

DP Barcode: D237791

MRID No.: 442873-03

DATA EVALUATION RECORD

§ 71-2(B) -- WATERFOWL DIETARY LC₅₀ TEST1. CHEMICAL: 2-chloro-4,6-bis(isopropylamino)-s-triazinePC Code No.: 0808082. TEST MATERIAL: PropazinePurity: 98%3. CITATIONAuthors: C.E. Jameson; J. VeltriTitle: Acute dietary toxicity of propazine to mallard ducks (*Anas platyrhynchos*)Study Completion Date: 3/13/95Laboratory: ABC Laboratories, Inc.Sponsor: Griffin CorporationLaboratory Report ID: ABC #41759MRID No.: 442873-034. REVIEWED BY: Thomas M. Steeger, Ph.D., Fishery Biologist, EFED, ERB IV, U.S. EPASignature: *Thomas M. Steeger*Date: *10/12/98*5. APPROVED BY: Ann Stavola, Aquatic Biologist, EFED, ERB IV, U.S. EPASignature: *Ann Stavola*Date: *10/15/98*6. STUDY PARAMETERSScientific Name of Test Organism: *Anas platyrhynchos*

Age of Test Organisms at Test Initiation: 9 days

Definitive Study Duration: 192 hr

7. CONCLUSIONS: This study is scientifically sound and fulfills the 71-2 (B) guideline requirements for waterfowl dietary LD₅₀ toxicity tests on mallard ducks; however, the study raises serious questions regarding the no-observed effect level and the possibility of a chemically-induced anorexia. No animals died at any dose levels tested; thus a statistical LD₅₀ could not be determined. The LD₅₀ is greater than the highest level tested, i.e., 5,140 mg a.i./kg. Feed consumption by Mallard Ducks exhibited a significant negative correlation (Pearson correlation coefficient = -0.9372; P < 0.0018) with Propazine levels in the diet. Similarly, regression analysis of feed consumption over Propazine levels revealed that 87.84% of the variability associated with feed consumption rates was accounted for by dose (slope -0.00565; P < 0.0018). Thus,



food consumption rates and resultant growth, during the period that ducks were exposed to propazine in their diets, were dose-dependent. These data suggest a chemically-induced anorexia that was also exhibited in Bobwhite Quail oral and dietary exposure studies. Differences in feed consumption rates and growth were insignificant after propazine had been removed from diets.

Results Synopsis

LC₅₀: >5,140 ppm ai 95% C.I.: _____ - _____ ppm ai
NOEL: _____ ppm ai Probit Slope: _____

8. ADEQUACY OF THE STUDY

A. Classification: Core

B. Rationale:

C. Repairability:

9. GUIDELINE DEVIATIONS

1. Although brooders were to be maintained from 24 - 35°C, on three occasions prior to and two occasions after exposure, the brooder temperature was recorded above 35°C but less than 39°C. The researchers commented that cages had sufficient floor space to allow birds to seek refuge from temperature extremes.

2. (etc.)

10. SUBMISSION PURPOSE: Acute dietary bioassay to determine the 120-hr and end time LC₅₀ levels for propazine in mallard duck.

11. MATERIALS AND METHODS

A. Test Organisms

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Guideline Criteria	Reported Information
Species: A wild waterfowl species, preferably the mallard (<i>Anas platyrhynchos</i>).	<i>Anas platyrhynchos</i>
Age at beginning of test: 5-10 days old (preferably 5).	8-days old
Supplier	Whistling Wings, Inc.
Chicks appeared healthy and did not have excessive mortality before the test?	Yes
Acclimation period: As long as possible.	7 days

B. Test System

Guideline Criteria	Reported Information
Pen size: about 70 x 100 x 24 cm	97.8 x 68.6 x 24.1 cm
Brooder temperature: about 35°C (95°F)	34 - 39°C
Room temperature: 22-27°C (71-81°F)	21 - 26°C
Relative humidity: 30-80%	49 - 74%
Adequate ventilation?	(Yes/No/Not Reported)
Photoperiod Minimum of 14 h of light.	14-hr daylight
Diet: A commercial waterfowl feed.	Standard gamebird mash (Purina Gamebird Startena)

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	Yes
<u>Definitive Test</u> Nominal concentrations: Four minimum, 5 or 6 strongly recommended, in a geometric scale, unless $LC_{50} > 5000$ ppm.	Control, vehicle control, 650, 1,080, 1,800, 3,000 and 5,000 ppm feed
<u>Controls:</u> Control group tested with diet containing the maximum amount of vehicle used in treated diets?	Yes
Number of birds per group: 10 (strongly recommended)	10
<u>Vehicle:</u> Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	Corn oil/acetone (assumed acetone would evaporate during the mixing process)
Vehicle amount (% of diet by weight): Not more than 2%.	2.6% in 5,000 ppm treatment group
<u>Test durations:</u> 5 days with treated feed and at least 3 days observation with "clean" feed.	5 days (120 hr) exposed 3 days (72 hr) post-exposed
No mortality during last 72 hr of observations?	No mortality

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?	Yes (see raw data)

Guideline Criteria	Reported Information
Estimated consumption per pen reported for pretreatment, treatment, and observation periods?	Yes (see raw data)
Control Mortality: Not more than 10%	no mortality
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes

Mortality

Conc. (ppm)		No. of Birds	Cumulative Number of Dead								
Nominal	Mean Measured		Day of Study								
			1	2	3	4	5	6	7	8	
Control	--	10	0	0	0	0	0	0	0	0	0
Vehicle Control	--	10	0	0	0	0	0	0	0	0	0
650	603	10	0	0	0	0	0	0	0	0	0
1,080	1,000	10	0	0	0	0	0	0	0	0	0
1,800	1,850	10	0	0	0	0	0	0	0	0	0
3,000	2,910	10	0	0	0	0	0	0	0	0	0
5,000	5,140	10	0	0	0	0	0	0	0	0	0

Other Significant Results:

Depressed feed consumption in all treatment groups. Body weight gains in the four highest treated groups were depressed through the exposure period.

Statistical Results

Statistical Method:

LC₅₀: >5,000 ppm

95% C.I.: _____ ppm

NOEL: _____ ppm

Probit Slope: _____

13. Verification of Statistical Results

Statistical Method:

LC₅₀: >5,140 ppm 95% C.I.: _____ - _____ ppm

NOEL: _____ ppm Probit Slope: _____

Adjusted for active ingredient:LC₅₀: >5,140 ppm ai 95% C.I.: _____ - _____ ppm ai

NOEL: _____ ppm ai

14. REVIEWER'S COMMENTS:

Feed consumption was depressed in all treatment groups. Body weight gains were depressed through the exposure period. Once treated groups received basal diet, their feed consumption and body weight gains improved. Researchers concluded the effect was indicative of feed avoidance. If test animals don't consume their diet at a rate similar to the control, then it is unlikely they received the nominal treatment. Thus, it is difficult to conclude that the LC₅₀ > 5,000 ppm.

Additionally, in a study performed on bobwhite quail, the animals exhibited a similar weight loss through decreased food consumption. It is noteworthy that bobwhite quail administered an acute oral dose of Propazine exhibited a dose-related loss of weight that was not related to dietary exposure. Food avoidance may not just be related to feed palatability but rather result from a chemically-induced anorexia. In the present study growth, expressed as weight gain, was negatively correlated (Pearson correlation coefficient = -0.91459; P < 0.0039) with dosage. Mallard ducks in the control and vehicle control groups gained between 128 to 135 g during days 1 to 5; ducks treated with 5,000 ppm propazine gained 14 g. Regression analysis of growth over dose revealed that 83.6% of the variability in growth was explained by dosage alone. The regression equation relating growth to dose is:

$$\text{grams} = -0.022970 (\text{ppm propazine}) + 112.121$$

Feed consumption by mallard ducks also showed a significant negative correlation (Pearson correlation coefficient = -0.93722; P < 0.0018) with Propazine levels in the diet. Similarly, regression analysis of feed consumption over Propazine levels revealed that 87.84% of the variability associated with feed consumption rates was accounted for by dose (slope -0.00565; Prob

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≤ 0.0018).

This demonstrates that in mallard ducks, food consumption rates and growth during the period that the ducks were exposed to Propazine in their diets were dose-dependent. These data suggest a chemically-induced anorexia that was also exhibited by Bobwhite Quail dosed with Propazine (acute oral and acute dietary exposure).

Based on information provided in the appendices, 48.5 g propazine and 250 g corn oil was added to 9,201.5 g feed to yield 9,500 feed stock. This stock feed contained 5,000 ppm propazine and represented a 2.6% corn oil formulation. The maximum recommended vehicle amount, i.e., percentage of diet, is 2.0%.

This study is classified as core.