9-22-98

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

1. **CHEMICAL:** Chlorfenapyr Soil Metabolite, CL 325,195 PC Code No.: 444526-12

2. **TEST MATERIAL:** 2-Pyrroline-3-carbonitrile,2(p-chlorophenyl)-5-hydroxy-4-oxo-5-(trifluoromethyl); Lot # AC9014-93B, cream colored powder.
Purity: 97%

3. **CITATION**

Authors:	J. A. Gagne, S. R. Mortensen, Md. Sayed Ahmed, and T. Harris.
Title:	Avian Single-Dose Oral LD50 Test with CL 325,195 in Mallard Duck (*Anas platyrhynchos*)
Study Completion Date:	10 December 1997
Laboratory:	Genesis Laboratories, Inc., Wellington, CO
Sponsor:	American Cyanamid Company, Princeton, NJ
Laboratory Report ID:	ECO-97-258
MRID No.:	

4. **REVIEWED BY:** Regina Hirsch, Wildlife Ecologist, ERB1, EFED

Signature: Regina Hirsch **Date:** 1/16/98

5. **APPROVED BY:** Arnet Jones, Chief, ERB1, EFED Section 4 Rpm

Signature: Arnet Jones **Date:** 09/22/98

6. **STUDY PARAMETERS**

Test Organisms Age/Size: 20 weeks old at test initiation.
Definitive Study Duration: 14 days.

7. **CONCLUSIONS:**

Results Synopsis
LD_{50}: > 2250 mg ai/kg
NOEL: 2250 mg ai/kg

8. **ADEQUACY OF THE STUDY**

A. Classification: Core.

B. Rationale: N/A

C. Repairability: N/A

9. GUIDELINE DEVIATIONS

1. Nutritional content, and pesticide contaminant analyses of the feed and water used to maintain the Mallard Ducks during holding, acclimation, and the test period, were not performed.

10. SUBMISSION PURPOSE: To support Chlorfenapyr registration and tolerance petition.

11. MATERIALS AND METHODS

A. Test Organisms

Guideline Criteria	Reported Information
Species: A wild waterfowl species, preferably the mallard (*Anas platyrhynchos*), or an upland game bird species, preferably the bobwhite (*Colinus virginianus*).	*Anas platyrhynchos*
Age at beginning of test: At least 16 weeks old.	20 weeks old at test initiation
Supplier	Whistling Wings, Inc., Hanover, IL
Acclimation period: At least 15 days.	At least 15 days

B. Test System

Guideline Criteria	Reported Information
Pen facilities adequate?	Yes
Photoperiod: 10-h light, 14-h dark is recommended.	10-h light, 14-h dark
Diet was nutritious and appropriate for species?	Yes

Guideline Criteria	Reported Information
Feed withheld at least 15 hours prior to dosing?	Yes

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	Yes, five treatment groups (5, 25, 125, 625, and 2000 mg ai/ kg body weight) were tested with 4 birds per group. No mortality occurred in any group.
Definitive Test **Nominal concentrations:** At least five, in a geometric scale, unless LD_{50} > 2000 mg ai / kg.	Vehicle control (7 empty gelatin capsules), 292, 486, 810, 1350, 2250 mg ai/kg body weight.
Controls: Water control or vehicle control (if vehicle is used)	Vehicle control (7 empty gelatin capsules)
Number of birds per group: 10 (strongly recommended)	10 (5 males and 5 females)
Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	7 gelatin capsules per bird for both treatment and control.
Amount of vehicle per body weight: Constant volume/weight % of body weight, not to exceed 1% (1ml/100g).	N/A
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, individual body weights were measured on days 0 (dosing day), 3, 7, and 14.
Mean feed consumption measured at beginning of test, on day 14, and at end of test if extended beyond 14 days?	Yes, feed consumption (grams/bird/day) was measured and data were pooled for days 1-3, 4-7, and 8-14. Feed consumption spillage was monitored daily to estimate the relative amounts of spillage for each treatment and control group pair.
Control Mortality: Not more than 10%	0%
Raw data included?	No
Signs of toxicity (if any) were described?	Yes

Mortality

Dosage (mg/kg)	No. of Birds	Cumulative Number of Dead							
		Day of Study							
		1	2	3	4	5	6-8	9-11	12-14
Control	10	0	0	0	0	0	0	0	0
292	10	0	0	0	0	0	0	0	0
486	10	0	0	0	0	0	0	0	0
810	10	0	0	0	0	0	0	0	0
1350	10	0	0	0	0	0	0	0	0
2250	10	0	0	0	0	0	0	0	0

4

Other Significant Results:

No test related mortality, moribundity, or signs of intoxication were observed in any treatment level. No significant dose related effects on the body weights were observed for days 0, 3, 7, and 14. Mean feed consumption (grams/bird/day) in the 292 and 1350 mg ai/kg were found to be significantly different from the control group during days 1-3. Gross pathological examinations were conducted on 24 birds (4 from each group), no abnormalities were detected.

Reported Statistical Results

Statistical Method: None

LD_{50}: > 2250 mg/kg

NOEL: 2250 mg/kg

13. Verification of Statistical Results

Statistical Method: None needed as no mortality occurred.

LD_{50}: > 2250 mg/kg

NOEL: 2250 mg/kg

15. REVIEWER'S COMMENTS:

Study appears to be scientifically valid. Special attention should be paid to the non-mortality findings, feed consumption.

5

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

1. **CHEMICAL:** Chlorfenapyr Soil Metabolite, CL 303,267 PC Code No.: 444526-02

2. **TEST MATERIAL:** Pyrrole-3-carbonitrile,2(p-chlorophenyl)-5-(trifluoromthyl); Lot # AC7618-148A, Cas No. 122454-23-3; yellow powder.
   Purity: 98.1 % ± 0.5 %

3. **CITATION**

Authors:	J. A. Gagne, S. R. Mortensen, Md. Sayed Ahmed, and T. Harris.
Title:	Avian Single-Dose Oral LD50 Test with CL 303,267 in Mallard Duck (*Anas platyrhynchos*).
Study Completion Date:	10 December 1997
Laboratory:	Genesis Laboratories, Inc., Wellington, CO
Sponsor:	American Cyanamid Company, Princeton, NJ
Laboratory Report ID:	ECO-97-250
MRID No.:	

4. **REVIEWED BY:** Regina Hirsch, Wildlife Ecologist, ERB1, EFED
   Signature: Regina Hirsch **Date:** 1/16/98

5. **APPROVED BY:** Arnet Jones, Chief, ERB1, EFED Secondary Reviewer
   Signature: Arnet Jones **Date:** 09/22/98

6. **STUDY PARAMETERS**

   Test Organisms Age/Size: 26 weeks old at test initiation.
   Definitive Study Duration: 14 days.

7. **CONCLUSIONS:**

   Results Synopsis
   LD_{50}: > 2250 mg ai/kg
   NOEL: 2250 mg ai/kg

8. **ADEQUACY OF THE STUDY**

   A. Classification: Core.

   B. Rationale: N/A

C. Repairability: N/A

9. GUIDELINE DEVIATIONS

1. Nutritional content, and pesticide contaminant analyses of the feed and water used to maintain the Mallard Ducks during holding, acclimation, and the test period, were not performed.

10. SUBMISSION PURPOSE: To support Chlorfenapyr registration and tolerance petition.

11. MATERIALS AND METHODS

A. Test Organisms

Guideline Criteria	Reported Information
Species: A wild waterfowl species, preferably the mallard (*Anas platyrhynchos*), or an upland game bird species, preferably the bobwhite (*Colinus virginianus*).	*Anas platyrhynchos*
Age at beginning of test: At least 16 weeks old.	26 weeks old at test initiation
Supplier	Whistling Wings Inc., Hanover, IL
Acclimation period: At least 15 days.	at least 15 days.

B. Test System

Guideline Criteria	Reported Information
Pen facilities adequate?	Yes
Photoperiod: 10-h light, 14-h dark is recommended.	10-h light, 14-h dark
Diet was nutritious and appropriate for species?	Yes

Guideline Criteria	Reported Information
Feed withheld at least 15 hours prior to dosing?	Yes

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	Yes, five treatment levels were tested (5, 25, 125, 625, and 2000 mg ai/kg body weight) with four birds at each level. No mortality in any group was observed.
Definitive Test **Nominal concentrations:** At least five, in a geometric scale, unless LD_{50} > 2000 mg ai / kg.	Vehicle Control (5 empty gelatin capsules), 292, 486, 810, 1350, and 2250 mg ai/kg body weight
Controls: Water control or vehicle control (if vehicle is used)	Vehicle Control (5 empty gelatin capsules)
Number of birds per group: 10 (strongly recommended)	10 (5 males and 5 females) per group
Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	5 gelatin capsules per bird for both treatment and control
Amount of vehicle per body weight: Constant volume/weight % of body weight, not to exceed 1% (1ml/100g).	N/A
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, body weights for each individual were measured on days 0 (dosing day), 3, 7, and 14.
Mean feed consumption measured at beginning of test, on day 14, and at end of test if extended beyond 14 days?	Yes, feed consumption (grams/bird/day) was measured and data were pooled for days 1-3, 4-7, and 8-14. Feed consumption spillage was monitored daily to estimate the relative amounts of spillage for each treatment and control group pair.
Control Mortality: Not more than 10%	0%
Raw data included?	No
Signs of toxicity (if any) were described?	Yes

Mortality

Dosage (mg/kg)	No. of Birds	Cumulative Number of Dead							
		Day of Study							
		1	2	3	4	5	6-8	9-11	12-14
Control	10	0	0	0	0	0	0	0	0
292	10	0	0	0	0	0	0	0	0
486	10	0	0	0	0	0	0	0	0
810	10	0	0	0	0	0	0	0	0
1350	10	0	0	0	0	0	0	0	0
2250	10	0	0	0	0	0	0	0	0

9

Other Significant Results:

No test related mortality, moribundity, or signs of intoxication were observed in any treatment level. No significant dose related effects on the body weights were observed for days 0, 3, 7, and 14. No significant differences in feed consumption were found for days 1-3, 4-7, or 8-14. Gross pathological examinations were conducted on 24 birds (4 from each group), no abnormalities were detected.

Reported Statistical Results

Statistical Method: None as no mortality occurred

LD_{50}: > 2250 mg/kg

NOEL: 2250 mg/kg

13. Verification of Statistical Results

Statistical Method: None as no mortalities occurred.

LD_{50}: > 2250 mg/kg

NOEL: 2250 mg/kg

15. REVIEWER'S COMMENTS:

Study appears to be scientifically valid.