

**DATA EVALUATION RECORD
UPLAND GAME BIRD DIETARY LC₅₀ TEST
GUIDELINE 71-2**

1. CHEMICAL: Spinosed (also known as Factor A and Factor D)
Shaughnessey #: 110003
2. TEST MATERIAL: XDE-105; Lot ACD13651; 88% potency as combined compounds 232105 (Factor A) and 275043 (Factor D); light grey to white solid
3. CITATION A. G. Murray, J. L. Seacat, and D. W. Grothe 1992. The Toxicity of XDE-105 to Juvenile Bobwhite in a 5-Day Dietary Study; Laboratory Project ID A00791; Lilly Research Laboratories, Greenfield, IN 46140; Submitted by DowElanco, Indianapolis, IN 46258-1189; MRID 43414531
4. REVIEWED BY:

Joanne S. Edwards
Entomologist
Ecological Effects Branch
Environmental Fate and
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Signature: *Joanne S. Edwards*
Date: 3/14/95
5. APPROVED BY:

Leslie W. Touart
Section Head
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Signature: *L. W. T.*
Date: 3/24/95
6. CONCLUSIONS: This study is scientifically sound and satisfies the guideline requirement (Gdln 71-2) for an avian subacute LC₅₀ study. Based upon visual examination of the data, the single oral LD₅₀ for bobwhite quail exposed to XDE-105 is >5156 ppm, the highest dose level tested. This classifies XDE-105 as practically nontoxic to birds on a subacute dietary basis. The No Observable Effect Concentration (NOEC) is 656 ppm based upon a significant reduction in body weight observed at \geq 1335 ppm levels.
7. ADEQUACY OF THE STUDY: Core
8. RATIONAL FOR CLASSIFICATION: N/A
9. BACKGROUND: New chemical EUP.
10. MATERIALS AND METHODS:

A. Test Organisms:

Guideline Criteria	Reported Information
Species: An upland game bird species, preferably the bobwhite (<i>Colinus virginianus</i>).	bobwhite (<i>Colinus virginianus</i>); birds were from same hatch; mean body wt of 30.4 ± 2.7 g at test initiation
Age at beginning of test: 10-14 days old.	13 days
Supplier	Barrett's Quail Farm, Houston, TX
Acclimation period	13 days

B. Test System:

Guideline Criteria	Reported Information
Pen size: about 35 x 100 x 24 cm	floor space 61 x 46 cm; height 18 cm
Brooder temperature: about 35°C (95°F)	pen temperature was maintained at approx. 37 ° C
Room temperature: 22-27°C (71-81°F)	not specified, even though study authors indicate that room temperature was continuously monitored throughout the study.
Relative humidity: 30-80%	ranged from 40% to 53% during study
Adequate ventilation? (Y/N)	not indicated
Photoperiod Minimum of 14 h of light.	24 hrs light
Diet	Teklad AN15JQ (JQ-15) diet; specifications included in the report

C. Test Design:

Guideline Criteria	Reported Information
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Range finding test? (Y/N)	yes
Definitive Test Nominal concentrations: Four minimum, 5 or 6 strongly recommended, in a geometric scale, unless $LC_{50} > 5000$ ppm.	five test concentrations, 200, 625, 1250, 2500, and 5000 ppm a.i.; adjusted for purity of test substance
Controls: Control group tested with diet containing the maximum amount of vehicle used in treated diets? (Y/N)	1 control group (no carrier)
Number of birds per group: 10 (strongly recommended)	10 birds per group; randomly assigned (5 birds per pen)
Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	no vehicle
Vehicle amount (% of diet by weight): Not more than 2%	N/A
Test durations: 5 days with treated feed and at least 3 days observation with clean feed.	five day exposure with three days with untreated feed
No mortality during last 72 hr of observations? (Y/N)	one bird in the 260 ppm group was found dead on morning of 1st day of basal diet phase

11. REPORTED RESULTS:

Guideline Criteria	Reported Information
Body weights measured at beginning and end? (Y/N)	individual measurements at day 0, 5, and 8
Estimated consumption per pen reported for pretreatment, treatment, and observation periods? (Y/N)	reported for the 5 day treatment phase and 3 day basal diet phase
Control Mortality: Not more than 10%	no mortalities
Raw data included? (Y/N)	no

Guideline Criteria	Reported Information
Signs of toxicity (if any) were described? (Y/N)	yes

Mortality:

One bird died in each of the two highest treatment levels (morning of 5th day in 5253 ppm group; morning of 6th day in 260 ppm group). Also, loose feces were reported by the study authors in the 5253 ppm treatment group. No other signs of mortality or toxicity were noted.

Statistical Results: The pattern of mortality in the study did not facilitate calculation of an LC₅₀ value. Estimation of the LC₅₀ was made by visual inspection of the data. The dietary LC₅₀ was determined to be greater than 5253 ppm, the highest test concentration tested. The no observed effect concentration (NOEC) was reported to be 656 ppm (no mortality, behavioral signs of toxicity, changes in body weight gain, or changes in food consumption)

Analytical Findings

Measured concentrations of XDE-105 in freshly prepared diets were 210, 656, 1335, 2601, and 5253 ppm for nominal concentration levels 200, 625, 1250, 2500 and 5000 ppm, respectively (Table 1, attached). The concentrations ranged from 104% to 107% of the nominal concentrations.

The authors reported that stability and homogeneity were established prior to initiation of the study. Assays indicated that XDE-105 was evenly distributed in the diets and that coefficients of variation for concentrations of 50 and 5000 ppm were 2.6% and 1.8%, respectively. The authors reported that concentrations of XDE-105 were stable in the diet, ranging from 100% to 103% of the initial concentration after 2 weeks.

Body Weight/Food Consumption

Body Weight: The authors reported that during the 5 day treatment phase a slight reduction in mean body weight occurred in birds exposed to 210 ppm in the diet. The authors stated this decrease was not treatment related, since birds exposed to 656 ppm in the diet showed no statistically significant difference in mean body weight gain. Birds at ≥ 1335 ppm level showed a significant reduction in mean body weight gain. During the 3 day post-treatment phase of the

study, no significant reduction in body weight gain occurred at levels of ≤ 1335 ppm (Table 2, attached).

Food Consumption: The authors reported no statistically significant differences between the mean food consumption of control birds and consumption by birds fed diets containing XDE-105 ≤ 2601 ppm during the treatment phase. No significant differences were noted at any dietary level during the three day post-treatment phase of the study (Table 3, attached).

The authors reported the LD₅₀ of XDE-105 in the diet of bobwhite as >5156 ppm.

A GLP statement was included in the report indicating the study conformed with GLP Standards. A Quality Assurance Statement was also included.

12. REVIEWER'S DISCUSSION AND INTERPRETATION

Verification of Statistical Results:

The dietary LC₅₀ was determined by visual observation of the data to be in excess of 5156 ppm, the highest test concentration tested. The no observed effect concentration (NOEC) is 656 ppm based upon a significant reduction in body weight observed at ≥ 1335 ppm levels.

Guideline Deviations: The deficiencies noted are listed below. None one of these were found to affect the overall quality of the study.

Humidity and temperature readings were not provided.

Homogeneity and stability measurement were not included in the report.

Physical characteristics were not described in the report. In correspondence from DowElanco to A. Heyward dated February 15, 1995 it is indicated that the test material used in this study was a solid material, light grey to white in color.

Classification: Core

Rationale: N/A

Reparability: N/A

13. COMPLETION OF ONE-LINER FOR STUDY: Yes

DER dated 3/24/95 (MRID 4344531)

Spinwood

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