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DP Barcode: D222690

MRID No.: 438870-07

DATA EVALUATION RECORD
DERMAL TOXICITY TEST - UPLAND GAME BIRD
Guideline 70-1 (d)

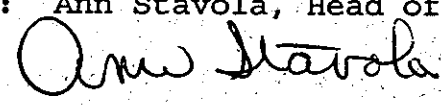
1. CHEMICAL: AC 303,630 3SC PC Code No.: 129093
2. TEST MATERIAL: PIRATE™ Purity: 30.30%
3. CITATION Authors: C.J. Driver, J.A. Gange and J.P. Sullivan
Title: Dermal Toxicity Study with AC 303,630 3SC
in Northern Bobwhite (*Collinus virginianus*).
Study Completion Date: December 22, 1995
Laboratory: Battelle Northwest Laboratories,
Richland, WA
Sponsor: American Cyanamid Company, Princeton, NJ
Laboratory Report ID: 954-94-134
MRID No.: 438870-07
DPBarcode: D222690

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

Signature: 

Date: 7/30/96

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

Signature: 

Date: 9/13/96

6. STUDY OBJECTIVE: To determine the dermal toxicity of AC 303,630 3SC to Northern bobwhite when they are exposed to treated soil and plants after a simulated field application.

7. CONCLUSIONS:

The study is scientifically sound and was conducted according to the company's test protocol. Deviations from the protocol were not severe enough to invalidate the study.

The study design is appropriate to assess exposure through physical contact with the dried chemical on contaminated soil and plant tissue and inhalation of active ingredient which has volatilized. This study was not designed to represent exposure during the application process.

Raw data for food consumption and body weight was not submitted with this report.

8. ADEQUACY OF THE STUDY

- A. **Classification:** Supplemental
- B. **Rationale:** The information provided by this study is not mandatory.
- C. **Repairability:** Nothing further is required to support this study.

9. GUIDELINE DEVIATIONS

- 1. Experimental starting date was 18 July 1994 instead of 15 July 1994.
- 2. Body weights ranged from 150 to 270 grams instead of 100 to 200 grams.
- 3. The birds were randomized as pairs rather than individuals.
- 4. The feathers collected to measure residues were plucked rather than clipped.
- 5. The soil used during the test was characterized to be 48.8% silt, 42.4% sand, and 7.8% clay, whereas the protocol stated the soil was to be 60% silt, 24% sand and 15% clay.
- 6. Spray volume and the time of spray are approximated for the first application of the 1X treatment group, due to spilling the test solution and a malfunctioning stopwatch, respectively.
- 7. Air samples were not collected for the 1X treatment group. Dislodgeable leaf residue samples were not collected for the 1X treatment group and only one sample was collected for the 4X treatment group. Only one cotton leaf sample was collected in the 0.05X and 2X treatment groups.
- 8. The Protocol, Section 17, states that the tank mix must have measured concentrations that are 80% to 120% of nominal concentrations. The tank mix sample for the 2X treatment did not fall in this range.
- 7. Raw data was not provided in the report for food consumption and body weight.

10. SUBMISSION PURPOSE:

To support the registration of AC 303,630.

11. MATERIALS AND METHODS

A. Test Organisms

Northern Bobwhite (*Colinus virginianus*) were purchased from Sand Prairie Quail Farm, Maquoketa, Iowa. After a 13 day quarantine period, they were paired (one male and one female), placed in stainless steel cages, and acclimated for 14 days to the environmental conditions of the post-exposure room. The birds were 85 days old at the beginning of the exposure period and weighed 150-235 grams. Health exams were performed on all birds prior to exposure. Pre-exposure mortality was 1.2%.

B. Test System

Exposure pens consisted of six, 58.4 x 73.7 x 12.7 cm, pans wired together in a 2 x 3 pattern. The pans contained 5 cm of soil (48.8% silt, 43.4% sand, and 7.8% clay) with 6 holes for the insertion of potted cotton plants. Each pot contained three cotton plants. The pots were installed in the soil pan so the soil levels were flush. The 6th pan in this 2 x 3 arrangement was used to transport the birds between the exposure cage and post-exposure facility and to feed the birds during the exposure period. The floor area of the sixth pan was restricted to discourage roosting.

Environmental conditions were similar in both the exposure and post-treatment areas. The air exchange rate in the exposure and post-exposure area was 19.2 and 19.5 changes per hour, respectively. The photo period was maintained at 16L:8D with an intensity of 75 to 125 footcandles at bird level. Relative humidity ranged between 50 % and 80% in all areas. The daytime maximum temperature was $89^{\circ} \pm 5^{\circ}\text{F}$. The evening minimum temperature was $72^{\circ} \pm 5^{\circ}\text{F}$.

Food (Purina Flight Conditioner) and water were provided *ad libitum* throughout out the test.

C. Test Design

Nominal concentrations of the chemical were based upon the recommended application rate of 0.35 lbs ai/acre (1X). Concentrations tested were 0, 0.25X, 0.5X, 1X, 2X, and 4X the recommended application rate. Test solutions were mixed immediately prior to application by inverting a flask.

containing the formula and distilled water 40 times. Duplicate samples of the test mixture were collected prior to each test to verify concentrations.

Field application was simulated in an environmentally controlled wind tunnel. Six soil/plant pans were arranged in a 16 foot row within the wind tunnel. Even application was obtained using a Teejet Flat Fan spray nozzle situated 58 cm above the soil surface which moved along a track the length of the wind tunnel. Prior to application, the system was calibrated for flow rate and movement along the track to provide the desired application rates. Each test concentration was applied to two sets of exposure pans.

Thirty-two birds were exposed at each treatment level. Each exposure cage received 16 quail, eight male and eight female, two hours after application. At one and 24 hours into the exposure, three birds were removed from each cage and sacrificed. The remaining birds were removed after a 24 hour exposure period and held in a clean environment. Three additional birds were sacrificed at seven and 18 days post-exposure and sacrificed. The remaining birds were sacrificed at 28 days.

Physical condition of the quail and behavior was assessed at routine intervals throughout the test. Body weight measurements were taken at the beginning of the acclimation period, after one week acclimation, immediately prior to exposure, and weekly during the post-exposure period. Gross necropsy of each bird was performed at the time of sacrifice. Food consumption was measured weekly. Behavioral observations were made twice daily.

D. Samples Collected for Residue Analysis

Quail tissues were collected for residue analysis at the time of necropsy. Internal tissues included the GI tract, (from the crop to the distal end of the large intestine) and the liver. External tissues included skin, fat, and feathers collected from the breast and back, and residues washed from feet with hexane.

Air concentrations were measured after application in the sixth treated soil/plant treated pan using two Supelco 6-4834 bubblers installed in series. Samples were collected from 0 to 15 minutes and 45 to 60 minutes post application.

Soil samples were collected from the sixth soil/plant treated pan immediately after application and from the other five treated pans after the twenty four hour treatment

period. Four, 250g samples were collected from each soil/plant containers. The collections represented all five cm of the soil profile.

Collections were made for leaf residues and dislodgeable leaf residues determination. One hour post application, 60 to 80 leaf disks were punched from the center of the leaves on plants in the sixth treated soil/plant pan. The total leaf surface area collected was between 200 to 300 cm². Identical collections were made in the five soil/plant pans after the birds were removed.

To determine dislodgeable leaf residues collections were made as above and the leaf disks were washed in 100 ml washing solution (4 drops 1:50 dilution of 70% dictylsulfosuccinate sodium salt per 100 ml).

12. REPORTED RESULTS

Guideline Criteria	Reported Information
Mortality (percent during exposure period and 28 day post treatment observation period)	No mortality occurred in any treatment group or during either time period.
Mean Body Weights	No significant differences were reported for any treatment group or during any time period.
Mean Feed Consumption	ANOVA showed a difference during the first 3 days after exposure, but no group was different from the controls.
Behavioral Observations (For the exposure period and the post-exposure period)	<u>Exposure period:</u> No abnormal behavior <u>Post-exposure period:</u> Six birds with fluffed feathers and 8 birds with diarrhea were reported. They determined the behaviors to be unrelated to test substance. Sexual maturation began to occur during the test and was evenly distributed among the groups.

Guideline Criteria	Reported Information
Pathology	Four birds had inflamed GI tracts. One had an infection throughout the abdominal organs observed at necropsy between Day 10 and Day 22 post-exposure. <i>Coccidia</i> was implicated. Enlargement of gonadal tissue was evenly distributed throughout all treatment groups.
Quality assurance and GLP compliance statements were included in the report?	Yes

Analytical Results

Sample matrix	Analytical results		
Tank Mix Concentration	Label Application Rate	Nominal Conc. (ug/ml)	% of Nominal
	0.25X	1500	103.3
	0.5X	3000	107.9
	1.0X	5900	106.3
	2.0X	12000	49.5
	4.0X	24000	104.6
Air Concentrations	Only the 4X treatment group had detectable residues post-treatment 0 to 15 min - 1.09 ppm 45 to 60 min - 0.21 ppm		
Soil Samples 250 g samples collected down to a depth of 5 cm	Nominal (ppm)	Residue (ppb)	
	Control	0.74	
	0.25X	265	
	0.5X	365	
	1.0X	901	
	2.0X	1916	
	4.0X	3128	

Sample matrix	Analytical results	
Cotton Leaf Samples	Nominal (ppm)	Residue (ng/cm ²)
	Control	0.13
	0.25X	19.75
	0.5X	39.1
	1.0X	71.6
	2.0X	221.0
	4.0X	320.0
Dislodgeable Residues	Nominal (ppm)	Residue (ppm)
	Control	<0.15
	0.25X	59.3
	0.5X	<1.5
	1.0X	ND
	2.0X	1369
	4.0X	1382
Foot Wash Samples	Only three birds had detectable residues 1X - 0.061 ppm 4X - 0.066 and 0.061 ppm	
Feather Wash Samples	Only 5 birds had detectable residues, all were in the 4X treatment group (0.09, 0.17, 0.05, 0.06, 0.09). Birds in the 1X, 0.5X and 0.25 treatment groups were not analyzed.	
Avian Tissue Samples (GI tract, liver, skin)	Not analyzed due to no observed mortality or morbidity	

13. Statistical Results

One-way analysis of variance followed by Dunnett's t-test was used to detect differences between treatment groups for body weight and food consumption data. No significant differences were observed. No mortality or behavioral changes occurred, so no statistical testing was required. Six birds were observed to have fluffed feathers and eight birds exhibited diarrhea. Neither of these symptoms were attributed to the active ingredient.

14. REVIEWER'S COMMENTS:

As written, this study is not designed to assess the impact of birds exposed wet chemical during application. The effect of exposure to wet and dry chemical may be entirely different.

Test animals started to sexually mature during the study. However, no statistical difference was observed between the numbers maturing in each treatment group.

Residues on cotton leaf samples collected in the 1X treatment group were slightly less (0.8X) than concentrations predicted by Fletcher (1995). Maximum residues found on cotton leaf samples were about 320 ppm after 4 applications at 0.35 lbs/A.