

US EPA ARCHIVE DOCUMENT

12/2/93

DATA EVALUATION RECORD

1. **CHEMICAL:** Oxyfluorfen
Shaughnessey Number: 111601
2. **TEST MATERIAL:** GOAL® Technical; 70.2% purity; Lot No. 8159;
TD No. 86-134.
3. **STUDY TYPE:** Avian Dietary LC₅₀ Test. Species Tested:
Mallard duck (Anas platyrhynchos).
4. **CITATION:** Fletcher, D.W. 1987. ^{71-2(b) Avian Dietary / Duck} 8-Day Dietary LC₅₀ Study
with GOAL® Technical Herbicide in Mallard Ducklings. Study
performed by Bio-Life Associates, Ltd., Neillsville,
Wisconsin. Laboratory project #86 RC-0076. Submitted by
Rohm & Haas Company, Philadelphia, PA. EPA MRID No.
92136104.
5. **REVIEWED BY:**
Marise H. Robbins, M.S.E.S., M.A. Signature: *Marise H. Robbins*
Associate Scientist Date: *May 3, 1991*
KBN Engineering and Applied Sciences, Inc.
6. **APPROVED BY:**
Michael L. Whitten, M.S. Signature: *Michael L. Whitten*
Wildlife Toxicologist Date: *5-3-91*
KBN Engineering and Applied Sciences, Inc.
Henry T. Craven, M.S. *John Nolis* Signature: *Henry T. Craven*
Supervisor, EEB/HED *5/4/92* Date: *12/2/93*
USEPA
7. **CONCLUSIONS:** Based on nominal concentrations, the dietary
LC₅₀ of GOAL® was greater than 5000 ppm a.i. This value
classifies the test material as practically non-toxic to
mallard ducklings. The NOEC was 312 ppm a.i. The study is
scientifically sound and fulfills the requirements for an
avian dietary LC₅₀ test.



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 5-day-old mallard ducklings (Anas platyrhynchos) obtained from Whistling Wings, Hanover, Illinois. The ducklings were too immature to differentiate by sex. All test birds were placed on a three day quarantine period to determine their suitability for the test based on their general physical condition and to acclimatize them to the laboratory conditions. Prior to the start of the test, all birds were examined and determined to be suitable for testing.
- B. **Test System:** All birds were housed indoors by test group in a thermostatically controlled, heated environment. The pens were constructed of wire with concrete flooring. Each pen measured 45.7 cm x 61.0 cm x 45.7 cm. The photoperiod was 24 hours of fluorescent light per day. Environmental monitoring of the room was recorded daily for the maximum and minimum temperatures, as well as the relative humidity. The animal room temperatures during the 8-day test ranged from 74°F (23°C) to 84°F (29°C) with relative humidity between 67% and 91%.
- C. **Dosage:** 8-day dietary LC₅₀ test. The dietary concentrations were adjusted for purity of the test substance. Therefore, all dietary concentrations and the LC₅₀ value are reported as parts per million active ingredient (ppm a.i.). Nominal dietary dosages used in this study were 312, 625, 1250, 2500, and 5000 ppm a.i.
- D. **Design:** Groups of ten mallard ducklings were arbitrarily assigned to each of five treatment groups and five control groups. Birds were identified by group with cards affixed to the cages. The test material was incorporated into a standard laboratory diet (Ralston Purina GameBird Startena) by mixing with corn oil. The control group received a standard laboratory diet (mixed with 199 ml corn oil) only. All test diets were prepared approximately 24 hours prior to initiation of the project.

Each group was fed the appropriate test or control diet for five days. Following the five-day exposure period, all groups were given untreated feed for three days.

Three 100 gram samples were collected from test group diets immediately after they were mixed; one from the top, one from the middle, and one from the bottom. One 500 gram sample was collected from the vehicle control diet immediately after it was mixed. A one ml sample of the test material and a one ml sample of the test material premix were also retained. A quality assurance sample was retained from each level. These samples were sent to Rohm and Haas Company.

Body weights by group were measured at 0 hour on test day 1, on test day 5, and again on test day 8. Food consumption was recorded for each group at the end of the five-day test period and at the end of the three-day recovery period.

All birds were observed daily for toxicological effects. Inspections were made daily for mortalities, abundance of food and water, and food spillage. The 5000 ppm a.i. bird found dead on test day 3 was subjected to a complete post-mortem examination. At the termination of the project, four birds from the vehicle control groups and four birds from each treatment group were subjected to complete gross pathological examinations.

E. Statistics: No statistics were presented.

12. **REPORTED RESULTS:** No abnormal reactions or systemic signs of toxicity were noted in birds fed GOAL® Technical Herbicide at dietary levels of 312, 625, 1250, and 2500 ppm a.i. or in the vehicle control birds at any time during the investigation. The only sign of toxicity noted in birds receiving GOAL® Technical Herbicide at 5000 ppm a.i. was anorexia which was noted at the end of day 2. At the end of test day 3, this group remained anorexic and not as active as the others. By the close of test day 4, all birds appeared to be normal and active and remained so for the balance of the investigation.

One mortality occurred in the 5000 ppm a.i. group on test day 3 (Table III, attached). A gross post-mortem examination of this bird revealed no abnormal tissue alterations. Gross pathological examinations of four vehicle control birds and four birds from each treatment concentration on test day 8 revealed no abnormal tissue

alterations.

Mean body weights at 0 hour on test day 1 in the test groups were comparable to those of the vehicle control groups (Table IV, attached). Mean body weight gains for all treatment concentrations except 5000 ppm a.i. were comparable to the vehicle control groups' values. The mean body weight on test day 5 in the 5000 ppm a.i. test group was lower than the average vehicle control group value. The mean body weight on test day 8, as well as the overall mean body weight gain in this test group were comparable to the vehicle control groups' values.

A dose-correlated depression in food consumption values was noted during the test period in the 625 through 5000 ppm a.i. test groups (Table V, attached). The test group recovery values were equal or less than those of the vehicle control groups during the recovery phase.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:**

"The 8-day dietary LC₅₀ of GOAL® Technical Herbicide was determined to be in excess of 5000 ppm a.i."

The report stated that the study was conducted in conformance with Good Laboratory Practice regulations. Quality assurance audits were conducted and the final report was signed by the Quality Assurance Officer of Bio-life Associates, Ltd.

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

- A. **Test Procedure:** The test procedures were in accordance with Subdivision E - Hazard Evaluation: Wildlife and Aquatic Organisms, ASTM and SEP guidelines except for the following deviations:

Results of the chemical analyses of treatment diets were not presented in the report.

The guidelines recommend that pens for mallard ducks be 70 cm x 100 cm (7000 cm²). The pens in this study were only 45.7 cm x 61.0 cm (2788 cm²), which could cause crowding.

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

Guidelines recommend that test birds be phenotypically indistinguishable from wild birds. This is not stated

in the report.

According to the guidelines, the birds must be randomly assigned to the pens. In this study, "arbitrary" assignments were made.

Several details regarding the procedure and materials used in the study were found only in the protocol (Appendix A). All appropriate information should be included in the body of the report.

The guidelines recommend a relative humidity in the room of 30-80%. The relative humidity in the test ranged slightly above this, between 67 and 91%.

- B. **Statistical Analysis:** Since no birds died in the test, the LC_{50} cannot be calculated and is assumed to be greater than 5000 ppm, the highest concentration tested.
- C. **Discussion/Results:** No mortalities occurred within the control group or in the four lowest treatment groups. One mortality occurred on day 3 in the 5000 ppm a.i. group. Although the 5000 ppm a.i. birds were anorexic during days 2 and 3, no other abnormal behavior was noted. No abnormal tissue alterations were found in the dead bird or other birds that underwent a gross pathological examination at the end of the study.

The 5000 ppm a.i. group had a reduced weight gain during the first 5 days in comparison to the control birds (Table IV, attached).

Dose-correlated reduced food consumption was observed during the 5-day treatment period in birds from all treatment concentrations except the lowest concentration (312 ppm a.i., Table V attached). During the recovery period, days 6-8, all treatment concentration groups had somewhat low food consumption. It is not clear whether the food consumption values during the recovery period indicate a treatment effect.

With an LC_{50} of greater than 5000 ppm a.i. (nominal concentrations), Goal® Technical herbicide is considered to be practically non-toxic to mallard ducklings. Based on the reduced food consumption during the exposure period, the NOEC is 312 ppm a.i.

The study is scientifically sound and fulfills the

requirements for an avian dietary LC₅₀ test.

D. Adequacy of the Study:

(1) **Classification:** Core.

(2) **Rationale:** N/A.

(3) **Repairability:** N/A.

15. COMPLETION OF ONE-LINER: Yes; May 3, 1991.

RIN 0637-00

EFED Review - Oxyfluorfen

Page is not included in this copy.

Pages 7 through ~~9~~ are not included.

The material not included contains the following type of information:

- 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.
- 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.

Shaughnessey # 111601 Chemical Name Oxyfluorfen Chemical Class T Page 1 of 1

Study/Species/Lab/
MRID # _____ Chemical
% a.i. _____ Results _____ Reviewer/
Date _____ Validation
Status _____

14-Day Single Oral LD₅₀ _____ mg/kg (95% C.L.) Control Mortality (%) = _____

Species _____ Slope = _____ # Animals/Level = _____ Age (Days) = _____ Sex = _____

Lab _____
MRID # _____ 14-Day Dose Level mg/kg/(% Mortality)
() () () () () ()

Comments: _____

8-Day Dietary LC₅₀ 10.29% LC₅₀ > 5000 ppm^{9d} (—) 95% C.L. Control Mortality (%) = 0

Species Mallard duck Slope = NA # Animals/Level = 10 Age (Days) = 5
Anas platyrhynchos Sex = Immature
Lab Bio-life Associates, Ltd. 50 N/A

MRID # 92136104 8-Day Dose Level ppm^{*} (% Mortality)
312 (0), 625 (0), 1250 (0), 2500 (0), 5000 (10)

Comments: NOEC is 312 ppm a.i.

10 Based on nominal concentrations.

M. Robbins
5/3/91 CORE