6/4/92

DATA EVALUATION RECORD

1. CHEMICAL: Oxyfluorfen
Shaughnessey Number: 111601

2. TEST MATERIAL: Goal Technical Herbicide, Lot No. 8159, TD No. 86-134, 70.2% active ingredient.

3. STUDY TYPE: Avian single dose oral LD_{50} test.
Species Tested: Bobwhite Quail (Colinus virginianus)
71-1(a) Avian Acute — Quail

4. CITATION: Fletcher, D.W. 1987. 21-Day Acute Oral Toxicity Study with Goal Technical Herbicide in Bobwhite Quail. Study performed by Bio Life Associates, Ltd., Neillsville, Wisconsin. Laboratory Identification Number 86 QD 76. Submitted by Rohm and Haas Company, Spring House, Pennsylvania. MRID No. 92136102.

5. REVIEWED BY:

Rosemary Graham Mora, M.S.
Associate Scientist
KBN Engineering and Applied Sciences, Inc.

Signature: Rosemary Graham Mora
Date: 4/30/91

6. APPROVED BY:

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

Signature: Michael L. Whitten
Date: 4/30/91

Henry T. Craven, M.S.
Supervisor, EEB/HED
USEPA

Signature: Henry T. Craven 6/4/92
Date: Concurrence Received 6/4/92

7. CONCLUSIONS: The study is scientifically sound and meets the requirements for an avian single dose oral LD_{50} test. With an LD_{50} greater than 2150 mg a.i./kg, the test material is considered to be practically non-toxic. The NOEL could not be determined.

8. RECOMMENDATIONS: N/A.

(1)

1 hrs

9. BACKGROUND:

~~10. DISCUSSION OF INDIVIDUAL TESTS: N/A.~~

11. MATERIALS AND METHODS:

A. Test Animals: The birds used in the study were 25 to 34 week old bobwhite quail obtained from Oak Ridge Game Farm, Gravette, Arkansas. Each treatment group and the control group contained five males and five females. All birds were acclimated to the caging and facilities for 16 weeks prior to test initiation. All birds were suitable for this study.

B. Test System: All birds were housed indoors in wire pens with dimensions 53.3 cm X 45.7 cm X 38.1 cm. Fluorescent lights provided 8 hours of light per day. The temperature range was 64°F to 80°F. The relative humidity range was 64% to 86%.

C. Dosage: Single dose oral LD_{50} test. Based upon a toxicity range study, nominal dosages selected for the study were 1470 and 2150 mg a.i./kg.

D. Design: Groups of ten birds (five males and five females) were randomly assigned to each of two treatment groups and one control vehicle group. Each dosage group was assigned one pen, containing five males and five females. All bird were fed Ralston Purina GameBird Flight Conditioner. Food and water were supplied ad libitum during acclimation and during the test, except for a 19.25 hour period prior to dosing, when feed was withheld.

The test substance was administered via gavage after mixing with corn oil. Each bird was individually weighed and dosed on the basis of milligrams of active ingredient per kilogram of body weight. The control birds were administered 4 mL of corn oil.

All birds were observed at least daily for mortality and signs of intoxication. The birds were individually weighed on days 1, 3, 7, 14, and 21 (Table IV, attached). Group food consumption was determined on days 3, 7, 14, and 21 (Table V, attached).

E. Statistics: The LD_{50} was greater than 2150 mg a.i./kg, since only 10% mortality was demonstrated in the 2150 mg a.i./kg by the end of the test. Statistical analysis of body weight data was conducted using

analysis of variance.

12. ~~REPORTED RESULTS: There was no mortality in the control~~ group. All birds were normal in appearance and behavior throughout the test period.

Birds in the 1470 mg/kg and 2150 mg a.i./kg dosage groups demonstrated signs of intoxication including weakness, anorexia, piloerection, and abnormal cage droppings. All bird had completely recovered by day 7 and were normal in appearance and behavior until test termination, except one bird at 2150 mg a.i./kg which showed signs of weakness and piloerection again on day 13. This bird died on day 14 (attached, Table III). A necropsy performed on this bird revealed gas-filled intestines and severe emaciation. Other necropsies revealed only one abnormality which was, in the opinion of the author, non-treatment related.

No significant differences in group body weights were noted. Food consumption was severely depressed in the 1470 mg a.i./kg group during the first three days of the study, and in the 2150 mg a.i./kg group during the first seven days of the study.

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

The acute LD_{50} for bobwhite exposed to Goal Technical Herbicide was greater than 2150 mg a.i./kg.

The report stated that the study was conducted in conformance with Good Laboratory Practice regulations. The Compliance Statement was signed by the Study Director.

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 exceptions:

Birds were not of the same hatch. Ages of birds ranged from 25 to 34 weeks old.

A photoperiod of 10 hour light/14 hour dark was not provided. They provided 8 hour light.

Amounts of test material and diluent administered to each bird were not presented in the report. But was submitted in a later response.

B. Statistical Analysis: The LD_{50} could not be calculated

and is assumed to be greater than 2150 mg a.i./kg.

C. Discussion/Results: With an LD_{50} greater than 2150 mg a.i./kg the test material is considered practically non-toxic. Behavioral signs of toxicity were noted in birds from both treatment groups. Although not clear from the report, apparently all birds dosed with the test chemical displayed the noted signs of toxicity. Furthermore, food consumption and group body weights appear to have been reduced in both treatment groups. The author reported no significant differences in body weights, but failed to comment on the fact that 19 to 20 treatment group birds lost weight during the first three days of the study, while none of the control birds lost weight during the same period (Table IV, attached). Due to behavioral signs of toxicity, reduced body weight, and reduced food consumption in both treatment groups, the NOEL could not be determined.

The study is scientifically sound and meets the requirements for an avian single dose oral LD_{50} study.

D. Adequacy of the Study:

(1) Classification: Core.

(2) Rationale: N/A

(3) Repairability: N/A

15. COMPLETION OF ONE-LINER: Yes; March 27, 1991.

RIN 0637-00

EFED Review - Oxyfluorfen

Page____ is not included in this copy.

Pages 5 through 7 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.

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____ 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.

Shaughnessy No. 111601 Chemical Name Oxyfluorfen Chemical Class ____

Study/Species/Lab/Accession	Chemical % a.i.	Results	Reviewer/Date	Validn Stat
14-Day Single Dose Oral LD_{50} Species Colinus virginianus Lab BioLife Ltd. Acc. MRID 92136102	>2150 mg ai/kg	LD50 = >2150 ai mg/kg (95% C.L. NA) Contr. Mort.(%) = 0% Slope = — # Animals/Level = 10 Age(Days) = 182-238 Sex = 5♂ 5♀ 14-Day Dose Level mg/kg/(% Mortality) 1470 (0%), 2150 (10%), ( ), ( ), ( ) Comments: Age of birds indicate that test birds not of same hatch	RGM 3/27/91	Cor
14-Day Single Dose Oral LD_{50} Species Lab Acc.		LD50 = mg/kg. (95% C.L.) Contr. Mort.(%) = Slope = # Animals/Level = Age(Days) = Sex = 14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( ) Comments:		
8-Day Dietary LC_{50} Species Lab Acc.		LC50 = ppm (95% C.L.) Contr. Mort.(%) = Slope = # Animals/Level = Age(Days) = Sex = 8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( ) Comments:		
8-Day Dietary LC_{50} Species Lab Acc.		LC50 = ppm (95% C.L.) Contr. Mort.(%) = Slope = # Animals/Level = Age(Days) = Sex = 8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( ) Comments:		
48-Hour LC_{50} Species Lab Acc.		LC50 = pp__ (95% C.L.) Contr. Mort.(%) = Sol. Contr. Mort.(%) = Slope = # Animals/Level = Temperature = 48-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( ) Comments:		
96-Hour LC_{50} Species Lab Acc.		LC50 = pp__ (95% C.L.) Con. Mor.(%) = Sol. Con. Mor.(%) = Slope = # Animals/Level = Temp. = 96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( ) Comments:		
96-Hour LC_{50} Species Lab Acc.		LC50 = pp__ (95% C.L.) Con. Mort.(%) = Sol. Con. Mort.(%) = Slope = # Animals/Level = Temp. = 96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( ) Comments:		

8