

US EPA ARCHIVE DOCUMENT

MRID No. 438789-01

DATA EVALUATION RECORD
S 71-1 - AVIAN SINGLE-DOSE LD₅₀ TEST

1. **CHEMICAL:** Diphenylamine PC Code No.: 038501

2. **TEST MATERIAL:** Diphenylamine Purity: 100%

3. **CITATION:**

Authors: S.J. Palmer and J.B. Beavers
Title: Diphenylamine: An Acute Oral Toxicity
 Study with the Northern Bobwhite

Study Completion Date: December 20, 1995

Laboratory: Wildlife International Ltd., Easton, MD

Laboratory Report ID: 436-102

Sponsor: Diphenylamine Task Force, c/o John Wise &
 Associates, Ltd., Liberty, MO

MRID No.: 438789-01

DP Barcode: D222425

4. **REVIEWED BY:** Mark A. Mossler, M.S., Toxicologist,
 KBN Engineering and Applied Sciences, Inc.

Signature: *Mark A. Mossler*

Date: 7/20/96

APPROVED BY: Pim Kosalwat, Ph.D., Senior Scientist,
 KBN Engineering and Applied Sciences, Inc.

Signature: *P. Kosalwat*

Date: 8/20/96

5. **APPROVED BY:**

Signature: *Richard M. Lee*

Date: 5/27/97

6. **STUDY PARAMETERS:**

Scientific Name of Test Organism: *Colinus virginianus*

Test Organisms Age/Size: 22 weeks/180-218 g

Definitive Study Duration: 14 days

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements for an acute oral toxicity test using bobwhite quail. The LD₅₀ was >2250 mg ai/kg, which classifies diphenylamine as practically non-toxic to the bobwhite quail.

Results Synopsis

LD₅₀: >2250 mg ai/kg
 NOEL: 1350 mg ai/kg

95% C.I.: N/A
 Probit Slope: N/A



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8. ADEQUACY OF THE STUDY:

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

9. GUIDELINE DEVIATIONS: None noted.

10. SUBMISSION PURPOSE:

11. MATERIALS AND METHODS:

A. Test Organisms

Guideline Criteria	Reported Information
Species: A wild waterfowl species, preferably the mallard (<i>Anas platyrhynchos</i>), or an upland game bird species, preferably the bobwhite (<i>Colinus virginianus</i>).	<i>Colinus virginianus</i>
Age at beginning of test: At least 16 weeks old.	22 weeks
Supplier	Top Flight Quail Farm, Belvidere, NJ
Acclimation period: At least 15 days.	4 weeks

B. Test System

Guideline Criteria	Reported Information
Pen facilities adequate?	Yes
Photoperiod: 10-h light, 14-h dark is recommended.	8-h light, 16-h dark
Diet was nutritious and appropriate for species?	Yes

Guideline Criteria	Reported Information
Feed withheld at least 15 hours prior to dosing?	Yes

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	No, test dosages based on known toxicity values
Definitive Test Nominal concentrations: At least five, in a geometric scale, unless LD ₅₀ > 2000 mg ai/kg.	292, 486, 810, 1350, and 2250 mg ai/kg
Controls: Water control or vehicle control (if vehicle is used)	Vehicle control
Number of birds per group: 10 (strongly recommended)	10, 5 male and 5 female
Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	Corn oil
Amount of vehicle per body weight: Constant volume/weight % of body weight, not to exceed 1% (1 ml/100 g).	6 ml/kg of body weight
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

Guideline Criteria	Reported Information
Individual body weights measured at beginning of test, on day 14 and at end of test if extended beyond 14 days?	Yes, individual body weights measured at initiation, day 3, day 7, and day 14 of the test
Mean feed consumption measured at beginning of test, on day 14, and at end of test if extended beyond 14 days?	Yes, food consumption measured on days 3, 7 and 14 of the test
Control Mortality: Not more than 10%	0%
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes

Mortality

Dosage (mg ai/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
292	10	0	0	0	0	0	0	0	0
486	10	0	0	0	0	0	0	0	0
810	10	0	0	0	0	0	0	0	0
1350	10	0	0	0	0	0	0	0	0
2250	10	0	0	0	0	0	0	0	0

Other Significant Results: No signs of toxicity were observed in either the control or treatment groups.

A treatment-related loss in body weight was observed among males at the highest dosage level. There were no treatment-related reductions in feed consumption.

Reported Statistical Results

Statistical Method: visual inspection

LD₅₀: >2250 mg ai/kg 95% C.I.: N/A
NOEL: 1350 mg ai/kg Probit Slope: N/A

13. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method: visual inspection

LD₅₀: >2250 mg ai/kg 95% C.I.: N/A
NOEL: 1350 mg ai/kg Probit Slope: N/A

14. REVIEWER'S COMMENTS: This study is scientifically sound and fulfills the guideline requirements for an acute oral toxicity test using bobwhite quail. The LD₅₀ was >2250 mg ai/kg, which classifies diphenylamine as practically non-toxic to the bobwhite quail. The NOEL was 1350 mg ai/kg based on reduction in body weight gain among males at the highest dosage level. The study is classified as **Core**.

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