DATA EVALUATION RECORD
§ 71-2 - WATERFOWL DIETARY LC_{50} 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: A Dietary LC_{50} Study with the Mallard
Study Completion Date:	December 20, 1995
Laboratory:	Wildlife International Ltd., Easton, MD
Laboratory Report ID:	436-101
Sponsor:	Diphenylamine Task Force, c/o John Wise & Associates, Ltd., Liberty, MO
MRID No.:	438791-01
DP Barcode:	D222425

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

Signature: M A Mossler **Date:** 8/20/96

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 N-Lee **Date:** 5/22/97

6. **STUDY PARAMETERS:**

Scientific Name of Test Organism: *Anas platyrhynchos*
Age of Test Organisms at Test Initiation: 10 days
Definitive Study Duration: 8 days

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements for an acute dietary toxicity test using the mallard duck. Based on the mean measured concentration, the LC_{50} was greater than 5205 ppm ai, which classifies diphenylamine as practically non-toxic to the mallard duck.

Results Synopsis

LC_{50}:	>5205 ppm ai	95% C.I.:	N/A
NOEC:	5205 ppm ai	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, preferable the mallard (*Anas platyrhynchos*).	*Anas platyrhynchos*
Age at beginning of test: 5-10 days old (preferably 5).	10 days old
Supplier	Whistling Wings, Hanover, IL
Ducklings appeared healthy and did not have excessive mortality before the test?	Birds appeared in good health at the initiation of testing
Acclimation period: As long as possible.	8 days

   B. Test System

Guideline Criteria	Reported Information
Pen size: about 70 x 100 x 24 cm	62 x 92 x 26 cm
Brooder temperature: about 35°C (95°F)	30 ±1°C
Room temperature: 22-27°C (71-81°F)	22 ±1°C
Relative humidity: 30-80%	55 ±10%

Guideline Criteria	Reported Information
Adequate ventilation?	Housing and husbandry based on NIH guidelines
Photoperiod Minimum of 14 h of light.	16 hours of light per day
Diet: A commercial waterfowl feed.	In-house game bird diet

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	No, test concentrations based on known toxicity values
Definitive Test **Nominal concentrations:** Four minimum, 5 or 6 strongly recommended, in a geometric scale, unless LC_{50} > 5000 ppm.	562, 1000, 1780, 3160, and 5620 ppm ai
Controls: Control group tested with diet containing the maximum amount of vehicle used in treated diets?	3 control groups; control diet contained the same amount of vehicle as that in the treated diets
Number of birds per group: 10 (strongly recommended)	10 birds per group
Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	Corn oil and acetone
Vehicle amount (% of diet by weight): Not more than 2%	2% corn oil; acetone was allowed to volatilize during mixing
Test durations: 5 days with treated feed and at least 3 days observation with "clean" feed.	Yes
No mortality during last 72 hr of observations?	No mortality in any group

12. **REPORTED RESULTS:**

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Body weights measured at beginning and end of study?	Yes, group body weights measured at initiation, day 5, and termination of the test
Estimated consumption per pen reported for pretreatment, treatment, and observation periods?	Pretreatment feed consumption values were not reported.
Control Mortality: Not more than 10%	No control mortality
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes

Mortality

Conc. (ppm ai)		No. of Birds	Cumulative Number of Dead							
			Day of Study							
Nominal	Mean Measured		1	2	3	4	5	6	7	8
Control	<10	30	0	0	0	0	0	0	0	0
562	504	10	0	0	0	0	0	0	0	0
1000	893	10	0	0	0	0	0	0	0	0
1780	1580	10	0	0	0	0	0	0	0	0
3160	2920	10	0	0	0	0	0	0	0	0
5620	5205	10	0	0	0	0	0	0	0	0

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

There did not appear to be a reduction in body weight gain or feed consumption when the treatment group values for each were compared to the control group values.

Statistical Results

Statistical Method: Visual interpretation (based on nominal concentration)

LC_{50}: >5620 ppm ai 95% C.I.: N/A
NOEC: 5620 ppm ai Probit Slope: N/A

13. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method: Visual interpretation (based on mean measured concentration)

LC_{50}: >5205 ppm ai 95% C.I.: N/A
NOEC: 5205 ppm ai Probit Slope: N/A

14. REVIEWER'S COMMENTS: This study is scientifically sound and fulfills the guideline requirements for an acute dietary toxicity test using the mallard. The LC_{50} was greater than 5205 ppm ai, which classifies diphenylamine as practically non-toxic to the mallard duck. The NOEC was determined to be 5205 ppm ai. The study is classified as **Core**.