DATA EVALUATION RECORD
UPLAND GAME BIRD DIETARY LC_{50} 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 and S. E. Woolwine 1992. The Toxicity of XDE-105 to Juvenile Mallards in a 5-Day Dietary Study; Laboratory Project ID A00891; Lilly Research Laboratories, Greenfield, IN 46140; Submitted by DowElanco, Indianapolis, IN 46258-1189; MRID 43414530

4. REVIEWED BY:

   Joanne S. Edwards
   Entomologist
   Ecological Effects Branch
   Environmental Fate and
   Effects Division (7507C)

   Signature: Joanne S. Edwards
   Date: 3/14/95

5. APPROVED BY:

   Leslie W. Touart
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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 LC_{50} study. Based upon visual examination of the data, the single oral LD_{50} for mallard 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. There were no mortalities or toxic effects noted at any test concentration. Based upon a significant reduction in body weight gain at the ≥1243 ppm dose levels, the no observed effect concentration (NOEC) is 302 ppm.

7. ADEQUACY OF THE STUDY: Core

8. RATIONAL FOR CLASSIFICATION: N/A

9. BACKGROUND: New chemical EUP.

A. Test Organisms:

Guideline Criteria	Reported Information
Species: A wild waterfowl species, preferably the mallard (*Anas platyrhynchos*).	mallard (*Anas platyrhynchos*); 1-day old birds
Age at beginning of test: 5-10 days old.	10 days; mean body weight 148.2 ± 23.9 g
Supplier	Whistling Wings, Box 1, 113 Washington St., Hanover, ILL
Acclimation period	9 days

B. Test System:

Guideline Criteria	Reported Information
Pen size: about 35 x 100 x 24 cm	floor space 43.2 x 75.2 cm; height 27.9 cm
Brooder temperature: about 35°C (95°F)	brooder pen temperature was maintained at approx 37 ° C
Room temperature: 22-27°C (71-81°F)	not specified, even though authors stated that room temperature was continuously recorded throughout the study
Relative humidity: 30-80%	ranged from 50% to 60% throughout the study
Adequate ventilation? (Y/N)	not indicated
Photoperiod Minimum of 14 h of light.	24 hrs light (fluorescent bulb lighting) throughout the acclimation period and study period
Diet	Teklad AN11DU (DU-11); specifications included in the report

C. Test Design:

Guideline Criteria	Reported Information
Range finding test? (Y/N)	no; doses selected based on results of bobwhite dietary study
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,followed by three days with untreated feed
No mortality during last 72 hr of observations? (Y/N)	no mortality observed

11. REPORTED RESULTS:

Guideline Criteria	Reported Information
Body weights measured at beginning and end? (Y/N)	individual measurements at day 0, 5, and 8

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

Mortality:

No signs of mortality or toxicity were noted.

Statistical Results: The pattern of mortality in the study did not facilitate calculation of an LC_{50} value. Estimation of the LC_{50} was made by visual inspection of the data. The dietary LC_{50} 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 76.4, 151, 302, 1243, 2566, and 5156 ppm for nominal concentration levels 75, 150, 300, 1250, 2500 and 5000 ppm, respectively (Table 1, attached). The concentrations ranged from 96% to 102% of the nominal concentrations.

The authors reported that stability and homogeneity were established prior to initiation of the study, and the assays indicated that XDE-105 was evenly distributed in the diets and that coefficients of variation for concentrations of 50 and 5000 ppm were both 1.9%. The authors reported that concentrations of XDE-105 were stable in the diet, ranging from 96% to 102% of the initial concentration after 2 weeks.

Body Weight/Food Consumption

Body Weight: The authors reported that during the 5 day treatment phase there was no significant difference between the mean body weight gain values of the control birds and

birds at dose levels ≤ 302 ppm. Birds at ≥ 1243 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 any of the treatment levels. (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. During the three day post-treatment phase of the study, the mean food consumption was significantly higher in the 5156 ppm group.

The authors reported the LD_{50} of XDE-105 in the diet of mallards 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 in the report.

12. REVIEWER'S DISCUSSION AND INTERPRETATION

Verification of Statistical Results:

The dietary LC_{50} was determined by visual observation of the data to be in excess of 5156 ppm, the highest test concentration tested. Based upon a significant reduction in body weight gain at the ≥ 1243 ppm dose levels, the no observed effect concentration (NOEC) is 302 ppm.

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

6

DER dated 3/24/95 (MRID 43414530) Afenoxad

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