DP Barcode: D222690 MRID No.: 438870-05

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

1. **CHEMICAL:** AC 312,094 Technical
A metabolite of AC 303,630 PC Code No.: 129093

2. **TEST MATERIAL:** AC 312,094 Technical Purity: 96.3%

3. **CITATION**

Authors: Brewer, L.W., J.A. Gange, J.P. Sullivan and L.C. Taliaferro
Title: 14-Day Acute Toxicity Test with AC 312,094 Technical in Mallard Ducks (*Anas platyrhynchos*)
Study Completion Date: December 19, 1995
Laboratory: Ecotoxicology and Biosystems Assoc., Inc. Snow Camp, NC
Sponsor: American Cyanamid Company, Princeton, NJ
Laboratory Report ID: 039403
MRID No.: 438870-05

4. **REVIEWED BY:** John D. Eisemann, Wildlife Biologist, EEB, EFED
Signature: John D. Eisemann **Date:** 7/30/96

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: *Anas platyrhynchos*
Test Organisms Age/Size: 20 weeks/ 1115 grams (759-1425 g)
Definitive Study Duration: 14 days

7. **CONCLUSIONS:**

This study is scientifically sound and was conducted in accordance with accepted protocols. It fully meets the requirements for an avian acute oral toxicity test. AC 312,268, a metabolite of AC 303,630, is practically non-toxic to Mallards on an acute oral basis.

Results Synopsis

LD_{50}: >2400 mg ai/kg 95% C.I.: not calculated

NOEL(Mortality): >2400 mg ai/kg Probit Slope: not calculated

8. **ADEQUACY OF THE STUDY**

A. **Classification:** Supplemental

B. **Rational:** This study was not required.

C. **Repairability:** No additional data needs to be submitted.

9. **GUIDELINE DEVIATIONS**

1. Humidity was inadvertently not recorded for 8-18-94 to 8-24-94.

2. The protocol, section 11.1, requires that test animals should weigh between 800 and 1600 grams at test initiation. One female weighed 758 grams was dosed with 600 mg ai/kg and survived to test termination.

3. Animal weights in the 600 and 1200 mg/kg dose groups were statistically different from the controls at the time of dosing.

4. Dose preparation formulas and calculations were not provided. The percent vehicle/body weight could not be determined and dose preparation could not be verified.

5. The photoperiod was 7 hours light to 17 hours dark.

10. **SUBMISSION PURPOSE:**

To support registration of PIRATE (AC 303,360)

11. **MATERIALS AND METHODS**

A. **Test Organisms**

Guideline Criteria	Reported Information
Species:	*Anas platyrhynchos*
Age at beginning of test:	20 weeks
Supplier::	Whistling Wings

Guideline Criteria	Reported Information
Acclimation period: At least 15 days.	14 days

B. Test System

Guideline Criteria	Reported Information
Pen facilities adequate?	Yes, 76 cm x 129 cm x 44 cm polycarbonate-coated wire mesh
Photoperiod: 10-h light, 14-h dark is recommended.	7-hr light, 17-hr dark 6 foot candles at bird level
Diet was nutritious and appropriate for species?	Yes, Purina Game Bird Ration
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, 150, 300, 600, 1200, and 2500 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 - (5 male and 5 female)
Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	Corn oil

Guideline Criteria	Reported Information
Amount of vehicle per body weight: Constant volume/weight % of body weight, not to exceed 1% (1ml/100g).	Not reported
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 - However, weights are not associated with individual animals. Individual 14 day weight changes can not be calculated.
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 - lacking dose mixing calculations
Signs of toxicity (if any) were described?	Yes

Mortality

No mortality occurred during the 14 day test period in any treatment group or the controls.

Other Significant Results:

No differences were reported for weight change, food consumption, behavior or mortality.

Reported Statistical Results

Statistical Method: visual inspection of the data

LD_{50}: >2400 mg ai/kg 95% C.I.: not calculated

NOEL: (Survival): >2400 mg ai/kg Probit Slope: n/a

13. **Verification of Statistical Results**

Statistical Method: visual inspection of the data

LD_{50}: >2400 mg ai/kg 95% C.I.: not calculated

NOEL: (Survival) >2400 mg ai/kg Probit Slope: n/a

15. **REVIEWER'S COMMENTS:**

This study is scientifically sound and was conducted in accordance with accepted protocols. It fully meets the requirements for an avian acute oral toxicity test. AC 312,094, is practically non-toxic to Mallards on an acute oral basis.

Animal weights were statistically different from the control in the 600 and 1200 mg ai/kg dose groups at the start of the test. However, at the time of random assignment to treatment groups, prior to acclimation, the animal weights were not statistically different from the controls. Control animals lost 54 grams during the 14 day test. All of the treatment groups gained approximately 40.1 grams during the test period.

Dose preparation formulas and calculations were not provided. The percent vehicle/body weight could not be determined and dose preparation could not be verified.