9-12-86

9

DATA EVALUATION RECORD

1. Chemical: PP 321

2. Test Material: PP 321, 96% ai

3. Study/Action Type: Avian Acute Oral Study - Mallard Duck

4. Study ID: PP 321: The acute oral toxicity of PP 321 to the mallard duck, N.L. Roberts and C. Fairley, ICI, February 29, 1984. EPA Accession No. 259807.

5. Reviewed By: Ann Stavola
Aquatic Biologist
EEB/HED
Signature: Ann Stavola
Date: Sept 5, 1986

6. Approved By: Doug Urban
Supervisory Biologist
EEB/HED
Signature:
Date:

7. Conclusions:

The study is scientifically sound and meets EPA Guidelines requirement for an avian acute oral study. With an LD_{50} > 3950 mg/kg, PP 321 is practically nontoxic to birds.

8. Recommendations: N/A.

9. Background:

This study was submitted to support the EUP for Karate 1 EC Insecticide.

10. Materials and Methods:

a. Test Animals: Mallard duck (Anas platyrhynchos), five males and five females per treatment group, age at start of study - over 16 weeks. Source: The County Game Farm, Home Farm, Hothfield, Ashford, Kent.

b. Dose: There were six treatment groups - one was the negative control and the other five groups were administered different doses of PP 321, 96%. The doses were 739, 1040, 1620, 2580, and 3950 mg/kg. Corn oil was used for the negative control and as a vehicle for the test compound. The doses were administered by oral intubation. Each bird received the same dose volume per unit of body weight, 10 mL/kg.

c. Study Design: The birds were housed in groups of 10 in steel pens measuring 1.2 m x 1.5 m. Relative humidity was 80 percent, and mean mininum and maximum temperatures were 19 °C and 21 °C, respectively. Photoperiod was 7 light and 17 dark. Birds were maintained under test conditions for 14 days prior to dosing. After dosing there was a 14-day observation period, during which the birds were fed standard feed. The birds were starved overnight prior to dosing.

d. Statistics: None used since no birds died.

11. Reported Results:

There were no mortalities at any dosage level. All group mean body weights, body weight changes, and food consumption were within normal limits, and there were no treatment-related differences. One bird in Group 5 (2580 mg/kg) had small lesions on the liver, but these were not attributed to the treatment.

12. Study Author's Conclusions/QA Measures:

The oral LD_{50} value > 3950 mg/kg, the maximum dose level tested.

QA: "To the best of my knowledge and belief, this study was conducted in compliance with Good Laboratory Practices regulations as set forth in Title 21 of the U.S. Code of Federal Regulations, Part 58; with the exception of minor items, none of which is considered to have an impact on the validity of the data or the interpretation of the results in the report."

13. Reviewer's Discussion and Interpretation of Results:

a. Test Procedures: The study protocol is sound as it follows the protocol recommended by EPA's Pesticide Guidelines of 1982.

b. Statistical Analysis: None was done since no birds died.

c. Discussion/Results: The results indicate that with an LD_{50} > 3950 mg/kg PP 321, 96% ai, is practically nontoxic on an acute basis to birds.

d. Adequacy of Study:

1. Classification: Core.

2. Rationale: The study is scientifically sound and meets EPA Guidelines requirement for an avian acute oral study.