

US EPA ARCHIVE DOCUMENT

9-12-86

DATA EVALUATION RECORD

- 1. Chemical: PP 321
- 2. Test Material: PP 321, 96.5% ai
- 3. Study/Action Type: Avian Subacute Dietary Mallard Duck
- 4. Study ID: PP 321: The subacute dietary toxicity of PP 321 to the mallard duck, N.L. Roberts, C. Fairley, A. Anderson, and I. Dawe, ICI, March 29, 1985, 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: *Douglas Urban*
 Date: *9/12/86*

7. Conclusions:
 The study is scientifically sound and meets EPA Guidelines requirement for an avian dietary study with waterfowl. It indicates that technical PP 321, 96.5% ai is slightly toxic to waterfowl.

8. Recommendations: N/A.

9. Background:
 This study was submitted to support the EUP application for Karate 1 EC Insecticide.

10. Materials and Methods:

- a. Test Animals: Mallard ducklings (Anas platyrhynchos). Age at start of treatment: 8 days old. Source: The County Game Farms, Home Farm, Hothfield, Ashford, Kent County.
- b. Dose: Test diets were prepared by premixing PP 321 with chick diet to give a nominal level of 50,000 ppm of PP 321 ai. The premix was used to mix the final diets. The diets were analyzed for PP 321 content by HPLC.
- c. Study Design: The birds were randomly allocated to the test groups and acclimated for 3 days before being given the treated diets. There were 10 birds per group: 3 control groups and 6 treatment groups. The measured concentration of the treatment groups were: 508, 1030, 2030, 3020, 4020, and 5040 ppm. The birds were fed the treated diets for 5 days and were observed for an additional 4 days.
- d. Statistical Analysis: The LC₅₀ value was calculated using Finney's Probit Time Analysis With a Maximum Likelihood Programme.

11. Reported Results:

Treatment (ppm)	No. of Birds	Mortality Treatment Days					Total Mortalities
		2	3	4	5	6	
Controls	30						0
508	10						0
1030	10						0
2030	10						2
3020	10	1	1		2	2	6
4020	10		1	1	5		7
5040	10		2		1		3

LC₅₀ = 3948 ppm

95% ci: 2868-7602 ppm

Slope: 2.74119

S.E. slope: 0.87270 (using log transformation of the dose)

Birds fed 3020 to 5040 ppm showed signs of subdued behavior and unsteadiness over days 2 to 7. Birds fed 2030 ppm were subdued and unsteady on day 3 only.

Over the 5-day treatment period there was a treatment-related increase in group mean body weight in the controls (72-84%) and in the groups fed 508 and 1030 ppm (18.3% and 3%, respectively). There were decreases in body weight in the other treatment groups (10.6%, 11.2%, 21.6%, and 33.9% in increasing concentrations of PP 321 in the diets). All groups showed a mean increase in body weight over days 5 to 9.

There was a dose-related reduction in group mean food consumption during the 5-day treatment period in birds fed PP 321. The reduction over the 5-day period in the treatment groups as compared to the controls were (in increasing order of concentration) 48%, 57.1%, 46.5%, 70.9%, 79.8%, and 78.4%.

12. Study Author's Conclusions/QA Measure:

The dietary LC₅₀ value for PP 321, 96.5% ai in the mallard duck was 3948 (2868-7602) ppm.

QA: "To the best of our knowledge and belief the study described in this report was conducted in compliance with the following Good Laboratory Practices Standards: U.S. EPA, Title 40 CFR 160, FEDERAL REGISTER, November 29, 1983."

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, Subdivision E, 1982.
- b. Statistical Analysis: The statistiacal method used is acceptable, and the reported LC₅₀ was validated by EEB's statistical analysis.
- c. Discussion/Results: The results indicate that with an LC₅₀ value of 3948 ppm technical PP 321, 96.5% ai is slightly toxic to waterfowl on a dietary basis.
- d. Adequacy of Study:
 1. Classification: Core.
 2. Rationale: The study is scientifically sound and meets EPA Guidelines requirement for an avian dietary study.

STAVOLA PP321 MALLARD DIETARY

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
5040	10	3	30	17.1875
4020	10	7	70	17.1875
3020	10	6	60.00001	37.69531
2030	10	2	20	5.46875
1030	10	0	0	9.765625E-02
508	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 1030 AND +INFINITY CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 0

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	.3479205	2908.043	2193.581	4536.682

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H
5	.362835	1

- 7.591093E-02

SLOPE = 2.741118
 95 PERCENT CONFIDENCE LIMITS = 1.089984 AND 4.392252

LC50 = 3948.266
 95 PERCENT CONFIDENCE LIMITS = 2868.965 AND 7560.83

LC10 = 1358.602
 95 PERCENT CONFIDENCE LIMITS = 378.4125 AND 2013.862
