

US EPA ARCHIVE DOCUMENT

DATA EVALUATION RECORD

1. CHEMICAL: Paclobutrazol

2. FORMULATION: Technical (PP. 333)

3. CITATION: Ross, D.B., N.L. Roberts, and C.N.R. Phillips. 1979.
The acute oral toxicity 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: 1-14-83

6. TEST TYPE: Avian acute oral toxicity (LD₅₀)

A) Test Species: Mallard Duck (Anas platyrhynchos)

7. REPORTED RESULTS: "From the results obtained, it was not possible to
establish an LD₅₀ value for PP 333 to the mallard duck.
However, its toxicity was shown to be low, with an LD₅₀
value in excess of 7913 mg/kg.

8. REVIEWER'S CONCLUSIONS: The study is scientifically sound and with an
LD₅₀ >7913 mg/kg, paclobutrazol is "practically non-toxic"
to mallard ducks. The study however, does not fulfill
a guidelines requirement for an avian LD₅₀ because the
choice of diet needs to be explained, and the precise
age of the birds needs to be reported.

9. Materials/Methods

A. Test procedure: a preliminary "range finder" test indicated that the test compound was not toxic at the "maximum practicable dose volume" of 20 ml with a 40% w/v concentration of corn oil. To confirm this, two groups of ten birds were dosed at this maximum level. Control birds were dosed with 20 ml of corn oil only. Groups 2 & 3 were dosed at 7913 mg/kg PP. 333 and 7737 mg/kg PP. 333 respectively. Groups consisted of 5 males and 5 females per group. Birds were maintained under test conditions for 14 days prior to dosing. Food was withdrawn overnight prior to administration of the test compound.

Compound was administered by oral gavage, using a CH 14 Nelaton rubber catheter and disposable syringe. Observation period was the 14 days after dosing. Gross post-mortem examinations were performed on four birds (2 male + 2 female) per group, plus any birds which died on test.

Birds were given standard "H.R.C." chick diet in meal form, with no antibiotics nor growth promoters. Diet was offered ad libitum, as well as water, except as noted above. Birds used were described simply as "young adults".

B. Statistical analysis: none was performed since only one bird died on test.

10. Results

Mortalities - one bird died during the acclimation period and was replaced. One bird in Group 2 (7913 mg/kg) died on Day 8 as a result of "bullying" by the other birds of the group. No other mortalities occurred.

Bobyweight - changes calculated from group mean bodyweights were judged to be within normal limits.

Foal Consumption - Group mean food consumption results indicated there was no evidence that dosing Mallards with PP 333 had any adverse effect on food consumption.

Gross Post-Mortem Examination - One bird dosed at 7913 mg/kg was found to have a pale liver and necrotic lumps in the body cavity. There was also a developing egg present which contained large amounts of blood. The authors said these findings were not treatment related. This bird was not the bird which died on test in Group 2. No other "abnormalities" were found on other birds examined.

11. Reviewer's Evaluation

A. Test procedures: acceptable under the proposed guidelines for avian testing, except that the precise age of buds ("young adults") was not reported, but they were fed "standard HRC Chick diet." This appears to be inconsistent or a misprint. Needs explanation.

B. Statistics: N/A

C. Results: Results conform to the raw data presented with reasonable interpretations made. The reviewer agrees that the substance appears to be "practically" non-toxic (acutely) to mallards. When administered as oral gavage the acute LD50 is greater than 7913 mg/kg. 95% c.i. is not needed. (But we don't know the age of the birds - although they were likely to be of an acceptable age).

D. Conclusions:

1. Category: Supplemental.
2. Rationale: precise Age of birds not reported.
3. Repair: to Core; Report precise age of birds. explain why "young adults" were given "chick" diet.