2-6-91

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DATA EVALUATION RECORD

1. CHEMICAL: OCTHILINONE

2. TEST MATERIAL: Octhilinone technical 98.5% active ingredient Lot #3192, yellow/tan liquid

3. STUDY TYPE: 8-Day Acute Dietary LC50 Bioassay

4. CITATION: Pedersen, C.A. (1990). Octhilinone: 8-Day Acute Dietary LC50 Study in Bobwhite Quail. Study conducted by Bio-Life Associates, Ltd. Neillsville, WI. BLAL # 89 QC 142, R & H Protocol # 90P-021, R & H Report #90RC-0021. Submitted by Rohm and Haas Company, Spring House, PA. Accession No. 416080-02.

5. REVIEWED BY:

Greg Susanke, Biologist 11/27/90
Ecological Effects Branch
Environmental Fate and Effects Division (H7507 C)

6. APPROVED BY: 2/6/91

for Doug Urban, Deputy Branch Chief
Ecological Effects Branch
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7. CONCLUSION:

This study appears scientifically sound and fulfills the Guideline requirement (71-2) for an acute dietary LC50 study on Bobwhite Quail. The LC50 of octhilinone is >3267 ppm, therefore it is considered slightly toxic. The NOEL is 1288 ppm.

8. MATERIALS AND METHODS:

A. Test Organisms:

Species- Bobwhite Quail (Colinus virginianus)

Supplier- Oak Ridge Game Farm, Gravette, AR.

Age- 11 days at test initiation

Acclimation period- All birds were hatched from eggs. They were then quarantined for 11 days to determine their suitability and to acclimate them to laboratory conditions: 96-114 °F; 23-58% relative humidity, 24 hours/day fluorescent lighting. All birds were fed Purina Game Bird Startena. Well water was supplied ad libitum. Of the 467 hatched quail 34 died during the quarantine period.

B. Test System:

Pen size- 45.7 x 61.0 x 45.7 cm wire pens

Environmental temperature- 92 - 112 °F

Relative humidity- 41 - 73%

Photoperiod- fluorescent lights on 24-hours/day

Dose preparation- A solution of octhilinone and acetone (< 2% total feed weight) was mixed with Purina Game Bird Startena by hammer-milling. This test diet became the highest concentration. The subsequently lower treatment concentrations were prepared by mixing equal amounts (6.5 kg each) of hammer-milled stock diet and the next higher test level diet.

C. Test Design:

Range finding test- not reported

Definitive test

Nominal concentrations- 5,000, 2,500, 1250, 625, and 312 ppm a.i. (concentrations at 50% increments)

Controls- 5 vehicle control groups were prepared by mixing 194 g acetone and 13 kg hammer-milled stock diet in a hobart mixer.

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Number of test organisms- Ten randomly selected birds per treatment level and controls (sex undetermined).

Biological observations- Observations were made daily for toxic effects and mortalities.

Physical parameter measurements- Birds were weighed by treatment group at 0-hour on test day 1 and on test days 5 and 8. Total food consumption for each treatment group and food consumption/bird/day was estimated for the treatment and observation periods.

Feeding- A large amount of feed at each concentration was prepared (feed, acetone, and octhilinone) then kept refrigerated (51-57 F) during the feeding period. A portion was taken out and fed daily for the 5 day treatment period. In the five control groups the same diet but without the octhilinone was provided. During the 3 day observation period untreated Purina Game Bird Startena that was not hammer-milled was given to all treatment and control birds.

9. REPORTED RESULTS:

Recovery of chemical- At day 0 octhilinone had a recovery rate of 86.9% at the lowest nominal concentration of 312 ppm and the highest recovery rate of 97.4% at the highest nominal concentration of 5000 ppm. The average observed concentration was within 92% (RSD +/- 4.2%) of the nominal concentrations.

Body weights- The ranges of the mean weight of the control groups at 0 hour were 22-27 g, at day 5 were 34-38 g, and at day 8 were 43-48 g. The ranges of the mean weight of the treatment groups at 0 hour were 23-28 g, at day 5 were 31-40 g, and at day 8 were 41-49 g.

Food consumption- The amount of food consumed/bird/day in the controls was 5-6 g through day 5 and 7-8 g by day 8. The amount of food consumed/bird/day in the treatment groups was 4-6 g through day 5 and 7-8 g by day 8.

Mortality and observations- Only one mortality occurred in the study and that was at the 5000 ppm level on day four. No abnormal behavior or signs of toxicity occurred in the controls or the four lowest treatment groups. Lethargy and anorexia were observed in the 5000 ppm treatment group. By the end of day 5 there was a complete remission of these signs.

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Gross pathology- Examinations of the bird that died and of 24 arbitrarily selected survivors revealed no abnormal pathological findings.

10. STUDY AUTHORS'S CONCLUSIONS / QUALITY ASSURANCE MEASURES:

The average body weight on test day 5, the body weight change during the test period, and the food consumption during the test period were slightly depressed in the 5000 ppm a.i. treatment group compared to the control groups.

Octhilinone was shown to have been homogeneously mixed in the feed and to be stable in avian feed while kept in refrigerated storage (37 - 39 °F) for seven days. At 312 ppm the average recovery was 88.0%, and at 5000 ppm the average recovery was 92.0%. It was also shown that octhilinone will degrade more rapidly at high temperatures. After one day at 92-112 °F, 312 and 5000 ppm a.i. will degrade by 86% and 35% respectively, where as the same concentrations kept at 75-81 °F for seven days will only degrade by 41% and 13%, respectively.

The 8-day acute dietary LC50 of octhilinone was determined to be > 5000 ppm a.i. One mortality occurred at 5000 ppm a.i. The NOEL was determined to be 2,500.

Quality Assurance and Good Laboratory Practice Regulation Statements were included in the report, indicating that the study was conducted in accordance with the FIFRA Good Laboratory Practice Standards set forth in 40 CFR Part 160.

11. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:

A. Test Procedure: The test procedures were generally in accordance with protocols recommended by the Guidelines. The protocol deviation listed below is not expected to affect the results of the study.

- Estimates of the average food consumption per pen were not reported. It was reported per treatment group only.

B. Statistical Analysis: The LC50 was calculated by the Ecological Effects Branch Toxanal computer program which used the Probit Method.

C. Discussion/Results: The study results appear to be scientifically valid. Analysis of the avian test feed showed that their was considerable degradation of octhilinone from the nominal concentrations after one day at the test temperature of 92-112 °F, therefore the average concentrations of 3267, 1288, 470, 149, and 44 ppm a.i. which were recovered from the test feed will be used to determine the LC50. Since only one mortality occurred in the study and that was at 3267 ppm a.i., the LC50 is >3267 ppm a.i. The NOEL is 1288 ppm a.i.

If the application or use rate of octhilinone produces estimated environmental concentrations above 3267 ppm then an additional dietary study will be required to determine the LC50 value.

D. Adequacy of the Study:

1. Classification: Core

2. Rationale: N/A

3. Repairability: N/A

12. COMPLETION OF ONE-LINER FOR STUDY: yes

Greg Susanke octhilinone Bobwhite Quail LC50

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
3267	10	1	10	1.074219
1288	10	0	0	9.765625E-02
470	10	0	0	9.765625E-02
149	10	0	0	9.765625E-02
44	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 3267 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

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

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