

US EPA ARCHIVE DOCUMENT

## DATA EVALUATION RECORD

12/2/1993

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 LC<sub>50</sub> Test. Species Tested:  
Bobwhite quail (Colinus virginianus).
4. **CITATION:** Fletcher, D.W. 1987. 8-Day Dietary LC<sub>50</sub> Study  
with GOAL® Technical Herbicide in Bobwhite Quail. Study  
performed by Bio-Life Associates, Ltd., Neillsville,  
Wisconsin. Laboratory project #86 RC-0075. Submitted by  
Rohm & Haas Company, Philadelphia, PA. EPA MRID No.  
92136103.  
*71-2(a) Avian Dietary - Quail*
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. Signature: *Henry T. Craven*  
Supervisor, EEB/HED Date: *12/2/93*  
USEPA *John Nolas 5/5/92*
7. **CONCLUSIONS:** Based on nominal concentrations, the dietary  
LC<sub>50</sub> of GOAL® Technical herbicide was greater than 5000 ppm  
a.i., the highest concentration tested. This value  
classifies the test material as practically non-toxic to  
bobwhite quail chicks. The NOEC was 625 ppm a.i. The study  
is scientifically sound and fulfills the requirements for an  
avian dietary LC<sub>50</sub> 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 13-day-old bobwhite quail (Colinus virginianus) obtained from Thompson Quail Farm, Franksville, Wisconsin. The chicks were too immature to differentiate by sex. All test birds were placed on a two 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 mesh. 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 90°F (32°C) to 103°F (39°C) with relative humidity between 52% and 69%.
- C. Dosage: 8-day dietary LC<sub>50</sub> test. The dietary concentrations were adjusted for purity of the test substance. Therefore, all dietary concentrations and the LC<sub>50</sub> 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 bobwhite 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 Game Bird 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 26 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. 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, and 1250 ppm a.i. Food avoidance was observed on test days 3, 4, and 5 in the 2500 ppm a.i. and 5000 ppm a.i. test groups. When the birds were placed on recovery diets, it was noted that the 2500 and 5000 ppm a.i. test groups' body weights were depressed. Also, at termination, it was noted in the 5000 ppm a.i. test group that the birds appeared to be smaller. However, during the recovery period, the 2500 ppm a.i. and 5000 ppm a.i. birds appeared normal and active. All vehicle control, 312, 625, and 1250 ppm a.i. birds appeared to be normal and active throughout the test and recovery periods.

Gross pathological examinations performed on test day 8 on four vehicle control birds and four birds from each treatment level revealed no abnormal tissue alterations. No mortalities occurred during the investigation.

Mean body weights at 0 hour on test day 1 in the test groups were comparable to those of the vehicle control groups (Table III, attached). Mean body weight changes on test day

5 in the two lowest test groups were comparable to the vehicle control values. Mean body weight changes on test day 5 in the three highest test groups were depressed (dose correlated) when compared to the vehicle control groups' values. Overall mean body weight gains during the 8-day investigation in the three lowest test groups were comparable to those of the vehicle control groups' values. The gains were (dose-correlated) lower in the two highest test groups when compared to the vehicle control values.

Severe dose-correlated food consumption depressions were noted in the 2500 and 5000 ppm a.i. test groups during the test period when compared to the food consumption values in the vehicle control groups (Table IV, attached). All test groups food consumption values during the recovery periods were comparable to or greater than those of the vehicle control groups.

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

"When GOAL® Technical Herbicide was administered in the diet for five consecutive days to Bobwhite Quail, a no observable effect level was attained at a concentration of 1250 ppm a.i. The 8-day dietary LC<sub>50</sub> 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:

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

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

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 room temperature of 22-27°C during the test. The results show a range of temperatures that is above these recommended levels (32°C to 39°C). The room temperature was in the range specified for brooder temperature (35°C).

- 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:** The author contradicted himself by stating in the conclusion that the NOEC was 1250 ppm a.i., while in the results he stated that by day 5, the T-III (1250 ppm a.i.) group had a depressed body weight gain when compared to the control group.

It appears from Table III (attached) that the 1250 and 2500 ppm a.i. groups showed reduced mean body weight gains (38% and 32%, respectively) during days 0-5 of the test. The 5000 ppm a.i. group showed a weight loss by day 5. All treatment concentration groups were comparable to controls in mean body weight gain and mean food consumption during the recovery phase (days 5-8). Birds in the two highest treatment concentrations, 2500 and 5000 ppm a.i., displayed food avoidance during days 3-5 and reduced food consumption was measured during days 0-5.

With an  $LC_{50}$  of greater than 5000 ppm a.i. (nominal concentration), Goal® Technical herbicide is considered to be practically non-toxic to bobwhite quail chicks. However, food consumption was reduced at 2500 and 5000 ppm a.i., and body weight gain was reduced at 1250, 2500, and 5000 ppm a.i. These effects should be considered in a risk assessment of this chemical. Altered growth or development of birds caused by exposure to these concentrations in the wild might result in reduced survival rates. Based on reduced average body weight gain, the NOEC is 625 ppm a.i. The study is scientifically sound and fulfills the

requirements for an avian dietary LC<sub>50</sub> 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

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Pages 7 through 8 are not included.

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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.

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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.

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

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

14-Day Single Oral LD<sub>50</sub> \_\_\_\_\_ mg/kg ( \_\_\_\_\_ ) 95% C.L. \_\_\_\_\_ Control Mortality (%) = \_\_\_\_\_

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

Lab \_\_\_\_\_

14-Day Dose Level mg/kg/(% Mortality)  
( ), ( ), ( ), ( ), ( )

Comments:

MRID # \_\_\_\_\_

8-Day Dietary LC<sub>50</sub> 70.2% LC<sub>50</sub> > 5000 ppm ( --- ) 95% C.L. \_\_\_\_\_ Control Mortality (%) = 0%

Species Colinus virginianus Slope = NA # Animals/Level = 10 Age (Days) = 13  
Bobwhite quail Sex = Immature  
Bio-Life 50 N/A  
Associates

M. Robbins  
5/3/94  
CORB

8-Day Dose Level ppm/(% Mortality)  
312(0), 625(0), 1250(10), 2500(0), 5000(0)

MRID # 92136103

Comments: The NOEC is 625 ppm a.i.

\* Based on nominal concentrations

