

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**.