6-3-04

DP Barcode: 299969 MRID #:460626-32

DATA EVALUATION RECORD
AVIAN SINGLE-DOSE LD_{50} TEST
GUIDELINE OPPTS 850.2100/OPPS71-1

1. **CHEMICAL:** PXTS **PC Code No.:** 006929

2. **TEST MATERIAL:** PXTS TECHNICAL **Purity:** 100 %
   Batch No. 1685-9-1
   EPA File Symbol 75799-R

3. **CITATION**

   Authors: Gallagher, S.P; Grimes, J.; Beavers, J.B.
   Title: PXTS: An Acute Oral Toxicity Study with the Mallard
   Study Completion Date: January 24, 2002
   Laboratory: Wildlife International, Ltd.
   8598 Commerce Drive
   Easton, MD 21601
   Sponsor: Akzo Nobel Functional Chemicals LLC
   5 Livingston Avenue
   Dobbs Ferry, NY 10522
   Laboratory Report ID: 497-101
   MRID No.: 460626-32

4. **REVIEWED BY:** Srinivas Gowda
   US EPA/OPP/AD/RASSB/Team 1

   Signature: Srinivas Gowda **Date:** 05-13-04

5. **APPROVED BY:** Norm Cook, Chief
   US EPA/OPP/AD/RASSB

   Signature: Norman J. Cook **Date:** 6/3/04

6. **STUDY PARAMETERS**

Scientific Name of Test Organism:	*Anas platyrhynchos*
Test Organisms Age/Size:	17 weeks/824-1233 grams
Definitive Study Duration:	14 days

7. CONCLUSIONS:

Results Synopsis:

LD50: >2250 mg/kg
NOEL: 1350 mg/kg

This study is scientifically sound and fulfills the guideline requirements for an avian acute oral toxicity test. Based on nominal concentrations, the acute oral LD_{50} was greater than 2250 mg/kg, which classifies PXTS as practically non-toxic to mallard ducks. NOEC was 1350 mg/kg. The study can be classified as core for a technical grade active ingredient.

8. ADEQUACY OF THE STUDY

A. Classification: Core.

B. Rationale: Study not discounted for minor guideline deviations discussed in Section 9.

C. Repairability: Not applicable.

9. GUIDELINE DEVIATIONS

The following guideline deviations were based on EPA OPPTS Guideline 850.2100:

- **The photoperiod was only 8 hours light; not 10 hours as specified in the guidelines.**

10. SUBMISSION PURPOSE: Registration

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*** **(p.10)**
Age at beginning of test • At least 16 weeks old	• **17 weeks old (p.10)**
Supplier	• **Whistling Wings, Inc., Hanover, IL (p. 10)**

Guideline Criteria	Reported Information
Acclimation period • At least 15 days	• Acclimation to caging and facilities for 3 weeks prior to initiation of test (p. 10)

B. Test System

Guideline Criteria	Reported Information
Pen facilities adequate?	• Yes (p.11)
Photoperiod • 10-h light, 14-h dark is recommended.	• 8 hours light/day, 16 hours dark/day (p.11)
Diet was nutritious and appropriate for species?	• Yes (p.10)
Feed withheld at least 15 hours prior to dosing?	• Yes–birds fasted for about 18 hours prior to dosing (p.10)

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	• No–Study Report states that doses were chosen based on toxicity data provided by the Sponsor (p.9)
Definitive Test • Nominal concentrations: At least five, in a geometric scale, unless LD_{50} > 2000 mg ai / kg	• Six nominal concentrations: 0, 292, 486, 810, 1,350, and 2,250 mg/kg (p.9)
Controls • Water control or vehicle control (if vehicle is used)	• Test substance dispersed in corn oil–used as control (p.11 and appendix III)
Number of birds per group • 10 (strongly recommended)	• 10 birds assigned to each treatment group–5 male/5 female (p.9)
Vehicle • Distilled water, corn oil, propylene glycol, 1% carboxymethylcelilulose, or gum arabic	• Corn oil (p.9)

Guideline Criteria	Reported Information
Amount of vehicle per body weight • Constant volume/weight % of body weight, not to exceed 1% (1ml/100g)	• All birds received constant dosage volume of 5 mL/kg of body weight (p.10)
Observations period • At least 14 days	• 14 days (p.15; table 1)

12. REPORTED RESULTS

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	• Yes (p. 3&4)
Individual body weights measured at beginning of test, on day 14 and at end of test if extended beyond 14 days?	• Yes (p.22–appendix IV)
Mean feed consumption measured at beginning of test, on day 14, and at end of test if extended beyond 14 days?	• Yes (p.17–table 3)
Control Mortality • Not more than 10%	• 0 % (p. 15–table 1)
Raw data included?	• Only for body weights; mean values provided for feed consumption (tables and appendices)
Signs of toxicity (if any) were described?	• Yes (p.12)

Mortality

Dosage (mg/kg)	No. of Birds	Cumulative Number of Dead: Day of Study													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14
Control	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0
292	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0
486	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Dosage (mg/kg)	No. of Birds	Cumulative Number of Deaths													
		Day of Study													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14
810	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1350	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2250	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Other Significant Results:

No overt signs of toxicity were observed in either the control or treatment groups. Frequent swallowing and lower limb weakness was observed in some birds, but these symptoms were reported to be isolated events and did not appear to have an impact on the birds' health. These symptoms, therefore, were not considered treatment related.

There were no apparent treatment-related effects on body weight at any of the dose levels. At the 2,250 mg/kg dose level, there was a reduction in feed consumption among the females, which was considered treatment related. According to the necropsy findings, one control female and one male at the 292 dose level were noted to have enlarged spleens. Additionally, some birds were noted to have foot lesions as a result of pen wear. The necropsy findings were not considered to be treatment related.

Statistical Results

Statistical Method: Since there were no treatment related mortalities, the Study Report stated that it was not possible to perform the calculation of an LD50. Rather, the LD50 was determined to be greater than the highest test concentration. The NOEL was determined based on the reduction in feed consumption data for female birds.

LD50: >2250 mg/kg
NOEL: 1350 mg/kg

13. VERIFICATION OF STATISTICAL RESULTS

Statistical Method: The LD50 was empirically estimated to be greater than the highest test concentration since there was no mortality in any treatment group. The NOEL could not be verified using the feed consumption for female birds, since only the mean was provided and not individual values.

LD_{50}: >2250 mg/kg

15. REVIEWER'S COMMENTS:

- The NOEC could not be verified by RASSB since only the mean feed consumption values were provided, not individual values.