12/18/81

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(13)

DATA EVALUATION RECORD

1. Chemical: Iprodione (Shaughnessy #109801)

2. Formulation: Technical (95% a.i.)

3. Citation: Beavers, Joann B. and R. Fink. 1981. One-generation reproduction study - mallard duck - Iprodione technical - Final report. Study by Wildlife International Ltd. dated 3/20/81 and submitted by Rhone-Paulenc, Inc. [within Accession #070443]

4. Reviewed by: James D. Felkel
   Wildlife Biologist
   Ecological Effects Branch/HED

5. Date Reviewed: 12/18/81

6. Test Type: Avian Reproduction

   A. Test Species: Mallard duck (Anas platyrhynchos)

7. Reported Results: Behavioral effects on adults were seen at 300 and 1000 ppm. The only statistically significant reproductive impairment was in numbers of 14-day old survivors of hatchlings reared at 1000 ppm ($p < 0.01$).

8. Reviewer's Conclusions: The study is scientifically sound and meets the intent of proposed subpart E guidelines (7/10/78). Statistical analyses confirm that significant reproductive impairment ($p = 0.219$) occurred only at 1000 ppm nominal test concentration (890.0 - 1001.0 "uncorrected" measured concentration). Behavioral effects on adults were reported at 300 and 1000 ppm nominal test concentrations.

Materials/Methods Reported (Summary)

Pen-reared mallard ducks, disease - free and previously untreated, were obtained form the production flock at Wildlife International Ltd., St. Michaels, Maryland. They were 6 months old at the initiation of the study (i.e., approaching their first breeding season). 96 mallards were randomly distributed into the following groups:

Group No.	Concentration (ppm)	No. pens
1 - Control	0	12
2 - Iprodione Tech.	100	12
3 - " "	300	12
4 - " "	1000	12

Each pen contained one drake and one hen. The photoperiod for the first seven weeks of the study was eight hours of light per day and increased to 17 hours of light per day for the remainder of the study. Adults received water and the appropriate diet ad libitum.

All adult birds were observed daily and a record maintained of all mortalities, signs of toxicity, and abnormal behavior. Body weights were recorded at initiation, weeks 2, 4, 6, 8, and termination, but not during egg-laying. Weekly, during egg-laying, one egg from every other pen was randomly selected for egg weight and eggshell thickness measurement. Feed consumption was measured every 2 weeks. Eggs were collected daily, marked, cleaned and then stored at 56.0°F ± 1.5°F and 85% relative humidity. Weekly, the eggs were placed in an incubator. Prior to incubation, all eggs were candled to detect cracks; on day 14 of incubation, embryo viability was measured and E. coli contaminated eggs were removed; on day 21, embryo survival was determined; on day 23, eggs were placed in a hatcher; on day 28, all hatchlings, unhatched eggs, and eggshells were removed and the average body weight of representative hatchlings determined. Hatchlings were housed in battery brooders until 14 days old.

An incubation temperature of 99.5°F ± 0.1°F and wet bulb humidityndex of 90.0°F ± 0.2°F were maintained; eggs were rotated automatically. Hatcher temperature was 99.1°F ± 0.3°F and the wet bulb humidity index was 91.0°F ± 1.8°F. Brooder temperature was 100.0°F from hatching to day 7 of brooding and then lowered to 75.0°F for the remainder of brooding. Starter ration and water were available ad libitum for hatchlings. They were weighed at 14 days of age.

Statistical Analysis Reported (Summary)

Analysis of Variance was used to evaluate body weight and other "measurement" variables. "Count" variables were subjected to an analysis based on Cochran's concept of extraneous variability for the binomial distribution.

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Results Reported (Summary)

No adult mortalities occurred in any test group. At the 300 ppm test level, one hen exhibited loss of coordination and lower limb weakness for 2 days and one hen had swollen tissues. At the 1000 ppm test level, two drakes and one hen exhibited lower limb weakness; one hen exhibited loss of coordination and lower limb weakness; one hen exhibited loss of coordination, lower limb weakness and rigidity, and wing droop.

No statistically significant effects on adult body weight or average feed consumption were seen at any test level. Mean eggshell thickness was approximately the same at all test level (0.341 - 0.343 mm). The only statistically significant ($p < 0.01$) reproductive impairment was seen at the 1000 ppm test level in numbers of 14-day old survivors of hatchlings reared. However, raw numbers of 14-day old survivors/hen and 14-day old survivors of eggs set do not indicate any adverse effect at this concentration. [Summary Tables attached].

Appendices report "found (uncorrected)" toxicant concentrations as follows for the mallard feed:

Nominal	Found (uncorrected)
control	none detected
100 ppm	105 - 196 ppm
300 ppm	278 - 503 ppm
1000 ppm	890.0- 1001.0 ppm

Reviewer's Analysis

Procedures and statistical analyses were generally consistent with proposed subpart E guidelines (7/10/78). However, contrary to Attachment III of the study, it is not required that mallards be tested as pairs (with 12 pens), rather than 2 drakes and 5 hens in each of 5 pens.

As an initial screen to check the reported results, a chi-square analysis was conducted that examines the entire set of reproductive data at once (i.e., the sums of values for each reproductive parameter at each test level). This analysis, with designated computer file name of "SUPER", is considered more sensitive than ARSIN analysis (R. Balcomb, personal communication). However, since at present this analysis does not take between - pen variation into account, differences detected must be confirmed by ARSIN.

Using the SUPER program, no significant overall impairment ($p > 0.05$) was seen, across all reproductive parameters (from eggs laid to 14-day

old suvivors), at any test level. Overall significant differences ($p < 0.05$) between treatments and control were detected, however, at 100 and 300 ppm nominal levels where reproductive success was the same or better than controls at all individual parameters. At the 1000 ppm nominal level, while no overall significant difference relative to controls was detected ($p > 0.05$), significantly fewer 14-day old survivors of hatchlings reared were seen ($p < 0.05$). This difference was confirmed by ARSIN analysis ($p = 0.0219$).

Pen-by-pen numbers of eggs laid were examined by ANOVA. Means were found not to be significantly different ($p > 0.05$).

In sum, significant reproductive impairment ($p<0.05$) was found only at the 1000 ppm nominal test level. This impairment was at one parameter, 14-day old survivors given hatchlings reared [i.e., a significantly greater ($p < 0.05$) loss of hatchlings compared to controls].

Conclusions

1. Category: Core

2. Rationale: Study meets the intent of proposed subpart E guidelines (7/10/78).

3. Repairability: N/A

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