42245201
MRID No.

067701
Shaughnessy No.

Data Evaluation Record

Diphacinone

Avian (Bobwhite quail) Acute Toxicity Test
Guideline 71-1.

1. TEST MATERIAL: Diphacinone

2. STUDY MATERIAL - Diphenylacetyl -1. -3, -indandione 96.9 %.

3. STUDY TYPE - Avian Dietary Single-dose Oral LD_{50}.

   Species tested- Bobwhite quail (*Colinus virginianus*).

4. STUDY IDENTIFICATION:

   Campbell, S., K.A. Hoxter, and G.J. Smith. 1991. An acute oral toxicity study with the Northern bobwhite. Wildlife International, 301 Commerce Drive, 301 Commerce Drive, Easton, MD 21601. Proj. No. 284-103. Submitted by Bell Laboratories, Inc, 3699 Kinsman Blvd., Madison, WI 53704. MRID 422452-01. D177986 S417455 Case Number 819047.

5. REVIEWED BY:

   James J. Goodyear
   Biologist, Section 1
   Ecological Effects Branch
   Environmental Fate and Effects Division (H7507C)

   Signature: James Goodyear
   Date: July 22, 1992

6. APPROVED BY:

   Leslie W. Touart
   Head, Section 1
   Ecological Effects Branch
   Environmental Fate and Effects Division (H7507C)

   Signature: L. W. T.
   Date: 8-3-92

7. CONCLUSIONS:

   The study is scientifically valid but does not meet the guideline requirements for the reregistration of Diphacinone because of an unacceptable confidence interval. $LD_{50} \geq 1630$ mg/kg. NOEL ≥ 80 mg/kg. If the results were valid Diphacinone would be categorized as being slightly toxic to Bobwhite quail when administered as a single dose.

8. RECOMMENDATIONS- N/A.

9. BACKGROUND- Submission of studies for reregistration.

10. DISCUSSION OF INDIVIDUAL TEST- N/A.

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11. MATERIALS AND METHODS:

A. TEST ANIMALS:

Bobwhite quail (*Colinus virginianus*) were obtained as immatures from Fritts' Quail Farm, RD#3, Box 362, Phillipsburg, NJ 08865 and raised until they were 25 weeks old (160 to 212 g) at the test's start.

B. DOSE:

The groups were given 0.64, 3.2, 16, 80, 400, and 2,000 mg/kg dissolved in corn oil. The geometrically spaced dosages were based upon known toxicity data and the known mode of action Diphacinone. The ten controls were given only 6 ml/kg of corn oil.

C. DESIGN:

Five males and five females were randomly assigned to each of the experimental and control groups. The birds were acclimated for three weeks and fasted for 18 hours before the test began.

The birds were put into pen by random draw. The bases of the pens were 78 X 51 cm and the height varied under a slopping roof from 20 to 25 cm. The "average temperature . . . was 22° C ± 3° C (SD) with an average relative humidity of 5% ± 14% (SD) (range 28% to 84%)," but the schedule for making these measurements was not given. The photoperiod was 8 hours of light per day.

"The study was conducted over a 21-day period because of the mode of action (anticoagulant) of the test substance. A record was maintained of all mortality, signs of toxicity, or abnormal behavior."

The body weights were measured individually at the start of the test and by groups on Days -3, -7, -14, and -21. Feed consumption was estimated on for Days 0-3, 4-7, 8-14, and 15-21 by measuring the change in the weight of the food presented.

"Experimental termination: June 1, 1990. Study completion: March 19, 1991."

D. STATISTICS-

Stephan, 1978. The binomial probability method was used.

12. REPORTED RESULTS:

There were no control mortalities.

$LD_{50} \geq 1630$ mg/kg. NOEL $\geq$ 80 mg/kg.

13. STUDY AUTHORS' CONCLUSIONS/QA MEASURES:

"The acute oral LD_{50} for northern bobwhite exposed to Diphacinone Technical as a single oral dosage was approximately 1630 mg/kg. The LD_{50} value was obtained by nonlinear interpolation between 400 mg/kg and 2000 mg/kg. The no-mortality level was 400 mg/kg. The no-observed-effect level was 80 mg/kg. The no-observed-effect

level was 80 mg/kg based upon the signs of toxicosis noted at the 400 mg/kg dosage."

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This study was conducted so as to conform with the Good Laboratory Practice Standards as published by the U.S. Environmental Protection Agency . . .

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF THE STUDY:

A. TEST PROCEDURES:

The test concentrations were a series of 5X dilutions of the previous dose. The recommended gradation is 1.6X. The highest level was too low.

B. STATISTICAL ANALYSIS:

Stephan, 1978.

C. DISCUSSION/RESULTS:

The wide separation of the levels is not disqualifying for a study, but it has led to unacceptable statistical results (C.I. 0 to ∞).

D. ADEQUACY OF THE STUDY:

Classification- Supplemental.

Rationale- Standard deviation is 0 to ∞.

Repair- Justify the confidence interval.

15. COMPLETION OF ONE-LINER FOR STUDY- Yes.

16. CBI APPENDIX- N/A.

LITERATURE CITED

Stephan, C.E. 1977. Methods for calculating an LC_{50}. in, Aquatic Toxicology and Hazard Evaluation. ASTM STP 634. F.L. Mayer and J.L. Hamelink, Eds. American Society for Testing and Materials. pp. 65-84.

JAMES J GOODYEAR DIPHACINONE BOBWHITE 07-22-92

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
2000	10	6	60	37.69531
400	10	0	0	9.765625E-02
80	10	0	0	9.765625E-02
16	10	0	0	9.765625E-02
3.2	10	0	0	9.765625E-02
.64	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 0 AND +INFINITY 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 1630.79

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

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