

US EPA ARCHIVE DOCUMENT

DATA EVALUATION RECORD

1. **CHEMICAL:** Tetramethrin. Shaughnessey Number: 69003.
2. **TEST MATERIAL:** Neo-Pynamin T.G.; Lot No. 90304; 95.3% active ingredient; a white to yellow powder or granule.
3. **STUDY TYPE:** Avian Single Dose Oral LD₅₀ Test.
Species Tested: Bobwhite quail (Colinus virginianus).
4. **CITATION:** Culotta, J., K.A. Hoxter, G.J. Smith and M. Jaber. 1990. Neo-Pynamin: an acute oral toxicity study with the bobwhite. Study performed by Wildlife International Ltd., Easton, Maryland. Laboratory study No. 166-135. Submitted by Sumitomo Chemical Company, Chuo-ku, Osaka, Japan. MRID No. 416096-04.
5. **REVIEWED BY:**

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| Michael L. Whitten, M.S. Wildlife Toxicologist KBN Engineering and Applied Sciences, Inc. | Signature: <i>Michael L. Whitten</i> Date: 2/19/91 |
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6. **APPROVED BY:**

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| Pim Kosalwat, Ph.D. Senior Scientist KBN Engineering and Applied Sciences, Inc. | Signature: <i>P. Kosalwat</i> Date: 2/20/91 |
| Henry T. Craven, M.S. Supervisor, EEB/HED USEPA | Signature: <i>Henry T. Craven</i> Date: 3/20/92 |
7. **CONCLUSIONS:** The study is scientifically sound and meets the requirements for an avian oral LD₅₀ test. With an LD₅₀ of greater than 2250 mg/kg, the test material is considered to be practically non-toxic to bobwhite quail. The NOEC was 2250 mg/kg. Notes
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 24-week old bobwhite quail (Colinus virginianus), obtained from Fritts Quail Farm, Phillipsburg, New Jersey. Each treatment and control group contained five males and five females. All birds were acclimated to the facilities for 12 weeks prior to initiation of the test. Birds exhibiting abnormal behavior or physical injury during acclimation were not used in the study.
- B. Test System:** All birds were housed indoors in pens constructed of galvanized wire and galvanized sheeting. Pen dimensions were 78 cm x 51 cm x 20-25 cm high. Fluorescent lights provided 8 hours of light per day. The average temperature was $19^{\circ}\text{C} \pm 2^{\circ}\text{C}$ (SD). The average relative humidity was $40\% \pm 10\%$ (SD).
- C. Dosage:** 21-day single dose oral LD₅₀ test. Based upon known toxicity data, dosages selected for the study were 292, 486, 810, 1350, and 2250 milligrams of Neo-Pynamin per kilogram of body weight (mg/kg). The dosages and reported LD₅₀ value were not corrected for purity of the test substance.
- D. Design:** Groups of ten birds (five males and five females) were randomly assigned to each of five treatment groups and one control group. All birds were fasted (with water allowed) for at least 15 hours prior to dosing. The test substance was dissolved in corn oil and intubated directly into the crop or proventriculus of each bird using a stainless steel catheter. Each bird was individually weighed and dosed on the basis of milligrams of test substance per kilogram of body weight. The control birds a corresponding volume of corn oil only.
- All birds were observed at least twice daily for mortalities, signs of toxicity, and abnormal behavior. The birds were individually weighed at test initiation and by group on days 3, 7, and 14. Group food consumption was determined for days 0-3, 4-7, and 8-14.
- E. Statistics:** Due to the pattern of mortality, the LD₅₀ was not calculated. An estimation of the LD₅₀ was made by a visual inspection of the mortality data.

12. **REPORTED RESULTS:** There were no mortalities in the control group. With the exception of one male with foot lesions, all birds in the control group were normal in appearance and behavior throughout the study.

There was one mortality in the treatment groups; a male in the 1350-mg/kg group was found dead on day 6. This bird appeared normal prior to death. Necropsy revealed indications of visceral gout. The mortality was not considered to be related to treatment, and was attributed to the visceral gout condition.

"No overt signs of toxicity were observed at any of the dosages tested." Two females and one male in the 1350-mg/kg group displayed a head lesions and submissive behavior. The conditions of these three birds were exacerbated by penmate cannibalism and resulted in a ruffled appearance and lethargy. These conditions and behaviors were not considered to be treatment related.

No apparent effects on body weight change or food consumption were noted at any test interval (Table 2, attached).

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The acute oral LD₅₀ of Neo-Pynamin was greater than 2250 mg/kg. There were no clinical signs of toxicity at any concentration. The no mortality concentration was 2250 mg/kg. The no-observed-effect concentration was 2250 mg/kg.

The report stated that the study was conducted in conformance with Good Laboratory Practice regulations with the exception that the dosing solutions were not sampled for confirmation of test concentration, stability, or homogeneity. The "Good Laboratory Practice Compliance Statement" was signed by representatives of Wildlife International Ltd. and Sumitomo Chemical Company.

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 exception:

Body weights were measured individually at test initiation and by group thereafter. Individual body weights should have been measured at all intervals.

- B. **Statistical Analysis:** The LD₅₀ could not be calculated and is assumed to be greater than 2250 mg/kg.

- C. Discussion/Results: The author's conclusion of no apparent effects on body weight change or food consumption is accepted after a visual inspection of Table 2 (attached).

With an LD₅₀ of greater than 2250 mg/kg, the test material is considered to be practically non-toxic to bobwhite quail. The NOEC was 2250 mg/kg.

The study is scientifically sound and meets the requirements for an avian oral LD₅₀ test.

- D. Adequacy of the Study:

- (1) Classification: Core.
- (2) Rationale: N/A.
- (3) Repairability: N/A.

15. COMPLETION OF ONE-LINER: Yes; February 19, 1991.

NR 205 416096-04

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Pages _____ through _____ are not included.

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- Identity of product inert ingredients.
- Identity of product 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.
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