0-3, 4-7, and 8-14 by measuring the change in the weight of the feed presented to the birds over a period of time.

E. **Statistics:** The LD_{50} was determined using a visual inspection of mortality data.

12. **REPORTED RESULTS:** There were no mortalities in the control group. All control birds were normal in appearance and behavior throughout the test period.

No treatment related mortalities were observed during the test at any dosage level. One incidental mortality due to a broken leg was recorded for a bird in the 486 mg/kg group. All other birds were normal in appearance and behavior throughout the study period.

When compared to the control, there was loss in the body weights of birds in the 1350 and 2250 mg/kg dosage levels from Day 0 to Day 3. Females in the 1350 group continued to lose weight through Day 7. Feed consumption was reduced for males at the 1350 dosage and all birds at 2250 mg/kg dosage levels from Day 0 to Day 3 (Table 2, attached).

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The acute oral LD_{50} value for northern bobwhite exposed to silver-copper zeolite as a single oral dose was greater than 2250 mg/kg, the highest dosage tested. The no-observed-effect level (NOEL) was 810 mg/kg, based on reduced body weight for birds at the 1350 and 2250 mg/kg dosage levels.

Quality Assurance and Good Laboratory Practice (GLP) statements were included in the report indicating compliance with the regulations set forth in 40 CFR Part 160, with the following exceptions:

Samples of the dosing solutions were not confirmed for test concentrations, homogeneity, or stability.

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.

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

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

Group body weights, rather than individual body weights, were recorded for the control group.

There was a discrepency regarding the length of the acclimation period. The report states 8 weeks and 22 weeks in separate places on Page 9, and 8 weeks on Page 10. It is assumed that the 22 week acclimation period was a typographic error, as 22 weeks was the age of the birds.

B. Statistical Analysis: Since only one bird died, and this death was not treatment related, the LD_{50} could not be calculated and was estimated to be greater than the highest dosage level.

C. Discussion/Results: Mortality data indicate no treatment related deaths at any dosage levels. One incidental death from a broken leg in the 486 mg/kg dosage group was reported. Body weight and food consumption were variable, but appeared to be reduced in the 1350 and 2250 mg/kg groups. The NOEL, therefore, was 810 mg/kg.

This study is scientifically sound and fulfills the requirements for an oral LD_{50} test using a formulated product. With an LD_{50} of greater than 2250 mg/kg, the test material is classified as practically non-toxic to northern bobwhite. The NOEL was 810 mg/kg based on reduced body weight and food consumption in the 1350 and 2250 mg/kg dosage groups.

D. Adequacy of the Study:

(1) Classification: Core.

(2) Rationale: Protocol deviations noted in Section 14.A above probably did not affect the validity of the study.

(3) Repairability: N/A.

15. COMPLETION OF ONE-LINER: Yes, 9/9/93.

(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 Zeolite, DFR

Page 9 is not included in this copy.

Pages ___ through ___ are not included in this copy.

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_____ Identity of product inert ingredients.

_____ Identity of product inert impurities.

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_____ A draft product label.

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