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| DR Barcode: D237791 | MRID No.: 442873-01 |
|--|--|
| | TA EVALUATION RECORD - AVIAN SINGLE-DOSE LD ₅₀ TEST |
| <u>CHEMICAL</u>: 2-chloro-4 <u>TEST MATERIAL</u>: Pro | 4,6-bis(isopropylamino)-s-triazine <u>PC_Code_No.</u> : 080808 ppazine <u>Purity</u> : 98.0% |
| <u>Title</u> : <u>Study Completion Date</u> : <u>Laboratory</u> : | ABC Laboratories, Inc. Griffin Corporation ABC Lab #41757 |

4. <u>REVIEWED BY</u>: Thomas M. Steeger, Ph.D., Fisherý Biologist, EFED, ERB IV, U.S. EPA

Signature: Thomas M Stuczer

APPROVED BY: Ann Stavola, Aquatic Biologist, EFED, ERB IV, U.S. EPA

In Starol. Signature:

STUDY PARAMETERS

6.

Scientific Name of Test Organism: Colinus virginianus Test Organisms Age/Size: 14 weeks Definitive Study Duration: 360 hours

CONCLUSIONS: This study is scientifically sound and does 7. fulfill the 71-1(A) guideline requirements for acute singledose LD_{50} toxicity tests for quail; however, feed consumption rates and growth were initially affected by Propazine treatments. No animals died at any dose levels tested; thus a statisitical LD_{50} could not be determined. The LD_{50} is greater than the highest level tested, i.e., 1,640 mg a.i./kg. Quail treated with 430 mg a.i./kg and above exhibited depressed feed consumption and related slow growth up to 72 hours after receiving Propazine. Weight of Bobwhite Quail exhibited a significant negative correlation $(P \leq 0.03)$ with the dosage of Propazine up to 72 hours after treatment; by 14 days, differences in feed consumption and weight were no longer apparent. This observation is supported by acute dietary exposure data from quail and suggests a possible chemical-induced anorexia. Thus, if



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Date: 10/5/97

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weight loss is considered up to 72 hours, a reasonable NOEL could be estimated at 244 mg a.i./kg.

Results Synopsis

 LD_{50} : >1,640 mg ai/kg NOEL: 244 mg ai/kg 95% C.I.: ____ mg ai/kg, Probit Slope; ____

8. ADEQUACY OF THE STUDY

A. Classification: Core

B. Rationale:

C. Repairability:

9. GUIDELINE DEVIATIONS

1. Quail were 14-wks old as opposed to the recommended 16 weeks.

2. Treatment group at 1,200 mg/kg contained 4 females and 5 males for a total of 9 quail as opposed to the recommended 10 animals(1 female quail discarded after receiving the wrong dose).

3. Instead of a liquid gavage dose, gelatin capsules were used to administer the test substance. A recorded amount of propazine was placed into a gelatin capsule and the remaining air spaces filled with powdered cellulose. Multiple capsules, i.e., 2 and 3 capsules, were required at the two highest dose levels, 1,200 and 2,000 mg/kg, respectively.

4. Group average weight was used to determine dose amounts. Precise capsule dosing of test material for each bird was viewed as impractical at the milligram level with the number of birds necessary to complete dosing.

5. On several days, the humidity fell below 30%, but not less than 20%.

10. <u>SUBMISSION PURPOSE</u>: To assess the acute oral toxicity of propazine to bobwhite quail.

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11. MATERIALS AND METHODS

A. Test Organisms

| Guideline Criteria | Reported Information | | | | |
|---|--------------------------|--|--|--|--|
| Species: A wild waterfowl species, pref- erably the mallard (<i>Anas platy-</i> <i>rhynchos</i>), or an upland game bird species, preferably the bobwhite (<i>Colinus virginianus</i>). | Colinus virginianus | | | | |
| Age at beginning of test: At least 1,6 weeks old. | 14 weeks | | | | |
| Supplier | Stevenson Game Bird Farm | | | | |
| Acclimation period: At least 15 days. | 14 days | | | | |

B. Test System

| Guideline Criteria | Reported Information | | | | |
|--|--|--|--|--|--|
| Pen facilities adequate? | Yes | | | | |
| Photoperiod: 10-h light, 14-h dark is recommended. | 8-hours light, 16-hours dark | | | | |
| Diet was nutritious and appro- priate for species? | Yes | | | | |
| Feed withheld at least 15 hours prior to dosing? | Not reported; however, ABC Lab protocol states that birds would be fasted a minimum of 15 hr prior to dosing. | | | | |

C. Test Design

| Guideliné Criteria | Reported Information |
|---------------------|----------------------|
| Range finding test? | Yes |

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| Guideline Criteria | Reported Information | | | | |
|---|---|--|--|--|--|
| Definitive Test Nominal concentrations: At least five, in a geometric scale, unless LD ₅₀ > 2000 mg ai / kg. | 260, 430, 720, 1,200, and 2,000 mg/kg | | | | |
| Controls: Water control or vehicle con- trol (if vehicle is used) | Control and vehicle control | | | | |
| Number of birds per group: 10 (strongly recommended) | 5 males + 5 females | | | | |
| Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxy- methylcellulose, or gum arabic. | 100% cellulose powder | | | | |
| Amount of vehicle per body weight: Constant volume/weight % of body weight, not to exceed 1% (1ml/100g). | Not reported; however, ABC Lab SOP states that carrier should not exceed 5mL/kg; may go up to 8 ml/kg. | | | | |
| Observations period: At least 14 days. | 14 days | | | | |

12. <u>REPORTED RESULTS</u>

| Guideline Criteria | Reportèd Information |
|--|----------------------|
| Quality assurance and GLP compliance statements were included in the report? | Yes |
| Individual body weights mea- sured at beginning of test, on day 14 and at end of test if extended beyond 14 days? | Yes |

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| Guideline Criteria | Reported Information | | | | |
|---|----------------------|--|--|--|--|
| Mean feed consumption measured at beginning of test, on day 14, and at end of test if ex- tended beyond 14 days? | Yes | | | | |
| Control Mortality: Not more than 10% | 0% | | | | |
| Raw data included? | Yes | | | | |
| Signs of toxicity (if any) were described? | Yes | | | | |

Mortality

| | é L | Cumulative Number of Dead | | | | | | | |
|--------------------|----------|---------------------------|----|---|---|----|-----|------|-----------|
| Dosage | No. of | Day of Study | | | | | | | |
| (mg/kg) | | 1 | 2 | 3 | 4 | 5 | 6-8 | 9-11 | 12-14 |
| Control | 10 | 0 | 0 | 0 | 0 | -0 | 0 | 0 | 0 |
| vehicle control | 10 | 0 | 0 | 0 | 0 | 0 | 0 | .0 | 0 |
| 260 | 10 | ò | Ó. | 0 | 0 | 0 | 0 | 0 | 0 |
| 430 | . 10 | 0 | O | 0 | 0 | Ò | 0 | 0 | 0 |
| 720 | <u> </u> | 0 | 0 | 0 | 0 | 0 | 0 | 0 | <u></u> 0 |
| 1200 | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2000 | 10 | 0 | 0 | 0 | 0 | 0 | 0 | Q. | 0 |

Other Significant Results: Quarl receiving >260 mg/kg exhibited depressed food consumption up to 48 hours after dosing. These birds also exhibited reduced body weights up to 72 hours after dosing.

Reported Statistical Results

Statistical Method:

LD₅₀: >2,000 mg/kg



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NOEL: _____mg/kg Probit Slope: _____

13. Verification of Statistical Results

Statistical Method: no mortality observed

LD₅₀: >1,640 mg/kg

95% C.I.: ____ mg/kg

NOEL: 244 mg/kg Probit Slope:

Adjusted for 100% active ingredient (optional if > 80% ai)

LD₅₀: >1640 mg/kg ai

95% C.I.: - mg/kg

NOEL: 244 mg/kg ai

15. REVIEWER'S COMMENTS:

Although there were no significant differences in body weight between treatment groups after 336 hours, it is noteworthy that groups treated at 430 mg/kg and above exhibited depressed feed consumption and related slow growth up to 72 hours after receiving propazine. Relative amounts of vehicle (cellulose) are not reported.

Weight of Bobwhite Quail exhibited a significant negative correlation with the dose of Propazine (Pearson correlation coefficient = 0.0311) (note: the r^2 value = 0.067).

ABC Laboratories did not report a NOEL; however, if weight loss is considered, a reasonable NOEL can be estimated at 244 ppm.