

DATA EVALUATION RECORD

1. CHEMICAL: Tetramethrin. Shaughnessey Number: 69003.
2. TEST MATERIAL: Neo-Pynamin T.G.; Lot No. 90304; 95.3% active ingredient; an off-white powder.
3. STUDY TYPE: Avian Dietary LC₅₀ Test.
Species Tested: Mallard (Anas platyrhynchos).
4. CITATION: Long, R.D., K.A. Hoxter, and G.J. Smith. 1990. Neo-Pynamin: a dietary LC₅₀ study with the mallard. Study performed by Wildlife International Ltd., Easton, Maryland. Laboratory study No. 166-134. Submitted by Sumitomo Chemical Company, Chuo-ku, Osaka, Japan. MRID No. 416096-06.

5. REVIEWED BY:

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Signature:

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6. APPROVED BY:

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5/14/92

7. CONCLUSIONS: The study is scientifically sound and fulfills the requirements for an avian dietary LC₅₀ test. Based upon nominal concentrations, the dietary LC₅₀ of neo-pynamin was greater than 5620 ppm. This value classifies neo-pynamin as practically non-toxic to mallard ducklings. The NOEC was 5620 ppm.
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 10-day old mallard ducklings (Anas platyrhynchos), obtained when 1-day old from Whistling Wings, Hanover, Illinois. The birds could not be differentiated by sex. All birds were acclimated to the facilities from the day of receipt until initiation of the study. 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 vinyl coated wire mesh. Pen dimensions were 62 cm x 92 cm x 25.5 cm high. Fluorescent lights provided 16 hours of light per day. The average temperature in the brooding compartment of the pens was $33^{\circ}\text{C} \pm 2^{\circ}\text{C}$ (SD). The average ambient room temperature was $24^{\circ}\text{C} \pm 1^{\circ}\text{C}$ (SD), with an average relative humidity of $71\% \pm 14\%$ (SD).
- C. Dosage: Acute dietary LC_{50} test. Nominal dietary concentrations selected for the study were 562, 1000, 1780, 3160, and 5620 parts per million (ppm). "The dietary concentrations were established based upon known toxicity data." The dietary concentrations were not adjusted for purity of the test substance. Therefore, the treatment concentrations and the LC_{50} are reported as ppm of the test substance as received.
- D. Design: Groups of ten ducklings were randomly assigned to each of three 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 the test.

The test diets were prepared by mixing the test substance into the basal diet with corn oil. The concentration of corn oil in the treatment and control diets was 2%. Treatment diets were prepared 13 days prior to test initiation and frozen until initiation. The control 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 for three days. 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. Samples were sent to Wildlife International's chemistry laboratory for analysis.

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Observations were made at least twice daily for mortalities, signs of toxicity, and abnormal behavior. Birds were weighed by group at test initiation, on day 5, and at termination of the test on day 8. Group food consumption was determined for the five-day exposure period and the three-day recovery period.

- E. Statistics: Due to the absence of mortality in all treatment groups, the LC_{50} was not calculated. An estimation of the LC_{50} was made by a visual inspection of the mortality data.

12. REPORTED RESULTS: Measured dietary concentrations are presented in detail in Appendix III of the report. The samples analyzed to verify the treatment concentrations on the day of diet preparation ranged from 71.3% to 90.8% of nominal values. Samples analyzed to verify the treatment concentration on Day 0 of the test ranged from 74.4% to 83.1% of nominal values. The samples used to assess homogeneity resulted in coefficients of variation of 8.4% (562 ppm) and 12.0% (5620 ppm). Stability samples stored frozen for four days showed 78.3% and 74.4% of nominal concentrations at 562 ppm and 5620 ppm, respectively. Stability samples taken five days after diet preparation and maintained under ambient conditions ranged from 83.5% to 105.5% of nominal concentrations.

No mortalities, abnormal behavioral reactions or clinical signs of toxicity were noted in the control group nor in any treatment group during the study.

There was no apparent effect on weight gain or food consumption at any concentration tested (Tables 3 and 4, attached).

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES: The dietary LC_{50} of neo-pynamin was determined to be greater than 5620 ppm, the highest concentration tested. The no mortality and no-observed-effect concentration was 5620 ppm.

The report stated that the study was conducted in conformance with Good Laboratory Practice regulations, and was signed by the quality assurance officer of Wildlife International Ltd.

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:

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

The pen dimensions (62 cm x 92 cm = 5704 cm²) were smaller than the recommended dimensions (70 cm x 100 cm = 7000 cm²).

The relative humidity averaged 71% ± 14% (SD); the guidelines recommend an upper limit of 80%.

- B. Statistical Analysis: Due to the absence of mortality during the test, the LC₅₀ could not be calculated and is assumed to be greater than 5620 ppm.

- C. Discussion/Results: The treatment diets that were prepared for this test were apparently also used for another test (laboratory study # 166-133) conducted concurrently by the testing facility. Chemical analysis of treatment diets indicates that measured values for homogeneity, stability and dose verification appear to have been within acceptable limits. The results of homogeneity tests at 5620 ppm are not as clear as desired, with mean values ranging from 73.5% to 105.5% of nominal concentrations (Appendix III, Tables 1-3A, attached). The mean value of samples taken to measure homogeneity at 5620 ppm was 4129 ppm (73.5% of nominal). Samples of this concentration taken for other analyses show mean measured values of 74.4%, 79.4%, and 105.5% of the nominal concentration. A risk assessment of this chemical should note that the birds in the highest treatment group were exposed to approximately 4200 ppm of active ingredient (75% of 5620 ppm).

With an LC₅₀ of greater than 5620 ppm (based upon nominal concentrations; see above discussion), the test material is considered to be practically non-toxic to mallard ducklings. The NOEC was 5620 ppm.

The study is scientifically sound and meets the requirements for an avian dietary LC₅₀ test.

D. Adequacy of the Study:

- (1) Classification: Core.
- (2) Rationale: The deviations from recommended protocols were minor and did not affect the validity of the study.
- (3) Repairability: N/A.

15. COMPLETION OF ONE-LINER: Yes; February 18, 1991.