

9/27/89

Accession No. 409958-02

DATA EVALUATION RECORD

1. CHEMICAL: Ametryn. Shaughnessey Number: 80801.
2. TEST MATERIAL: Ametryn Technical. FL # 862730. 99.0% active ingredient.
3. STUDY TYPE: Avian Dietary LC50 Test.
Species Tested: Mallard duck (Anas platyrhynchos).
4. CITATION: Grimes, J., and M. Jaber. 1988. Ametryn: A Dietary LC50 Study with the Mallard. Submitted by Ciba-Geigy Corporation, Greensboro, North Carolina. Study performed by Wildlife International Ltd., Easton, Maryland. Laboratory Study No. 108-290A. EPA Accession No. 409958-02.

5. REVIEWED BY:

Michael L. Whitten, M.S.
Wildlife Toxicologist
KBN Engineering and
Applied Sciences, Inc.

Signature: *Michael L. Whitten*

Date: 4-21-89

6. APPROVED BY:

James R. Newman, Ph.D.
Project Manager/
Principal Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: *James R. Newman*

Date: 4/21/89

Henry T. Craven, M.S.
Supervisor, EEB/HED
USEPA

Signature: *Henry T. Craven*

Date: 9/27/89

7. CONCLUSIONS: The dietary LC50 of Ametryn was determined to be greater than 5620 ppm, the highest concentration tested. This value classifies Ametryn as practically non-toxic to mallard ducklings. Sub-lethal effects were observed, however, and included abnormal behavior, reduced food consumption, loss of body weight, and reduced body weight gain. The no-observed-effect concentration was less than the lowest concentration tested (562 ppm) based on a reduction in body weight gain. The study is scientifically sound and meets the requirements for an avian dietary LC50 test.
8. RECOMMENDATIONS: N/A

9. BACKGROUND:

10. DISCUSSION OF INDIVIDUAL TESTS: N/A.

11. MATERIALS AND METHODS:

- A. Test Animals: The birds used in the study were 9-day old mallards (Anas platyrhynchos) obtained from Whistling Wings, Hanover Illinois. All birds were acclimated to the facilities for eight days prior to initiation of the study. Birds exhibiting abnormal behavior or physical injury during acclimation were not used in the test.
- B. Test System: All birds were housed indoors in 90 cm x 72 cm x 24 cm high wire pens. Fluorescent lights provided 16 hours of light per day. The temperature in the brooding compartments was $35^{\circ}\text{C} \pm 2^{\circ}\text{C}$. Average ambient room temperature was $22^{\circ}\text{C} \pm 1^{\circ}\text{C}$ with an average relative humidity of 44%.
- C. Dosage: Acute dietary LC50 test. The diets were prepared by mixing the test substance into the food with corn oil and acetone. Diets were prepared on the day of study initiation. Based on "known toxicity data" nominal dietary concentrations selected for the study were 562, 1000, 1780, 3160, and 5620 parts per million (ppm).
- D. Design: Groups of ten birds were randomly assigned to each of the five treatment groups and five control groups. The birds were too immature to differentiate by sex. The birds were fed a game bird ration formulated to Wildlife International Ltd.'s specifications. Food and water were supplied ad libitum. Each group was fed the appropriate test or control diet for five days. During the exposure period the control groups received an amount of carrier in their diet equivalent to the greatest amount used in the treated diets. Following the five day exposure period all groups were given untreated food for three days. All birds were observed at least twice each day during the test for mortalities and abnormal behavior. Birds were weighed by group at test initiation, on day 5, and at termination of the test on day 8. Group food consumption was determined at the end of the five-day exposure period and at the end of the three-day recovery period.

E. Statistics: The LD50 was not calculated, since no birds died during the study. No statistical analyses of body weight or food consumption were reported.

12. REPORTED RESULTS: There were no mortalities in any group during the study.

All birds in the control groups, and in the 562 and 1000 ppm groups, were normal in appearance and behavior throughout the study.

Behavioral abnormalities attributed to ametryn intoxication were noted in the 1780, 3160, and 5620 ppm groups. Symptoms included lethargy and ruffled appearance. At 1780 ppm, signs of toxicity were noted in one to two birds from the morning of Day 4 through the morning of Day 6. At 3160 ppm, signs of toxicity were noted from the afternoon of Day 2 through the morning of Day 6. At 5620 ppm, signs of toxicity were noted from the afternoon of Day 1 through the afternoon of Day 6.

When compared to controls, there was a concentration related reduction in body weight gain in the 562, 1000, 1780, and 3160 ppm groups and a loss in body weight in the 5620 ppm group during the five day exposure period. A reduction in food consumption was noted in the 1000, 1780, 3160, and 5620 ppm groups during the same period.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:

The mallard dietary LC50 for Ametryn was determined to be greater than 5620 ppm, the highest concentration tested. The no-observed-effect concentration was less than 562 ppm based on a reduction in body weight gain at 562 ppm.

The study was designed and conducted in conformance with Good Laboratory Practice regulations. The data were inspected and the final report signed by the Quality Assurance Officer of Wildlife International Ltd.

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:

A. Test Procedure: The test procedures were in accordance with SEP guidelines except for the following deviations:

Body weights were measured by group. Individual body weights should have been measured.

The SEP recommends that gross necropsies be performed on some survivors. This was not done.

- B. Statistical Analysis: Since no birds died during the study, the LD50 can not be calculated and is assumed to be greater than 5620 ppm, the highest concentration tested.
- C. Discussion/Results: Samples of diets were not analyzed for confirmation of test chemical concentrations. However, the chemical was mixed into the food with a vehicle. The nominal concentrations are therefore probably close to the actual concentrations.

The authors did not report the number of birds in the 3160 and 5620 ppm groups in which signs of toxicity were noted. These signs (lethargy and ruffled appearance) were noted as early as Day 1 in the 5620 ppm group and Day 2 in the 3160 ppm group.

Reductions in body weight gain were evident in all treatment groups during days 0-5 (Tables 3 & 4, attached). The magnitude of these reductions increased directly with increased concentration of test chemical. The birds in the 5620 ppm group actually lost weight during the exposure period. Food consumption during the same period decreased with increased concentration of test chemical. When compared to controls, food consumption was reduced in the 1000, 1780, 3160, and 5620 ppm groups during the exposure period.

The acute oral LD50 of Ametryn was determined to be greater than 5620 ppm, the highest concentration tested. This value classifies Ametryn as practically non-toxic to mallard ducklings. Sub-lethal effects were observed, however, and included abnormal behavior at the three highest concentrations, reduced food consumption at the four highest concentrations, loss of body weight at the highest concentration (5620 ppm), and reduced body weight gain in the remaining treatment groups. The no-observed-effect concentration was less than the lowest level tested (562 ppm) based on a reduction in body weight gain at that concentration.

The study is scientifically sound and meets the requirements for an avian dietary LC50 test.

D. Adequacy of the Study:

- (1) Classification: Core
- (2) Rationale: N/A

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(3) Repairability: N/A

15. COMPLETION OF ONE-LINER: Yes; April 21, 1989.

Ametryn

RIN 4475-95

P.C. 080801

Page 6 is not included in this copy.

Pages _____ through _____ are not included.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
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Shaughnessy No. 82801

Chemical Name Ametryn Chemical Class _____ Page 1 of 1

Study/Species/Lab/
Accession _____
14-Day Single Dose Oral LD₅₀

Species _____
Lab _____
Acc. _____

Results
LD₅₀ = mg/kg (95% C.L.) Contr. Mort.(X) = _____
Slope = _____ # Animals/Level = _____ Age(Days) = _____
Sex = _____
14-Day Dose Level mg/kg/(X Mortality)
() , () , () , () , ()

Reviewer/
Date _____
Validat
Statu _____

Comments:

14-Day Single Dose Oral LD₅₀

Species _____
Lab _____
Acc. _____

LD₅₀ = mg/kg. (95% C.L.) Contr. Mort.(X) = _____
Slope = _____ # Animals/Level = _____ Age(Days) = _____
Sex = _____
14-Day Dose Level mg/kg/(X Mortality)
() , () , () , () , ()

Comments:

8-Day Dietary LC₅₀

Species Mallard
Anas platyrhynchos 99.0%
Lab Wildlife International, Ltd
Acc. # 409958-02

GREATER THAN 95% C.L.
LC₅₀ = 5620ppm (N/A) Contr. Mort.(X) = 0
Slope = N/A # Animals/Level = 10 Age(Days) = 9
Sex = UNKNOWN
8-Day Dose Level ppm/(X Mortality)
562 (0) , 1000 (0) , 1780 (0) , 3160 (0) , 5620 (0)

M. WHITTEN CORE
4-21-89
NOEC = LESS THAN 562PPM
BOP, WEIG.

Comments: SUBLETHAL EFFECTS: ABNORMAL BEHAVIOR, REDUCED FOOD CONSUMPTION, BOP, WEIG.

8-Day Dietary LC₅₀

Species _____
Lab _____
Acc. _____

LC₅₀ = ppm (95% C.L.) Contr. Mort.(X) = _____
Slope = _____ # Animals/Level = _____ Age(Days) = _____
Sex = _____
8-Day Dose Level ppm/(X Mortality)
() , () , () , () , ()

Comments:

48-Hour L₅₀

Species _____
Lab _____
Acc. _____

LC₅₀ = (95% C.L.) Contr. Mort.(X) = _____
Slope = _____ # Animals/Level = _____ Sol. Contr. Mort.(X) = _____
Temp. = _____
48-Hour Dose Level / (X Mortality)
() , () , () , () , ()

Comments:

96-Hour LC₅₀

Species _____
Lab _____
Acc. _____

LC₅₀ = PP (95% C.L.) Con. Mor.(X) = _____
Slope = _____ # Animals/Level = _____ Sol. Con. Mor.(X) = _____
Temp. = _____
96-Hour Dose Level pp / (X Mortality)
() , () , () , () , ()

Comments:

96-Hour LC₅₀

Species _____
Lab _____
Acc. _____

LC₅₀ = PP (95% C.L.) Con. Mort.(X) = _____
Slope = _____ # Animals/Level = _____ Sol. Con. Mort.(X) = _____
Temp. = _____
96-Hour Dose Level pp / (X Mortality)
() , () , () , () , ()

Comments: