

US EPA ARCHIVE DOCUMENT

9/27/1991

DATA EVALUATION RECORD

- 1. **CHEMICAL:** Silver-Copper Zeolite.
Shaughnessey No. Not Available.
- 2. **TEST MATERIAL:** Silver-Copper Zeolite; 99% active ingredient; a light blue powder.
- 3. **STUDY TYPE:** Avian Dietary LC₅₀ Test.
Species Tested: Mallard Duck (Anas platyrhynchos).
- 4. **CITATION:** Culotta, J., K.A. Hoxter, G.J. Smith and M. Jaber. 1990. Silver-Copper Zeolite: A Dietary LC₅₀ Study with the Mallard. Project No. 278-102. Performed by Wildlife International Ltd., Easton, MD. Submitted by Kanebo Zeolite, USA, Inc. EPA MRID No. 416158-11.
- 5. **REVIEWED BY:**

Louis M. Rifici, M.S. Associate Scientist KBN Engineering and Applied Sciences, Inc.	Signature: <i>Louis M. Rifici</i> Date: 7/10/91
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- 6. **APPROVED BY:**

Michael L. Whitten, M.S. Wildlife Toxicologist KBN Engineering and Applied Sciences, Inc.	Signature: <i>Michael L. Whitten</i> Date: 7/10/91
Henry T. Craven, M.S. Supervisor, EEB/HED USEPA	Signature: <i>Allen W. Vaughan</i> 9-27-91 Date: <i>Henry T. Craven</i> 9/27/91
- 7. **CONCLUSIONS:** This study is scientifically sound but does not meet the guideline requirements for an avian dietary toxicity test. The concentration of the test material in the diet was measured but the results were not included in the report. Based on nominal concentrations, the LC₅₀ value of Silver-Copper Zeolite for mallard ducks was greater than the highest concentration tested, 5620 ppm. Therefore, Silver-Copper Zeolite is classified as practically non-toxic to mallard ducks. The NOEC was 5620 ppm.
- 8. **RECOMMENDATIONS:** See Section 14 D.

9. BACKGROUND:

10. DISCUSSION OF INDIVIDUAL TESTS: N/A.

11. MATERIALS AND METHODS:

- A. Test Animals: Mallard ducklings (Anas platyrhynchos) were one-day-old when obtained from a commercial supplier in Hanover, IL, and were phenotypically indistinguishable from wild birds. The birds were 10 days old at test initiation. During the holding period, water and a game bird ration were available ad libitum. The feed reportedly contained no antibiotics and the ingredients were given in the report.
- B. Test System: The indoor pens were battery brooders (62 x 92 x 25.5 cm high). The external walls, ceilings, and floors were constructed of vinyl-coated wire mesh. The temperature in the brooders was $29^{\circ}\pm 2^{\circ}\text{C}$ (SD). The average ambient room temperature was $21^{\circ}\pm 1^{\circ}\text{C}$ (SD) and the photoperiod was 16 hours of daylight per day. The average relative humidity was $42 \pm 8\%$ (SD).
- A sample of the test material was weighed to the nearest 0.0001 g. "Approximately three-quarters of the ration was weighed and placed in a Hobart mixer. The corn oil (130 mL) was added. The test substance was diluted with acetone and added to the material in the mixer. The beaker was rinsed with acetone. The remaining one-quarter of the ration was added and the final diet was mixed for approximately 6 minutes." The concentration of corn oil in the control and treated diets was 2%. An amount of test diet sufficient to last the five-day exposure period was offered to the birds at test initiation.
- C. Dosage: Eight-Day Avian Dietary LC_{50} test. The nominal concentrations selected for the study were 562, 1000, 1780, 3160, and 5620 ppm and a vehicle control. The concentrations were based on the total product as it was received.
- D. Design: The birds were assigned to the groups by random draw without regard to sex; 5 treatment and 4 control groups with 10 birds each were used. The birds were offered the treated diet or the control diet for 5 days and then the untreated diet for 3 days.

Group body weights were determined at test initiation, on day 5, and at test termination (day 8). Group food consumption was estimated during the exposure and observation periods. Symptoms of toxicity and mortality, if any, were recorded twice daily.

Samples of the test diets were shipped to the sponsor for verification of the test concentrations and confirmation of the stability and homogeneity of the test material in the diets.

E. Statistics: No statistics were required for this data set.

- 12. REPORTED RESULTS:** There was one mortality in the control on day 6. In all other groups (control and treatment) there were no mortalities, overt signs of toxicity, or abnormal behavior. Body weight gain and feed consumption in the treatment groups were similar to the controls (Tables 3 and 4).

The mallard dietary LC₅₀ value was therefore greater than 5620 ppm, the highest concentration tested. The no observed effects concentration (NOEC) was 5620 ppm.

- 13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:**
The authors made no conclusions other than those noted above.

Quality Assurance and GLP statements were included in the report indicating compliance with Good Laboratory Practice regulations under the Federal Insecticide, Fungicide, and Rodenticide Act.

- 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 report states that samples of the diets were taken to determine the concentrations of the test material. The results of the analyses were not provided in the report.

The lot number or some other identifying code for the test material was not included in the report.

Body weights were measured by group. Individual body weights should have been measured.

- B. **Statistical Analysis:** No statistics were required for this data set.
- C. **Discussion/Results:** This study is scientifically sound but does not meet the guideline requirements for an avian dietary toxicity test. The concentration of the test material in the diets were measured but the results were not included in the report. Based on nominal concentrations, the LC₅₀ value of Silver-Copper Zeolite for mallard ducks was greater than the highest concentration tested, 5620 ppm. Therefore, Silver-Copper Zeolite is classified as practically non-toxic to mallard ducks. The NOEC was 5620 ppm.
- D. **Adequacy of the Study:**
- (1) **Classification:** Supplemental.
 - (2) **Rationale:** The concentration of the test material in the diets was measured but the results were not included in the report.
 - (3) **Repairability:** The study can be upgraded to "Core" if the registrant provides satisfactory information regarding measured concentrations of test material in the diets.
15. **COMPLETION OF ONE-LINER:** Yes; 06/18/91.

Silver Ledit DEER

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Pages ___ through ___ are not included in this copy.

The material not included contains the following type of information:

- Identity of product inert ingredients.
- Identity of product inert 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.
- Information about a pending registration action.
- FIFRA registration data.
- The document is a duplicate of page(s) _____.
- The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
