

US EPA ARCHIVE DOCUMENT

DP Barcode: D213874

MRID No.: 435732-34

DATA EVALUATION RECORD
§ 71-2(B) -- WATERFOWL DIETARY LC₅₀ 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.
Title: 8 Day Acute Dietary LC₅₀ Study in Mallard Ducklings

Study Completion Date: May 25, 1994

Laboratory: Bio-Life Associates, Ltd

Sponsor: Rhone-Poulenc Ag Company

Laboratory Report ID: BLAL # 108-024-02

MRID No.: 435732-34

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

Signature: Michael Davy

Date: 5-25-95

5. PEER REVIEWER: Francis Mastrotta, ERCB, EFED

Signature: F. Nicholas Mastrotta

Date: 5-30-95

6. STUDY PARAMETERS

Scientific Name of Test Organism: *Anas platyrhynchos*

Age of Test Organisms at Test Initiation: 5 days old

Definitive Study Duration: 8 days

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

Results Synopsis

LC₅₀: >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: A wild waterfowl species, preferably the mallard (<i>Anas platyrhynchos</i>).	<i>Anas platyrhynchos</i>
Age at beginning of test: 5-10 days old (preferably 5)	5 days
Supplier	Whistling Wings
Chicks appeared healthy and did not have excessive mortality before the test?	Yes
Acclimation period: As long as possible.	2 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)	36°C dry bulb
Room temperature: 22-27°C (71-81°F)	24°C
Relative humidity: 30-80%	38%
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

Guideline Criteria	Reported Information
Control Mortality: Not more than 10%	none
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes, excoriation

Mortality

Conc. (ppm)		No. of Birds	Cumulative Number of Dead								
Nominal	Mean Measured		Day of Study								
			1	2	3	4	5	6	7	8	
Control	0	10	0	0	0	0	0	0	0	0	0
312	284	10	0	0	0	0	0	0	0	0	0
625	451	10	0	0	0	0	0	0	0	0	0
1250	793	10	0	0	0	0	0	0	0	0	0
2500	2590	10	0	0	1	1	1	1	1	1	1
5000	4255	10	0	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
 LC₅₀: >5000 ppm NOEL: >5000 ppm

13. Verification of Statistical Results

Statistical Method: observational using mean measured concentrations
 LC₅₀: >4255 ppm ai NOEL: >4255 ppm ai

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

ISOXAFLOTOLE REVIEW 123000

Page is not included in this copy.

Pages 5 through 8 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.
