

DP Barcode: D213874

MRID No.: 43573231

DATA EVALUATION RECORD
§ 71-1(A) - AVIAN SINGLE-DOSE LD₅₀ TEST

5/30/1995

1. CHEMICAL: RPA 201772 (Isoxaflutole) PC Code No.: 123000

2. TEST MATERIAL: Batch No. 21 ADM 93 Purity: 98.7%

3. CITATION Authors: Petersen, C.A. and S.M. Thompson
Title: 14 Day Acute Oral LD₅₀ Study in Bobwhite Quail

Study Completion Date: March 15, 1994

Laboratory: Bio-Life Associates, Ltd

Sponsor: Rhone-Poulenc Ag Company

Laboratory Report ID: BLAL # 108-025-03

MRID No.: 435732-31

4. REVIEWED BY: Michael Davy, Agronomist, ERCB, EFED

Signature: Michael Davy

Date: 5-25-95

5. PEER REVIEWER: Francis Mastrola, ERCB, EFED

Signature: F. Nicholas Mastrola

Date: 5-30-95

6. STUDY PARAMETERS

Scientific Name of Test Organism: *Colinus virginianus*

Test Organisms Age/Size: 26 weeks old

Definitive Study Duration: 14 days

7. CONCLUSIONS: This study is scientifically sound and meets all guideline requirements for 71-1 Avian Acute LD₅₀ Oral Dose. This herbicide is considered to be practically non-toxic to bobwhite quails with LD₅₀ > 2150 mg/kg and NOEL > 2150 mg/kg.

8. ADEQUACY OF THE STUDY

A. Classification: Core

B. Rationale: N/A

C. Repairability: n/a

9. GUIDELINE DEVIATIONS: None noted.

10. SUBMISSION PURPOSE: EUP

11. MATERIALS AND METHODS**A. Test Organisms**

Guideline Criteria	Reported Information
Species: A wild waterfowl species, preferably the mallard (<i>Anas platyrhynchos</i>), or an upland game bird species, preferably the bobwhite (<i>Colinus virginianus</i>).	Bobwhite quail
Age at beginning of test: At least 16 weeks old.	52 weeks
Supplier	Oak Ridge Game Farms
Acclimation period: At least 15 days.	60 days

B. Test System

Guideline Criteria	Reported Information
Pen facilities adequate?	61 x 53 x 38 cm pens, Yes
Photoperiod: 10-h light, 14-h dark	10 hour light, 14 hour dark
Diet was nutritious and appropriate for species?	Yes
Feed withheld at least 15 hours prior to dosing?	Yes, 20 hours

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	Yes
Definitive Test Nominal concentrations: At least five, in a geometric scale, unless $LD_{50} > 2000$ mg ai / kg.	control, 464 mg/kg, 681 mg/kg, 1000 mg/kg, 1470 mg/kg, 2150 mg/kg
Controls: Water control or vehicle control (if vehicle is used)	empty gelatin capsules
Number of birds per group: 10 (strongly recommended)	5 male and 5 female
Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	gelatin capsules
Amount of vehicle per body weight: Constant volume/weight % of body weight, not to exceed 1% (1ml/100g).	nil
Observations period: At least 14 days.	14 days

12. REPORTED RESULTS

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Individual body weights measured at beginning of test, on day 14 and at end of test if extended beyond 14 days?	Yes
Mean feed consumption measured at beginning of test, on day 14, and at end of test if extended beyond 14 days?	Yes
Control Mortality: Not more than 10%	0 %
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes

Mortality

Dosage (mg/kg)	No. of Birds	Cumulative Number of Dead							
		Day of Study							
		1	2	3	4	5	6-8	9-11	12-14
Control	10	0	0	0	0	0	0	0	0
464	10	0	0	0	0	0	0	0	0
681	10	0	0	0	0	0	0	0	0
1000	10	0	0	0	0	0	0	0	0
1470	10	0	0	0	0	0	0	0	0
2150	10	0	0	0	0	0	0	0	0

Other Significant Results: Feed consumption is normal and no gross observations or mortalities noted.

Reported Statistical Results

Statistical Method: observational

LD₅₀: > 2150 mg/kg

NOEL: >2150 mg/kg

13. Verification of Statistical Results

Statistical Method: observational

LD₅₀: >2150 mg/kg

NOEL: >2150 mg/kg

- 15. REVIEWER'S COMMENTS:** This study is scientifically sound and meets all guideline requirements for 71-1 Avian Acute LD₅₀ Oral Dose. This herbicide is considered to be practically non-toxic to bobwhite quails with LD₅₀ > 2150 mg/kg and NOEL >2150 mg/kg.

ISOXAFLOL Review 123000

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