UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

4 FEB 1983

MEMORANDUM:

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: W. Nelson, PM Team 17
Insecticides/Rodenticides Branch,
RD (TS-767C)

THRU: Norm Cook, Section Head
Section #2, EEB (TS-769C)

THRU: Clayton Bushong, Chief
EEB (TS-769C)

SUBJECT: EEB Review of Avian Data Submitted for
Margosine-O, EPA Reg. No. 100-AN, Due RD 2/5/83.

I have reviewed and validated the avian acute toxicity data on Margosine-O. The avian acute oral LD50 data are acceptable to support registration. The avian dietary LC50 data are acceptable to support registration pending our review of the proposed label (not yet submitted), and our determination of the estimated environmental concentrations from the proposed use.

I am reviewing the aquatic data and my report will be sent to you on Monday, February 7.

Douglas J. Urban
Wildlife Biologist
EEB, (TS-769C)

Attachments

Avian Data

INERT INGREDIENT INFORMATION IS NOT INCLUDED

DATA EVALUATION RECORD

1. CHEMICAL: Azadirachtin (Neem tree extract)

2. FORMULATION: Margasine-O concentrate

3. CITATION: Roth, R. 1982. Avian Dietary LC50 Study with Bobwhite Quail, Product Safety Labs (Agri-pharm), 725 Cranbury Rd., East Brunswick, New Jersey 08816; Report No. T-2475; Dates of Test: 9/9-10/82; Submitted by Vikwood Ltd., 1221A Superior, WI 53801; (Shaughnessy Number ? Accession Number).
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4. REVIEWED BY: Douglas J. Urban
Wildlife Biologist

5. DATE REVIEWED: 1/31/83

6. TEST TYPE: Avian Dietary LC50 Test

A. Test Species: Bobwhite quail

B. Test Material: Margosine-O, containing 0.3% Azodiractin, [redacted]

7. REPORTED RESULTS: The avian acute LC50 of Margosine-O concentrate to bobwhite quail is greater than 7000 ppm. No gross signs of toxicity were observed.

8. REVIEWER'S CONCLUSIONS: This study is scientifically sound and with an LC50 greater than 21 ppm, Azadirachtin could be from very highly toxic to practically non-toxic. This study does fulfill the requirement for an LC50 to upland game birds where the estimated environmental concentration of Azadirachtin in avian food from the use of Margosine-O is less than or equal to 21 ppm.

Methods and Materials Quail were housed in thermostatically controlled Petersine brooder units with wire bottom floors (26X36X10 inches). The brooder temperature was 85-95°F, there were ten quail per pen. Feed and water were provided ad libitum. Lighting (incandescent) was provided continuously. Birds were received at one day of age and acclimated for 16 days. On day 17, they were fasted 4 hours and placed in test groups. Gross autopsies were performed on all mortalities. Ten quail were assigned to each treatment group.

Statistical Analysis

None reported.

Results No mortality was reported in the control or the test groups (1000, 2000, 3000, 4000, 5000, 6000, and 7000 ppm). The average initial (day-0) and final (day-8) body weights ranged from 24.1 g-30.0g and 47.0g to 56.8g, respectively.

REVIEWER'S EVALUATION

A. Test Procedure The 1978 Subpart E guidelines were referenced and generally followed. An arithmetic dose progression was used (1000-7000 ppm) instead of a geometric dose spacing. This deviation is not significant since there was no mortality reported at any level.

B. Statistical Analysis

None performed

C. Discussion/Results The nominal test concentrations had to be corrected. The nominal concentrations were based on the assumption that Margosine-0 concentrate was 100% active (See Telephone report-1/31/83). In fact, the percentage active ingredient is 0.03 (See Telephone report-1/27/83). Therefore, the actual concentrations are as follows:

Nominal (ppm)	Actual (ppm-Azadirachtin)
1000	3
2000	6
3000	9
4000	12
5000	15
6000	18
7000	21

The avian dietary LC50, then, is greater than 21 ppm for bobwhite.

The avian dietary LC50 then, is greater than 21 ppm for bobwhite.

Conclusions

1. Category: Core for uses where the estimated environmental concentrations of Azadirachtin in avian food is less than or equal to 21 ppm.

2. Rationale: Where EEC's are at or below 21 ppm, the test accurately describes the hazard to birds via dietary exposure.

3. Repairability: N/A

INERT INGREDIENT INFORMATION IS NOT INCLUDED

DATA EVALUATION RECORD

1. CHEMICAL: Azadirachtin (Neem tree extract)

2. FORMULATION: Margosine-O concentrate

3. CITATION: Roth, R. 1982. Avian Single Dose Oral LD50, Product Safety Labs, (Agri-Pharm) 725 Cranbury Rd., East Brunswick, New Jersey 08816; Report No. T-2494; Dates of Test: 8/24-9/4/82; Submittted by Vikwood LTD., 1221A Superior, WI 53801; (Shaughnessy Number ?; Accession Number?).

4. REVIEWED BY: Douglas J. Urban
Wildlife Biologist

5. DATE REVIEWED: 2/1/83

6. TEST TYPE: Avian Acute Oral LD50

A. Test Species: Mallard Duck

B. Test Material: Margosine-O, containing 0,3% Azadirachtin, [redacted]

7. REPORTED RESULTS: The avian acute oral LD50 of Margosine-O concentrate to mallard ducks is greater than 16 ml/kg. Diet consumption decreased as the dose level of each group increased. There was a marked reduction at the highest dose level.

8. REVIEWER'S CONCLUSIONS: This study is scientifically sound and with an LD50 greater than 16.64 g/kg, Azadirachtin is practically non-toxic to mallard ducks. This study does fulfill the requirement for an LD50 to waterfowl.

Methods and Materials: Ducks were housed in thermostatically controlled Petersime brooder units with wire bottom floors (26X36X10 inches). The brooder temperature was 85-95°F. There were 10 ducks per pen. Feed and water were provided ad libitum. Lighting (incandescent) was provided continuously. Birds were received at one day of age and acclimated for 10 days. On day 11, they were fasted for 4 hours and placed in test groups. Ten ducks were assigned to each treatment group. Gross autopsies were performed on all mortalities.

Statistical Analysis

None reported.

Results

No mortality was reported in the control or test groups (1000, 2000, 4000, 5000, 6000, 7000 ppm). The average initial (day-0) and final (day-8) body weight ranged from 282g-310g and 447g-482g, respectively. Food consumption was slightly depressed at the highest test level.

REVIEWER'S EVALUATION

A. Test Procedure The 1978 Subpart E guidelines were referenced and generally followed. An arithmetic dose progression was used (1000-7000 ppm) instead of a geometric dose spacing. This deviation is not significant since there was no mortality reported at any level. Also, the brooder pen is smaller than that recommended (9360 sq.in. versus 9966 sq. in.). Again, this deviation is not significant since the growth and food consumption of the birds was normal.

B. Statistical Analysis

None performed.

C. Discussion/Results The nominal test concentrations had to be corrected. The nominal concentration were based on the assumption that Margosine-O concentrate was 100% active (See Telephone report-1/31/83). In fact, the percentage active ingredient is 0.03 (See Telephone report-1/27/83). Therefore, the octual concentrations are as follows:

Nominal (ppm)	Actual (ppm-Azadirachtin)
1000	3
2000	6
3000	9
4000	12
5000	15
6000	18
7000	21

Conclusions

1. Category: Core for uses where the estimated environmental concentrations of Azadirachtin in avian food is less than or equal to 21 ppm.

2. Rationale: Where EEC's are at or below 21 ppm, the test accurately describes the hazard to birds via dietary exposure.

3. Repairability: N/A

DATA EVALUATION RECORD

1. CHEMICAL: Azadirachtin (Neem tree extract)

2. FORMULATION: Margosine-O concentrate

3. CITATION: Roth, R. 1982. Avian Dietary LC50 Study with Mallard Ducks, Product Safety Labs (Agri-Pharm); 725 Cranbury Rd., East Brunswick, New Jersey 08816; Report No. T-2464; Dates of Test: 9/9/82-start; Submitted by Vikwood LTD., 1221 A Superior, WI 53801; (Shaughnessy Number ?; Accession Number ?).

4. REVIEWED BY: Douglas J. Urban
Wildlife Biologist

5. DATE REVIEWED: 2/1/83

6. TEST TYPE: Avian Dietary LC50 Test

A. Test Species: Mallard duck

B. Test Material: Margosine-O, containing 0.3% Azadirachtin, [redacted]

7. REPORTED RESULTS: The avian acute LC50 of Margosine-O concentrate to mallard ducks is greater than 7000 ppm. The ducks appeared active and healthy throughout the test phase and recovery phase.

8. REVIEWER'S CONCLUSIONS: This study is scientifically sound and with an LC50 greater than 21 ppm, Azadirachtin could be from very highly toxic to practically non-toxic to mallard ducks. This study does fulfill the requirement for an LC50 to waterfowl where the estimated environmental concentration of Azadirachtin in avian feed from the use of Margosine-O is less than or equal to 21 ppm.

Methods and Materials The Ducks were housed indoors at ambient temperatures in 5 ft X10ft pens. Incandescent lighting was provided continuously. Feed (anti-biotic free) and water were provided ad libitum. Twenty-five males and twenty-five females, all older than 16 weeks, were fasted 18 hours and then intubated. The ducks were individually weighed prior to dosing. Five females and five males were randously assigned to each dose level. No control group was run.

Statistical Analysis

None reported

Results

No mortality was reported in the test groups (1,2,4,8,16 mg/kg). The average initial weight (IW) weight at 14 days (14W), and percentage food consumption per body weight, follows:

Dose	IW(g)	14W(g)	FC/BW(%)**
1	1.08	1.16	14.4
2	1.08	1.15	10.4
4	1.085	1.195	12.0
8	1.115	1.19	12.0
16	1.03	1.09	5.9

REVIEWER'S EVALUATION

A. Test Procedure

The test procedure generally follow those in the 1978 Subpart E guidelines.

B. Statistical Analysis

None performed.

C. Discussion/Results

The test results were converted from ml/kg to g/kg based on the following information: 1 ml of Margosine-O concentrate equals 1.04 (See Telephone report, 1/31/83). Therefore, the avian acute oral LD50 is greater than 16.64 g/kg for mallard duck.

Conclusions

1. Category: Core
2. Rationale: N/A
3. Repairability: N/A