US ERA ARCHIVE DOCUMENT

DATA EVALUATION RECORD § 71-2(A) -- UPLAND GAME BIRD DIETARY LC₅₀ TEST 5 30 1985

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.

Title: 8 Day Acute Dietary LC₅₀ Study in Bobwhite

Quail

Study Completion Date: May 25, 1994

Laboratory: Bio-Life Associates, Ltd

Sponsor: Rhone-Poulenc Ag Company

Laboratory Report ID: BLAL # 108-023-01

MRID No.: 435732-33

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

Signature: Muchael Jamy Date: 5-25-95

5. PEER REVIEWER: Francis Mastrota, ERCB, EFED

Signature: F. Micholas Mastrota Date: 5-30-95

6. STUDY PARAMETERS

Scientific Name of Test Organism: Colinus virginianus Age of Test Organisms at Test Initiation: 10 days old Definitive Study Duration: 8 days

7. <u>CONCLUSIONS</u>: This study is scientifically valid and meets all the guidelines for avian acute dietary study.

Results Synopsis

 LC_{50} : >4255 ppm ai NOEL: >4255 ppm ai

8. ADEQUACY OF THE STUDY

A. Classification: Core

B. Rationale: meets guidelines

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: An upland game bird species, preferably the bobwhite (Colinus virginianus). | Colinus virginianus |
| Age at beginning of test: 10-14 days old. | 10 days |
| Supplier | Oak Ridge Game Farm |
| Chicks appeared healthy and did not have excessive mortality before the test? | Yes |
| Acclimation period: As long as possible. | 9 days |

B. Test System

| Guideline Criteria | Reported Information |
|---|---------------------------|
| Pen size: about 35 x 100 x 24 cm | 28" x 36" x 11" |
| Brooder temperature: about 35°C (95°F) | 38°C dry bulb |
| Room temperature: 22-27°C (71-81°F) | 24°C _, |
| Relative humidity: 30-80% | 35-36% |
| Adequate ventilation? | Yes |
| Photoperiod Minimum of 14 h of light. | 24 hour |
| Diet: A commercial diet for game birds. | Purina Game Bird Startena |

C. Test Design

| Guideline Criteria | Reported Information |
|--|--------------------------------|
| Range finding test? | Yes |
| Definitive Test Nominal concentrations: Four minimum in a geometric scale, unless LC ₅₀ > 5000 ppm. | 312, 625, 1250, 2500, 5000 ppm |
| Controls: Control group tested with diet containing the maximum amount of vehicle used in treated diets? | Yes |
| Number of birds per group: 10 (strongly recommended) | 10 |
| Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic. | no vehicle used |
| Vehicle amount (% of diet by weight): Not more than 2% | not applicable |
| Test durations: 5 days with treated feed and at least 3 days observation with "clean" feed. | yes |
| No mortality during last 72 hr of observations? | NONE |

12. REPORTED RESULTS

| Guideline Criteria | Reported Information |
|--|----------------------|
| Quality assurance and GLP compliance statements were included in the report? | Yes |
| Body weights measured at beginning and end of study? | Yes |
| Estimated consumption per pen reported for pretreatment, treatment, and observation periods? | Yes |
| Control Mortality: Not more than 10% | none |
| Raw data included? | Yes |
| Signs of toxicity (if any) were described? | Yes, excoriation |

Mortality

| LIOI CULTEY | , , | | | a | | a Nicolai | | £ Das | , a | |
|-------------|------------------|-------------|---------------------------|---|---|-----------|---|-------|-----|----|
| Conc. | (ppm) | | Cumulative Number of Dead | | | | | | | |
| | | No. | No. Day of Study | | | | | | | |
| Nominal | Mean Measured | of Birds | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Control | 0 | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 312 | 284 | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 625 | 451 | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1250 | 793 | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2500 | 2590 | 10 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 |
| 5000 | 4255 | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0. |

Other Significant Results: One death in 2500 ppm group is result of excoriation and is considered not to be related to the chemical. "Average body weight, body weight changes and feed consumption were reduced in the 2500 ppm test group. Values for these parameters were considered to be normal in all other test groups when compared to the control."

Statistical Results

Statistical Method: observational LC_{50} : >5000 ppm NOEL: >5000 ppm

13. Verification of Statistical Results

Statistical Method: observational using mean measured concentrations LC_{50} : >4255 ppm ai NOEL: >4255 ppm ai

14. <u>REVIEWER'S COMMENTS</u>: This study is scientifically valid and meets all the guidelines for avian acute dietary study.

| Isoxaflutole Review 123000 |
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