DP Barcode: D222690

MRID No.: 438870-04

DATA EVALUATION RECORD
§ 71-1(A) - AVIAN SINGLE-DOSE LD_{50} TEST

1. **CHEMICAL:** AC 303,630 Technical PC Code No.: 129093

2. **TEST MATERIAL:** AC 303,630 Technical Purity: 94.5%

3. **CITATION**

Authors: Brewer, L.W., J.A. Gange, J.P. Sullivan and L.C. Taliaferro
Title: 14-Day Acute Toxicity Test with AC 303,630 Technical in Red-winged Blackbirds (*Agelaius phoeniceus*)
Study Completion Date: December 21, 1995
Laboratory: Ecotoxicology and Biosystems Assoc., Inc. Snow Camp, NC
Sponsor: American Cyanamid Company, Princton, NJ
Laboratory Report ID: 039504
MRID No.: 438870-04

4. **REVIEWED BY:** John D. Eisemann, Wildlife Biologist, EEB, EFED

Signature: John D. Eisemann **Date:** 9/13/96

5. **APPROVED BY:** Ann Stavola, Head, Section (5), EEB, EFED

Signature: Ann Stavola **Date:** 9/13/96

6. **STUDY PARAMETERS**

Scientific Name of Test Organism: *Agelaius phoeniceus*
Test Organisms Age/Size: Approx 1 year / 56-70 grams
Definitive Study Duration: 14 days

7. **CONCLUSIONS:**

This study was conducted in accordance with accepted protocols. It fully meets the requirements for an avian acute oral toxicity test. AC 303,360 Technical is very highly toxic to Red-winged blackbirds on an acute oral basis. However, only one treatment group had partial mortality.

This test was conducted in outdoor pens. Consequently, controlled environmental conditions as in laboratory studies were not maintained.

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Results Synopsis

LD_{50}: 2.21 mg ai/kg 95% C.I.: 1.5 - 4.0 mg ai/kg

NOEL(Survival): 0.63 mg ai/kg Probit Slope: not calculated

8. ADEQUACY OF THE STUDY

A. Classification: Supplemental

B. Rational: This is not a required study.

C. Repairability: No additional data needs to be submitted. This is an interim study. The registrant will submit the results of the tissue residue analysis in tissues at a later date.

9. GUIDELINE DEVIATIONS

1. After the definitive test it was not possible to immediately schedule the dosing of the extra group of birds for the tissue residue portion of the study. By the time it was possible to do so, there had been some additional mortality. It was felt that the remaining birds would not provided a suitably large sample size.

2. The assay of the test substance yielded a purity of 94.9%, so this value was inadvertently used instead of the Certificate of Analysis original purity assignment of 94.5%.

3. The range-finding samples were inadvertently included in the study report, but were in good agreement with the definitive study results.

4. Section 11.3 of the laboratory protocol states "at least 4 birds will be submitted for a disease and parasite screen with an avian pathologist". An avian pathologist could not be located in the Sisters, OR vicinity. Therefore, Larry Brewer examined 4 birds for general health, external parasites and gross internal pathology.

5. Section 15.2 and Protocol Amendment No. 1 of the laboratory protocol specify that the capsules will be administered to the blackbirds on the day they are received from EBA Laboratory. However, the capsules were received on Monday May 15 and were administered to the birds on Wednesday May 17.

6. Section 16.4 of the laboratory protocol states "mortality and morbidity will be determined by making observations of each test animal at least twice daily until death of the test animal or the conclusion of the in-life portion of the study". During the conduct of the study birds were observed twice daily on days 0-7 and once on days 8-14.

7. The photoperiod maintained throughout the test and light intensity at bird level was reduced from protocol specification to reduce aggressive behavior in the birds that would have been detrimental to the bird health and condition.

8. Only male birds were captured in trapping efforts. Male and female Red-winged blackbirds migrate separately and at the time of trapping only males were present.

9. Section 14.2 indicates that the temperature will be monitored with a continuously recording thermometer. This study was conducted outdoors. The temperature was taken (in the outbuilding where birds were housed) via a standard maximum-minimum thermometer. Additionally, temperature and humidity were taken and recorded every 30 minutes during the study at a computerized weather station near the study site in Bend, Oregon.

10. The dates that inspections were reported to the Testing Site's representative were not included the report.

11. Humidity data was not recorded according to GLP guidelines.

10. **SUBMISSION PURPOSE:**

To support registration of PIRATE (AC 303,360)

11. MATERIALS AND METHODS

A. Test Organisms

Guideline Criteria	Reported Information
Species:	*Agelaius phoeniceus*
Age at beginning of test:	Approx. 1 year
Supplier::	Wild captured
Acclimation period: At least 15 days.	≥ 14 days

B. Test System

Guideline Criteria	Reported Information
Pen facilities adequate?	Yes, 24'x 24'x 30' providing 1ft^3/bird Pens were located in a outbuilding which was not climate controlled
Photoperiod: 10-h light, 14-h dark is recommended.	6-hr light, 18-hr dark 3.7 foot candles at bird level -Photoperiod was shortened to reduce aggression
Diet was nutritious and appropriate for species?	Yes, Nutrena Gamebird Grower and wild Bird Seed Mix, U.S. Wildbird Food Co.
Feed withheld at least 15 hours prior to dosing?	Yes - 15 hours

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	Yes
Definitive Test **Nominal concentrations:** At least five, in a geometric scale, unless LD_{50} > 2000 mg ai / kg.	0, 0.10, 0.25, 0.63, 1.50, and 4.0 mg ai/kg body weight
Controls: Water control or vehicle control (if vehicle is used)	Vehicle control
Number of birds per group: 10 (strongly recommended)	10 - all males
Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	Acetone in a gelatin capsule
Amount of vehicle per body weight: Constant volume/weight % of body weight, not to exceed 1% (1ml/100g).	Doses were mixed in acetone and measured into gelatin capsules. Prior to administration the acetone was evaporated from the capsule.
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,
Individual body weights measured at beginning of test, on day 14 and at end of test if extended beyond 14 days?	Yes
Mean feed consumption measured at beginning of test, on day 14, and at end of test if extended beyond 14 days?	Yes
Control Mortality: Not more than 10%	0 %
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes

Mortality

Dosage (mg/kg)	No. of Birds	Cumulative Number of Dead							
		Day of Study							
		0	1	2	3	4	5-8	9-11	12-14
Control	10	0	0	0	0	0	0	0	0
0.1	10	0	0	0	0	0	0	0	0
0.25	10	0	0	0	0	0	0	1	1
0.63	10	0	0	0	0	0	0	0	0
1.5	10	1	1	1	1	1	1	1	1
4.0	10	1	7	10	10	10	10	10	10

Other Significant Results:

Statistical comparisons conducted on food consumption and weight data showed no significant differences between the

controls and any treatment group.

Abnormal behavior was observed only in the 4.0 mg/kg treatment group. These birds were less active than the other groups.

The single mortality observed in the 0.25 mg/kg treatment group was not attributed to the treatment. At necropsy it was noted to be emaciated and had no food in the GI tract. The authors attributed the death to starvation resulting from aggression.

Treatment caused mortality occurred within the first two days of the experiment. All birds in the 4.0 mg/kg treatment group were dead by the morning of the 2nd day.

Post-mortem necropsy (of all the birds which died during the study and on 4 surviving birds in dose groups and controls that survived the study) revealed no abnormal conditions.

GI tract, liver, and skin with associated fat were collected from each bird. These will be analyzed for residues. This data was not submitted for review.

Reported Statistical Results

Statistical Method: binomial probability

LD_{50}: 2.21 mg/kg 95% C.I.: 1.5 - 4.0 mg/kg

NOEL: (Survival): 0.63 mg/kg Probit Slope: 2.804

13. **Verification of Statistical Results**

Statistical Method: Binomial probability

LD_{50}: 2.21 mg/kg 95% C.I.: 1.5 - 4.0 mg/kg

NOEL (Survival): 0.63 mg/kg Probit Slope: Not calculated

15. **REVIEWER'S COMMENTS:**

This study is conducted in accordance with accepted protocols. It fully meets the requirements for an avian acute oral toxicity test. AC 303,630 is very highly toxic to Red-winged blackbirds on an acute oral basis.

Since only one treatment group had partial mortality the confidence placed in the LD_{50} estimate is compromised and Probit analysis could not be used to calculate the LD^{50}.

Weight data was reported. However, but the reviewer could not match weights to individuals. Consequently, weight change over the test could not be statistically tested. Visual examination of the means indicates weight was not significantly effected.

Dose preparation formula and calculations were not provided. Dose concentrations could not be verified.