US ERA ARCHIVE DOCUMENT

DATA EVALUATION RECORD

- 1. CHEMICAL: Pyrethin I
- 2. <u>TEST MATERIAL</u>: Pyrethrum Extract, a yellow liquid with a reported purity of 57.57% active ingredient
- 3. <u>TEST TYPE</u>: Avian Acute Oral for the Bobwhite quail (<u>Colinus</u> <u>virginianus</u>)
- 4. <u>STUDY IDENTIFICATION</u>: Campbell, S. and Lynn, S. P. 1991. An Acute Oral Toxicity Study with Pyrethrum Extract in the Northern Bobwhite Quail. Wildlife International Ltd. Project No. 326-103 FIFRA Guideline 71-1 MRID# 420109-01

Submitted by:

Pyrethrin Joint Venture - Chemical
Specialties Manufacturers Assoc.

1913 Eye Street, NW
Washington, DC 20006

Test Facility:
Wildlife International Ltd.
305 Commerce Drive
Easton, MD 21601

5. REVIEWED BY:

Sara R. Ager, Biologist Ecological Effects Branch (H7507C) Environmental Fate and Effects Division signature: Jua K. Uge

Date

6. APPROVED BY:

Ann Stavola, Section Head, Section V Ecological Effects Branch (H7507C) Environmental Fate and Effects Division Signature:

Date: 3/0/92

7. <u>CONCLUSIONS</u>: This study appears to be scientifically sound and meets the guideline requirements for an avian acute oral study. The exact LD₅₀ was not calculated but was determined to be greater than 2000 mg/kg. This level is classified as practically non-toxic. The no mortality level was 2000 mg/kg (the highest level tested) and the NOEL was 250 mg/kg, based on signs of toxicity.

- 8. RECOMMENDATIONS: N/A
- 9. BACKGROUND: N/A
- 10. DISCUSSION OF INDIVIDUAL TESTS: N/A
- 11. MATERIALS AND METHODS:
 - A. <u>Test Organisms:</u> The Northern bobwhite quails (<u>Colinus</u> <u>virginianus</u>) used for the study were 21 weeks old at test

initiation and reproductively immature. All of the birds, obtained from Top Flight Quail Farm, Belvidere, NJ 07823, were from the same hatch, pen-reared and phenotypically indistinguishable from wild birds. The birds were acclimated for six weeks and were not fed 15 hours prior to receiving the dose material. Injured birds and birds displaying irregular behavior were not used in the test. At test initiation, body weights ranged from 160 grams to 216 grams.

- B. <u>Dosage Form:</u> The nominal concentrations tested were 125, 250, 500, 1000 and 2000 mg active ingredient per kilogram. Dosage levels were adjusted to reflect 100% active ingredient. The test substance was diluted in corn oil and intubated with a stainless steel cannula directly into the crop or proventriculus of the bird. The control group was given corn oil only. All birds received a constant dosage volume of 4 milliliters per kilogram of body weight.
- C. <u>Design</u>: Ten bobwhite quails, five males and five females, were randomly assigned to each group. Birds were acclimated for 6 weeks, and were fasted 15 hours prior to dosing. Birds were tagged with colored leg bands. Throughout the study, birds were provided food and water <u>ad libitum</u>.

Birds were housed, separately by sex and concentration, in indoor pens measuring 78 x 51 cm with a sloped ceiling which ranged from 20 to 25 cm. The side walls were constructed of galvanized sheeting and the rest of the pen of galvanized wire.

The average temperature was 24.8°C and the average relative humidity was 68%. The photoperiod was eight hours of fluorescent light with 16 hours of darkness. Birds were observed twice a day for mortality, toxicity and abnormal behavior.

Birds were individually weighed at test initiation and on Days 1, 3, 7 and 14. The estimated feed consumption was determined for each group on Days 0 - 3, 4 - 7, and 8 - 14.

D. <u>Statistics</u>: Due to lack of mortality, a LD₅₀ was not statistically calculated.

12. REPORTED RESULTS:

No mortalities occurred in any of the controls or dosages tested. No toxic signs were observed at 125 or 250 mg ai/kg.

After 2 hours and 45 minutes, the birds, at the 500 mg ai/kg concentration, showed signs of toxicity including prostate posture, wing droop, lower limb weakness, shallow and rapid respiration, twitching, hyperexcitability, loss of coordination and lethargy.

After 2 hours, the birds, at the 1000 mg ai/kg concentration, showed signs of toxicity including lower limb weakness, hyperexcitability and lethargy. Females at this concentration had a slight decrease in food consumption and all birds at this concentration had a reduced body weight gain compared with the control birds.

After 2 hours and 10 minutes, the birds, at 2000 mg ai/kg concentration, showed signs of toxicity including shallow and rapid respiration, prostrate posture, lower limb weakness, loss of coordination, lethargy, hyperexcitability, reduced reaction to external stimuli (sound and movement) a ruffled appearance, and twitching. All birds as this concentration had a loss in body weight on Days 0 - 3.

On the morning of Day 5 all of the birds appeared to have

recovered.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:

The LD_{50} was shown to be greater than 2000 mg/kg. The no mortality level was 2000 mg/kg and the NOEL was 250 mg/kg.

The report states the study was conducted in compliance with Good Laboratory Practice Standards (US EPA, Title 40 CFR Part 160 Federal Register November 29, 1983) and was signed by a quality assurance officer.

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

- A. <u>Test Procedure</u>: The test procedures were in accordance with Subdivision E and SEP guidelines except for the following deviations:
 - the test was 8 hours of light and 16 hours of darkness; the guidelines recommend a photoperiod of 10 hours of light and 14 hours of darkness
 - gross necropsies were not performed.
- B. <u>Statistical Analysis</u>: Due to lack of mortality, a LD₅₀ was not statistically calculated.
- c. <u>Discussion/Results</u>: This study appears to be scientifically sound and meets the guideline requirements for an avian acute oral study. The exact LD₅₀ was not calculated but was determined to be greater than 2000 mg/kg. This level is classified as practically non-toxic. The no mortality level was 2000 mg/kg (the highest level tested) and the NOEL was 250 mg/kg, based on signs of toxicity.

D. Adequacy of the Study:

- (1) Classification: Core
- (2) Rationale: N/A
- (3) Repairability: N/A