

US EPA ARCHIVE DOCUMENT

1-18-94

MRID No. 417421-02

DATA EVALUATION RECORD

1. **CHEMICAL:** Mineral Oil.
Shaughnessey Number: 063502.
2. **TEST MATERIAL:** 90 Neutral Oil; 99% purity; a yellow liquid.
3. **STUDY TYPE:** 71-2. Avian Dietary LC₅₀ Test.
Species Tested: Mallard Duck (*Anas platyrhynchos*).
4. **CITATION:** Long, R.D., J. Foster, K.A. Hoxter, and G.J. Smith. 1990. 90 Neutral Oil: A Dietary LC₅₀ Study with the Mallard. Study performed by Wildlife International Ltd., Easton, Maryland. Laboratory Project No. 203-118. Submitted by Unocal Corporation (PureGro company), Los Angeles, California. EPA MRID No. 417421-02.

5. **REVIEWED BY:**

Nicole U. Jurczyk, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: *Nicole U. Jurczyk*
Date: 1/4/94

6. **APPROVED BY:**

Michael L. Whitten, M.S.
Wildlife Toxicologist
KBN Engineering and
Applied Sciences, Inc.

Signature: *Michael J. Whitten*
Date: 1/5/94

James J. Goodyear, Ph.D.
Project Officer, EEB/HED
USEPA

Signature: *W. Goodyear*, 1/13/94
Date: 1 18 94

7. **CONCLUSIONS:** The study is scientifically sound and fulfills the requirements for an avian dietary LC₅₀ test. Based on nominal concentrations, the dietary LC₅₀ was greater than 5620 ppm, the highest concentration tested. This classifies the test material as practically non-toxic to mallard ducklings. The no-observed-effect-concentration was 5620 ppm.

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

9. **BACKGROUND:**

6.5

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 ducks (*Anas platyrhynchos*) obtained from Whistling Wings, Hanover, Illinois. All birds were from the same hatch, pen-reared and phenotypically indistinguishable from wild birds. The birds were acclimated to the facilities for nine days. All birds appeared to be in good health at initiation of the test.
- B. **Test System:** Ten birds per pen were housed indoors in pens that measured 62 x 92 x 25.5 cm. The external walls, ceilings, and floors of the pens were constructed of galvanized steel wire and sheeting. The photoperiod (maintained by a time clock) was sixteen hours of light per day during the acclimation period and throughout the test. Fluorescent lights were used to approximate noon-day sunlight. The average ambient room temperature for the study was $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$ (SD) with an average relative humidity of $54\% \pm 13\%$ (SD). The average temperature in the brooding compartment of the pens was $31^{\circ}\text{C} \pm 2^{\circ}\text{C}$ (SD). The humidity in the brooding compartment of the pens was not reported.
- 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 which had a reported purity of 99%. The dietary concentrations were established based on known toxicity data.
- D. **Design:** Groups of ten birds were assigned by random draw to each of three control groups and five test groups. The birds were fed a game bird ration formulated by Wildlife International Ltd. Food and water were supplied *ad libitum* during acclimation and during the test.

All of the test diets were prepared on the day of test initiation. The test material was weighed and mixed with acetone before being mixed in with the basal diet. The control birds received clean feed without any carrier or solvent.

Upon initiation of the study, a sufficient amount of feed for the duration of the test (approximately six kilograms) was presented to the birds.

The birds were fed the appropriate dietary concentrations for five days, and then given untreated food during a three-day recovery period. The diets were not sampled for analysis.

During acclimation, all birds were observed daily. Birds exhibiting abnormal behavior or physical injury were not used for the test. The birds were observed at least twice daily during the test and recovery periods. A record was maintained of all mortality, signs of toxicity or abnormal behavior.

Birds were weighed by group at test initiation, day 5, and at test termination (day 8). Average group food consumption was determined for the exposure period, day 0-5, and for the recovery period, day 6-8. Feed consumption was determined by measuring the change in the weight of the feed presented to the birds over a given period of time.

E. **Statistics:** There were no mortalities during the study. Therefore no statistical methods were employed in determination of the LC_{50} .

12. **REPORTED RESULTS:** All control and test birds were normal in appearance and behavior throughout the test period.

When compared to the control groups, there were no effects on body weight or feed consumption at any of the concentrations tested.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** Based on nominal concentrations, the dietary LC_{50} was greater than 5620 ppm. The no-mortality-concentration and no-observed-effect-concentration was 5620 ppm, the highest concentration tested.

Quality Assurance and Good Laboratory Practice statements were included in the report indicating conformance with GLP regulations as set forth in 40 CFR Part 160 with the exception that no samples of test diets were taken for laboratory analysis.

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 average relative humidity was reported for the room, but not for the brooder compartments.

The concentration of the test substance in the diet was not confirmed by chemical analysis. This is recommended, but not required.

The vehicle (acetone) was not added to the untreated diets. The control birds received the basal diet throughout the study.

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

- B. Statistical Analysis: Since there were no mortalities during the test, the LC_{50} could not be calculated. Based on nominal concentrations, the LC_{50} was greater than 5620 ppm.
- C. Discussion/Results: The study generally conforms to the recommended procedures, except for the deviations listed above. There are no data to confirm test concentrations or the stability of the test substance during the course of the study. This lack of data leads to some uncertainty that the birds received the full test concentrations reported here.

The control birds were given feed without acetone. The test birds fed at a rate comparable to that of the control birds (Tables 3 and 4, attached). It appears that the deviation did not significantly affect the results of the study.

The study is scientifically sound and meets the requirements of an LC_{50} study. Based on nominal concentrations, the LC_{50} was greater than 5620 ppm. This classifies the test material as practically non-toxic to mallard ducklings. The no-observed-effect-concentration was 5620 ppm.

- D. Adequacy of the Study:
- (1) Classification: Core.
 - (2) Rationale: N/A.
 - (3) Repairability: N/A.

15. COMPLETION OF ONE-LINER: Yes; December 17, 1993.

Dr FOK MRA) 417421-02.

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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.

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