

DATA EVALUATION RECORD

1. CHEMICAL: Paclobutrazol
2. FORMULATION: Technical (PP. 333). 92.4% a.i.
3. CITATION: Roberts, N.L., C. Fairley, and R. Almond. 1982. The subacute dietary toxicity (LC₅₀) of PP. 333 to the mallard duck. Prepared by the Huntingdon Research Center (HRC), Huntingdon, England; submitted by ICI Americas, Inc., Wilmington, Del.; under Reg. No. 10182-TT; Acc. No. 248689.
4. REVIEWED BY: John J. Bascietto
Wildlife Biologist
EEB/HED
5. DATE REVIEWED: 1-17-83
6. TEST TYPE: Avian subacute (dietary) LC₅₀
A.) Test species: Mallard duck (Anas platyrhynchos)
7. REPORTED RESULTS: "It was not possible to determine a dietary LC₅₀ value for PP. 333 to the mallard duck. However, its toxicity was shown to be low with an LC₅₀ value in excess of 20,000 ppm".
8. REVIEWER'S CONCLUSIONS: The study is scientifically sound, and with an LC₅₀ > 20,000 ppm, paclobutrazol is "practically non toxic" to mallards when administered subacutely, in their diet. The study fulfills the guidelines requirement for a dietary LC₅₀ on a waterfowl species.

9. Materials/Methods

A. Test procedure:

1) Range Finder - Forty 10-day old mallards were tested (4 per group) from 0-20,000 ppm. No mortalities occurred.

2) Definitive study - 8-day old birds were randomly allocated to treatment and control groups. At 11 days of age birds were placed on test diets (after 3 day observation period).

- Three (3) Control Groups - 10 birds each (mixed sex)

- Five (5) Positive (Dieldrin) Groups - 10 birds each (" ")

- Seven (7) PP. 333 groups - 10 birds each (" ")

PP. 333 Group 9 -- 554 PPM

" 10 -- 1007 "

" 11 -- 1830 "

" 12 -- 3328 "

" 13 -- 6050 "

" 14 -- 11,000 "

" 15 -- 20,000 "

All birds were individually marked

Birds were housed in floor pens (1.2 m x 1.5 m); 10 per pen; steel sides; concrete floors; pen feeders and drinkers; temp 20°C-33°C, R.H. = 43-61%; continuous artificial light pattern adapted:

Birds were fed standard HRC chick diet until 11 days old - then controls got same diet; Dieldrin + chick diet for positive controls; chick diet + PP. 333 over the 5 day test period. HRC chick diet had no antibiotics or growth promoters. After 5 days dosing all birds were returned to HRC chick diet only. Water ad libitum (as well as diets). Dosed diets were prepared by homogenization. PP. 333 had no carrier; Dieldrin had corn oil at 0.469%. PP. 333 diets were made by premixing with chick meal, then storing in plastic bags at room temperature. All diets were stored in the same manner.

PP. 333 test diets were analyzed for homogeneity and stability by HRC - Dept. Analytical Chemistry. The report quotes "nominal" values only. "Analytical" values reported in an Appendix to report.

Observations

Mortalities : Daily

Bird health : Daily

Group Mean Body weight : Days - 3, 0 (prior to intro. of diet), 5, and 8

Group Mean Food consumption: Days -3 to -1

1 to 5 (daily)

6 to 8

Gross post-mortem exams: All birds examined macroscopically at death or termination of study.

B. Statistical Analysis:

- (-) Controls - N/A;
- Dieldrin (+) control - "Finney Probit" analysis proposed.
- PP. 333 - none performed. "Finney probit" would have been used if they found mortality.

10. Results -

Mortalities and LC50's

- 1) (-) Controls - none.
- 2) (+) Dieldrin controls - 0% at 50 ppm; 0% at 88 ppm; 30% at 153 ppm; 100% at 268 ppm; 100% at 469 ppm.
- 3) PP. 333 - none LC₅₀ > 20,000 ppm.

N.B. - they did not calculate an LC₅₀ for the (+) dieldrin controls because of too few responses between 0% and 100%, under the probit method. Dieldrin LC₅₀ reported to be > 153 < 268 ppm.

Health

- (-) Controls - good throughout study
- (+) Dieldrin controls - a total of three birds were described as "unsteady". Subsequently these were found dead at 153 and 268 ppm. All others died on test at higher doses.

Body weight

Mean weights increased for (-) controls. PP 333 weights were within "normal limits" - except for Groups 14 and 15 (11,000 + 20,000 ppm) over Days 0-5 when there was a "slightly" lower increase in comparison with other groups. Mean weight increases for dieldrin (+) controls were lower, over Day 0 to 5, than neg. controls; the increases becoming smaller with increasing dieldrin dose. A mean decrease was observed at 268 ppm dieldrin. Other weight changes were within "normal limits".

Food Consumption -

These data were in general agreement with bodyweight changes. There was evidence of slightly reduced food consumption in PP. 333 Groups 14 and 15 (11,000 and 20,000 ppm) over Days 1 to 5 in comparison to other groups.

There was also a marked dose-related reduction in food consumption in the groups given dieldrin, with the exception of a food spillage which occurred on Day 4 in Group 6 (Dieldrin 153 ppm), over Days 1 to 5.

All other Food Consumption data were within "normal limits".

Dietary analysis - The nominal concentrations were within 9% of analytical values except for one result in Group 9 where the analytical value was 19.3% above nominal.

11. Reviewer's Evaluation

A.) Test procedures: these were acceptable under the proposed guidelines.

B.) Statistics: N/A

C.) Results: these conformed to the raw data obtained, and reasonable interpretations were made. The reviewer agrees with the conclusion that the 8-day dietary LC₅₀ of PP. 330 is greater than 20,000 ppm.

The minor effects noted on Groups 14 and 15 for bodyweight and food consumption are considered to be of little importance since these groups were dosed at unrealistically high levels (11,000 ppm and 20,000 ppm respectively).

The analytical chemistry results validate the nominal concentrations tested.

D.) Conclusions:

1. Category - Core
2. Rationale - Guidelines study
3. Repair - N/A