10-20-95

DP Barcode: D219266 MRID No.: 437766-02

DATA EVALUATION RECORD
§ 71-1(~~A~~ B) - AVIAN SINGLE-DOSE LD_{50} TEST

1. **CHEMICAL:** Fipronil PC Code No.:129121

2. **TEST MATERIAL:** MB 46513 (Photodegredate) Purity: 99.7 %

3. **CITATION: see title**
Authors: B.R. Helsten and A.M. Solatycki
Title: 14-Day Acute Oral LD50 Study with MB46513 in Mallard Ducks.
Study Completion Date: 8/10/94
Laboratory: Bio-Life
Sponsor: Rhone-Poulenc Ag Co.
Laboratory Report ID: BLAL no. 108-027-04
MRID No.: 437766-02

4. **REVIEWED BY:** N.E. Federoff (Wildlife Biologist) EEB, EFED
Signature: N.E. Federoff **Date:** 10/20/95

5. **APPROVED BY:** Ann Stavola, Head, Section (5), EEB, EFED
Signature: Ann Stavola **Date:** 10/20/95

6. **STUDY PARAMETERS**

Scientific Name of Test Organism: (Anas platyrhynchos)
Test Organisms Age/Size: 26 weeks of age at test initiation.
Definitive Study Duration: 14 days

7. **CONCLUSIONS:** The study was scientifically sound and fulfills guideline requirements for an avian acute oral study. With an LD50 of 420 mg ai/kg, MB46513 is moderately toxic to waterfowl.

Results Synopsis
LD_{50}: 420 mg ai/kg 95% C.I.: 298-581 mg ai/kg
LOEL: 147 mg ai/kg Probit Slope: 3.34

8. **ADEQUACY OF THE STUDY**

A. Classification: Core
B. Rationale: N/A
C. Repairability: N/A

9. **GUIDELINE DEVIATIONS**

1. No NOEL was obtained.

10. **SUBMISSION PURPOSE:** Registration

11. **MATERIALS AND METHODS**

A. Test Organisms

Guideline Criteria	Reported Information
Species: A wild waterfowl species, preferably the mallard (*Anas platyrhynchos*), or an upland game bird species, preferably the bobwhite (*Colinus virginianus*).	Mallard Duck
Age at beginning of test: At least 16 weeks old.	26 weeks
Supplier	Whistling Wings
Acclimation period: At least 15 days.	70 days

B. Test System

Guideline Criteria	Reported Information
Pen facilities adequate?	122x122x122 cm steel wire pens
Photoperiod: 10-h light, 14-h dark is recommended.	10L/14D
Diet was nutritious and appropriate for species?	Yes
Feed withheld at least 15 hours prior to dosing?	Yes/21.5 hrs

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Other Significant Results: Clinical signs noted included lack of coordination, convulsions, lethargy, chalky droppings, and death as well as reductions in bodyweight and food consumption.

Reported Statistical Results

Statistical Method: Litchfield and Wilcoxon

LD_{50}: 437 mg/kg 95% C.I.: 332-576 mg/kg

NOEL: Not achieved Probit Slope: 1.88

13. Verification of Statistical Results

Statistical Method: Probit

LD_{50}: 420 mg/kg 95% C.I.: 298-581 mg/kg

LOEL: 147 mg/kg Probit Slope: 3.34

14. REVIEWER'S COMMENTS: None

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N.E.Federoff FIPRONIL MB46513 ACUTE ORAL LD50 (MALLARD)

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
2150	10	10	100	9.765625E-02
1470	10	10	100	9.765625E-02
1000	10	9	90	1.074219
464	10	4	40	37.69531
215	10	2	20	5.46875
147	10	1	10	1.074219

THE BINOMIAL TEST SHOWS THAT 147 AND 1000 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 533.6925

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
4	.118332	423.8456	302.661	574.3138

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
5	.1517387	1	.780214

SLOPE = 3.340668

95 PERCENT CONFIDENCE LIMITS = 2.039356 AND 4.64198

LD50 = 420.4598

95 PERCENT CONFIDENCE LIMITS = 297.5286 AND 581.2357

LC10 = 175.2109

95 PERCENT CONFIDENCE LIMITS = 85.96451 AND 255.403

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* THESE DATA CHARACTERIZE FIPRONIL MB46513 AS BEING MODERATELY TOXIC TO WATERFOWL ON AN ACUTE ORAL BASIS. - N.E. FEDEROFF

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	Yes
<u>Definitive Test</u> **Nominal concentrations:** At least five, in a geometric scale, unless LD_{50} > 2000 mg ai / kg.	147,215,464,1000,1470, and 2150 mg/kg
Controls: Water control or vehicle control (if vehicle is used)	Gelatin capsule
Number of birds per group: 10 (strongly recommended)	10 (5M/5F)
Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	None
Amount of vehicle per body weight: Constant volume/weight % of body weight, not to exceed 1% (1ml/100g).	N/A
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
147	10	0	1	1	1	1	1	1	1
215	10	0	1	2	2	2	2	2	2
464	10	1	2	3	3	4	4	4	4
1000	10	3	8	9	9	9	9	9	9
1470	10	4	9	10	10	10	10	10	10
2150	10	8	10	10	10	10	10	10	10

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