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 Mallard Ducklings. Study conducted by Bio-Life Associates, Ltd. Neillsville, WI. BLAL # 89 DC 138, R & H Protocol # 90P-022, R & H Report #90RC-0022. Submitted by Rohm and Haas Company, Spring House, PA. Accession No. 416080-03.

5. REVIEWED BY:

Greg Susanke, Biologist Greg Susanke 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
Environmental Fate and Effects Division (H7507 C)

7. CONCLUSION:

This study appears scientifically sound and fulfills the Guideline requirement (71-2) for an acute dietary LC50 study on mallard ducks. The LC50 of octhilinone to mallards is 1215 ppm, therefore it is considered slightly toxic. The NOEL was not determined.

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8. MATERIALS AND METHODS:

A. Test Organisms:

Species- (Anas platyrhynchos)

Supplier- Whistling Wings, Inc., Hanover, IL.

Age- 5 days at test initiation

Acclimation period- Three day quarantine period at testing conditions: temperature 70-74 °F; relative humidity 91-100%. All birds were fed Purina Game Bird Startena. Well water was supplied ad libitum. Five birds died the quarantine period.

B. Test System:

Pen size- 45.7 x 61.0 x 45.7 cm wire pens

Environmental temperature- 70 - 82 °F

Relative humidity- 52 - 96%

Photoperiod- fluorescent lights on 24-hours/day

Dose preparation- A solution of octhilinone and acetone (< 2% total 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 controls were prepared by mixing 194 g acetone and 13 kg hammer-milled stock diet in a hobart mixer.

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

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

Physical parameter measurements- Birds were weighed by group at 0-hour on test day 1 and on test days 5 and 8. Food consumption was estimated daily. Inspections were made daily for abundance of food and water, and food spillage.

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 44-51 g, at day 5 were 64-80 g, and at day 8 were 95-109 g. The average body weight increased 21-33 g by day 8 in the controls. The ranges of the mean weight of the treatment groups at 0 hour were 44-50g, at day 5 were 65-84 g, and at day 8 were 88-131 g. The average body weight increased 23-47 g by day 8 in the treatment groups.

Food consumption- The amount of food consumed/bird/day in the controls was 13-19 through day 5 and 22-26 g by day 8. The amount of food consumed/bird/day in the treatment groups was 2-14 g through day 5 and 15-26 g by day 8.

Mortality and observations- 2 mortalities occurred in two different control groups. At the end of day 5 all control birds were less active and alert than normal.

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5 day treatment period- 2 mortalities at 312 ppm, 2 mortalities at 625 ppm, 4 mortalities at 1,250 ppm, 8 mortalities at 2,500 ppm, and 10 mortalities at 5,000 ppm. Signs of toxicity were lethargy, the appearance of weakness, and anorexia) determined by reduced food consumption.

3 day observation period- One mortality occurred on day 6 at 625 ppm. Complete remission of all clinical toxicity signs was achieved by study termination.

Gross pathology- Examinations of the intestines and gizzards of the birds that died revealed a lack of food in three of the controls and two others in the treatment groups. Eighteen randomly selected survivors had no abnormal pathological findings at study termination.

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

The small size of the control ducklings, their lethargy and lack of alertness, and lack of food found in the digestive tracts during gross necropsy indicated a reduction in feeding probably caused by a decrease in palatability of hammer-milled feed. During the 3 day observation period unmilled feed was given the ducks and by study termination all abnormal behavior stopped.

The average body weights of ducklings in all treatment groups were comparable to those of the control groups. On day 5, food consumption values were reduced in the 312, 1,250, 2,500, and 5,000 ppm a.i. groups. Food consumption in the 312 ppm a.i. treatment group remained depressed throughout the recovery period. Gross pathological examinations of dead and surviving ducklings revealed no abnormal pathological findings attributable to treatment.

Octhilinone was shown 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 1,160 ppm a.i. with 95% confidence limits of 686 to 1,960 ppm a.i. Mortalities occurred in each treatment group therefore a no observed effect level could not be obtained.

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 was not reported. It was reported per treatment group only.

B. Statistical Analysis: Because there was control mortality, and none of the lower concentrations produced zero mortality, the data was adjusted to Abbott's correction. The LC50 was calculated by the Ecological Effects Branch Toxanol computer program which used the Probit Method.

C. Discussion/Results: The study results appear to be scientifically valid. The LC50 = 1215 ppm, and the 95% confidence limits are 767 - 1914 ppm. A NOEL was not determined. Octhilinone is classified as slightly toxic to mallard ducks.

D. Adequacy of the Study:

1. Classification: Core

2. Rationale: N/A

3. Repairability: N/A

12. COMPLETION OF ONE-LINER FOR STUDY: yes

NOTE: BECAUSE THERE WAS CONTROL MORTALITY, AND NONE
OF THE LOWER CONCENTRATIONS PRODUCED ZERO MORTALITY,
THE DATA HAS BEEN SUBJECTED TO ABBOTT'S CORRECTION.

Greg Susanke octhilinone Mallard LC50

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
5000	9.2	9.2	100	.1700293
2500	9.2	7.2	78.2609	7.821349
1250	9.2	3.2	34.7826	22.10381
625	9.2	2.2	23.913	7.821349
312	9.2	1.2	13.0435	1.700293

THE BINOMIAL TEST SHOWS THAT 312 AND 5000 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 1583.946

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
4	.2000573	1239.688	781.9442	1957.268

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	OODNESS OF FIT PROBABILITY
5	.2322074	1	.5459725

SLOPE = 2.504007
95 PERCENT CONFIDENCE LIMITS = 1.297378 AND 3.710635

LC50 = 1215.702
95 PERCENT CONFIDENCE LIMITS = 767.3345 AND 1914.238

LC10 = 378.1287
95 PERCENT CONFIDENCE LIMITS = 111.0257 AND 631.5393

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