10-20-95

DP Barcode: D219266 MRID No.: 437766-01

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

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

2. **TEST MATERIAL:** MB 46513 (Photodegredate)
Purity:98.6 %

3. **CITATION:** 21-Day Acute Oral LD50 Study In Bobwhite Quail.
Authors: C.A Pedersen and A.M. Solatycki
Title: see citation
Study Completion Date: 6/25/93
Laboratory: Bio-Life
Sponsor: Rhone-Poulenc Ag Company
Laboratory Report ID: 108-017-03
MRID No.: 437766-01

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: Colinus virginianus
Test Organisms Age/Size: 20 weeks of age
Definitive Study Duration: 21 days

7. **CONCLUSIONS:** This study is scientifically sound and fulfills guideline requirements for an acute oral study. With an LD50 of 5 mg/kg, MB 46513 is very highly toxic to upland gamebirds.

Results Synopsis
LD_{50}: 5 mg ai/kg 95% C.I.: 2.44-12 mg ai/kg
NOEL: 3.16 mg ai/kg Probit Slope: 3.62

8. **ADEQUACY OF THE STUDY**

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

9. **GUIDELINE DEVIATIONS**

1.

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*).	Bobwhite Quail
Age at beginning of test: At least 16 weeks old.	20 weeks
Supplier	Sand Prairie Quail Farm, IA.
Acclimation period: At least 15 days.	32 days

B. Test System

Guideline Criteria	Reported Information
Pen facilities adequate?	Yes in 61x53.3x38.1 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 hrs

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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.	31.6, 14.7, 6.81, 3.16, and 1.47 mg ai/kg
Controls: Water control or vehicle control (if vehicle is used)	Vehicle
Number of birds per group: 10 (strongly recommended)	10
Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	Evaporated Acetone in gelatin capsules
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.	21 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%	10%
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes

Mortality

Dosage (mg/kg)	# of Birds	Cumulative Number of Dead								
		Day of Study								
		1	2	3	4	5	6-8	9-11	12-14	15-21
control	10	0	0	0	0	0	0	0	1	1
1.47	10	0	0	0	0	0	0	0	0	0
3.16	10	0	0	0	0	0	1	2	2	4
6.81	10	0	0	0	0	0	0	0	0	0
14.7	10	0	0	1	1	1	4	4	6	6
31.6	10	1	1	2	3	3	7	9	10	10

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Other Significant Results: Reduced feed consumption was noted in all but the 1.47 mg/kg group. A significant reduction in body weight was noted in the 14.7 and 31.6 mg/kg groups on day 7 of the test. Chalky excreta was noted in all test groups.

Reported Statistical Results

Statistical Method: Litchfield and Wilcoxon

LD_{50}: 5.41 mg/kg 95% C.I.: 2.44-12 mg/kg

NOEL: 3.16 mg/kg Probit Slope: 3.62

13. Verification of Statistical Results

Statistical Method: Moving Average Method

LD_{50}: 10 mg/kg 95% C.I.: 7.09-15.57 mg/kg

NOEL: 3.16 mg/kg Probit Slope: N/A

15. REVIEWER'S COMMENTS: Conclusions were based on reported values, which were more toxic than EEB's results.

NOTE: THERE WAS CONTROL MORTALITY, BUT AT LEAST ONE
OF THE LOWER CONCENTRATIONS HAD ZERO MORTALITY.
THEREFORE, ABBOTT'S CORRECTION IS NOT APPLICABLE.

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

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
31.6	10	10	100	9.765625E-02
14.7	10	6	60.00001	37.69531
6.81	10	0	0	9.765625E-02
3.16	10	4	40	37.69531
1.47	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 1.47 AND 31.6 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 13.33347

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LD50	95 PERCENT CONFIDENCE LIMITS	
4	.1141993	10.00133	7.091886	15.56951

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
5	2.734219	4.643244	3.002226E-03

SINCE THE PROBABILITY IS LESS THAN 0.05, RESULTS CALCULATED
USING THE PROBIT METHOD PROBABLY SHOULD NOT BE USED.

SLOPE = 2.294582
95 PERCENT CONFIDENCE LIMITS =-1.499618 AND 6.088783

LC50 = 9.837345
95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

LC10 = 2.750428
95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

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* THESE DATA CHARACTERIZE FIPRONIL MB46513 AS BEING HIGHLY TOXIC TO UPLAND GAMEBIRD SPECIES ON AN ACUTE ORAL BASIS. - N.E. FEDEROFF