11/19/93

MRID No. 423229-01

DATA EVALUATION RECORD

1. **CHEMICAL:** Permethrin.
Shaughnessey No. 109701.

2. **TEST MATERIAL:** Pounce/Permethrin Technical; Lot No. B9152-247; 95.2% active ingredient; a brownish orange solid.

3. **STUDY TYPE:** 71-4. Avian Reproduction Study. Species Tested: Bobwhite quail (*Colinus virginianus*).

4. **CITATION:** Beavers, J.B., J.W. Foster, S.P. Lynn, and M. Jaber. 1992. Permethrin: A One-Generation Reproduction Study with the Northern Bobwhite (*Colinus virginianus*). Project No. 104-166. Conducted by Wildlife International Ltd., Easton, MD. Submitted by FMC Corporation, Philadelphia, PA. EPA MRID No. 423229-01.

5. **REVIEWED BY:**

Charles G. Nace Jr., M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Michael L. Whitten
For Charles G. Nace
Date: 2/26/93

6. **APPROVED BY:**

Michael L. Whitten, M.S.
Wildlife Toxicologist
KBN Engineering and
Applied Sciences, Inc.

Signature: Michael L. Whitten
Date: 2/26/93

Henry T. Craven, M.S.
Supervisor, EEB/EFED
USEPA

W. Linthurst, EEB, 11/16/93
Signature: Henry T. Craven
Date: 11/19/93

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements for an avian reproduction study. There were no treatment-related effects on mortality, weight gain, feed consumption, or reproduction at any concentration tested. Based on nominal concentrations, the no-observed-effect concentration (NOEC) was 500 ppm.

8. **RECOMMENDATIONS:** N/A.

9. **BACKGROUND:**

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

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11. MATERIALS AND METHODS:

A. Test Animals: Pen-reared, bobwhite quail (*Colinus virginianus*) were purchased from Top Flight Quail Farm, Phillipsburg, NJ. All birds were from the same hatch and were phenotypically indistinguishable from wild birds. The birds were acclimated to the facilities for 6 weeks prior to initiation of the test. At test initiation, all birds were examined for physical injuries and general health. Birds that did not appear healthy were discarded. Sex of the birds was determined by a visual examination of the plumage. The birds were 20 weeks of age at test initiation.

B. Dose/Diet Preparation/Food Consumption: Test diets were prepared by mixing the test material into a pre-mix which was used for weekly preparation of the final diet. The control diet and three test diets (25, 125, and 500 ppm) were prepared weekly and presented to the birds on Tuesday of each week. When necessary, additional feed was prepared. Each of the four groups of adult birds was fed the appropriate diet from test initiation until terminal sacrifice. Dietary concentrations were not adjusted for purity of the test substance. The control diet contained an amount of the solvent (acetone) and carrier (corn oil) equal to that in the treated diets.

Basal diet for adult birds and their offspring was formulated by Agway, Inc. The composition of the diet was presented in the report. The test substance was not mixed into the diet of the offspring. Food and water were supplied *ad libitum* during acclimation and during the test for adults and offspring.

Six samples from the control and each treatment were collected on day 0 of week 1 to determine the homogeneity of the test material in the diet. Single samples were collected from each concentration on day 0 of weeks 1, 2, 3, 4, 8, 12, 16, and 20 and from feed remaining in the feeders on day 7 of week 1. Samples were frozen and shipped on dry ice to Jim Bussard, ABC Laboratories, Columbia, MO for chemical analysis.

C. Design: The birds were randomly distributed into four groups as follows:

Permethrin Nominal Concentration	Number of Pens	Birds Per Pen	
		Males	Females
0 ppm	16	1	1
25 ppm	16	1	1
125 ppm	16	1	1
500 ppm	16	1	1

Treatment levels were based upon known toxicity data. Adult birds were identified by individual leg bands. The primary phases of the study and their approximate durations were as follows:

1. Acclimation - 6 weeks.
2. Pre-photostimulation - 7 weeks.
3. Pre-egg laying (with photostimulation)- 4 weeks
4. Egg laying - 10 weeks.
5. Post-adult sacrifice (final incubation, hatching, 14-day offspring rearing period) - 6 weeks.

D. **Pen Facilities:** Adult birds were housed indoors in pens constructed of galvanized wire grid and sheeting. The pens measured approximately 30 x 51 cm. Pen floors were sloped and ceiling height ranged from 21 to 26 cm. The average temperature in the adult study room was 22.5 ±2.8°C with an average relative humidity of 62 ±13%.

The photoperiod during acclimation and during the first 7 weeks of the study was 8 hours of light per day. The photoperiod was increased to 17 hours of light per day during week 8 and was maintained at that level until sacrifice of adult birds. The birds were exposed to approximately 501 lux of illumination throughout the study.

E. **Adult Observations/Gross Pathology:** All adult birds were observed at least once daily throughout the study for signs of toxicity or abnormal behavior. All birds that died during the study were necropsied. As soon as practical after the death of the bird, the pen mate was sacrificed and necropsied. At study termination, all surviving birds were sacrificed and necropsied. Adult birds were weighed at test initiation, on weeks 2, 4, 6, 8, and at study termination. Food consumption in each pen was determined once each week throughout the study.

F. **Eggs/Eggshell Thickness:** Eggs were collected daily from all pens, marked according to pen of origin, and fumigated to prevent pathogen contamination. The eggs were then stored at 13.5 ±1.0°C and 64 ±7% relative humidity until incubated. Eggs were removed from the storage room weekly and candled. Cracked or abnormal eggs were discarded. All eggs that were not cracked or used for egg shell thickness measurements were placed in an incubator at 37.5 ±0.0°C and 56% relative humidity. Eggs were candled on day 11 of incubation to determine embryo viability and on day 21 to determine embryo survival. All eggs were turned automatically while in the incubator. The eggs were placed in a hatcher on incubation day 21. The average temperature in the hatcher was 37.2 ±0.1°C with an average relative humidity of 76%.

Weekly throughout the egg laying period, one egg was collected, when available, from each of the odd numbered pens during the odd numbered weeks, and from each of the even numbered pens during the even numbered weeks. These eggs were opened, the contents removed, the shell washed thoroughly and allowed to air dry for at least one week. The average thickness of the dried shell plus membrane was determined by measuring (to the nearest 0.005 mm) five points around the waist of the egg using a micrometer.

G. **Hatchlings:** All hatchlings and unhatched eggs were removed from the hatcher on day 25 or 26 of incubation. The average body weight of the hatchlings by pen was then determined. Hatchlings were leg banded for identification by pen of origin and placed in brooding pens until 14 days of age. Each brooding pen measured 72 x 90 x 23 cm high, and was constructed of galvanized wire mesh and sheeting. Temperatures in the brooding compartments were approximately 38°C until the birds were 14 days of age. The photoperiod was maintained at 16 hours of light per day. At 14 days of age, the average body weight by parental pen of all survivors was determined.

H. **Statistics:** Upon completion of the study, Dunnett's method was used to determine statistically significant differences between the control group and each of the treatment groups. Sample units were the individual pens within each experimental group. Percentage data were examined using Dunnett's method following arcsine transformation. The pens in which mortality occurred were not used in statistical comparisons of the data.

Each of the following parameters was analyzed statistically:

Adult Body Weight
Adult Feed Consumption
Eggs Laid of Maximum Laid
Eggs Cracked of Eggs Laid
Viable Embryos of Eggs Set
Live 3-Week Embryos of Viable Embryos
Hatchlings of 3-Week Embryos
Hatchlings of Eggs Set
Offspring Body Weight
Hatchlings of Maximum Set
14-Day Old Survivors of Maximum Set
14-Day Old Survivors of Eggs Set
14-Day Old Survivors of of Hatchlings
Egg Shell Thickness

12. REPORTED RESULTS

A. Diet Analysis: Analytical results showed that the test diets were homogeneously mixed at 25, 125, and 500 ppm with percent recoveries of 82 (CV=4.1), 93 (CV=2.0), and 96% (CV=5.2), respectively (Appendix XII, Table III, attached). Permethrin concentrations remained stable over a 7-day period with a mean percent recovery of 92 ±7.1% (Appendix XII, Table IV, attached). Mean measured concentrations during the test were 23 ±4, 115 ±6, and 472 ±28 ppm, representing 92, 92, and 94% of nominal values, respectively (Appendix XII, Table V, attached).

B. Mortality and Behavioral Reactions: There were no treatment-related mortalities at any of the concentrations tested. There were three incidental mortalities at 25 ppm. Necropsies of the dead birds and their pen mates showed no treatment-related findings and all mortalities were considered to be incidental to treatment.

No overt signs of toxicity were observed at any concentration. Incidental clinical signs were noted in various groups during the course of the study. These incidental clinical signs were associated with physical injury and wear and/or interaction among pen mates. Except for the incidental mortalities and clinical signs noted previously, all birds at all concentrations appeared normal throughout the study.

C. Adult Body Weight and Food Consumption: No significant differences in body weights between the control and any treatment group were noted at any body weight interval (Table 1, attached).

There were no apparent treatment-related effects upon feed consumption among birds at any of the concentrations tested (Table 2, attached). When compared to the control group, food consumption showed a slight, but significant decrease at 25 ppm during week 3 and a slight, but significant increase at 500 ppm during weeks 4 and 19. These differences were not considered to be related to treatment.

D. **Reproduction:** When compared to the control group, there were no significant differences or apparent treatment-related effects in reproductive parameters at any concentration tested (Tables 3 & 3A, attached).

E. **Egg Shell Thickness:** When compared to the control group, there were no significant differences in egg shell thickness at any treatment concentration (Table 4, attached).

F. **Offspring Body Weight:** There were no significant differences between the control and any treatment group in body weights of offspring at hatching or at 14 days of age (Tables 5 & 5A, attached).

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** "There were no treatment related mortalities or overt signs of toxicity in any treatment group. There were no apparent treatment related effects upon body weight, feed consumption or any reproductive parameter at any of the concentrations tested. The no observed effect level in this study for northern bobwhite exposed to permethrin in the diet was 500 ppm, the highest concentration tested."

The report stated that the study was conducted in conformance with Good Laboratory Practices (GLP) (40 CFR Part 160). Quality assurance audits were conducted during the study and the final report was signed by a Quality Assurance Officer of Wildlife International Ltd. An additional statement of conformance with GLP (40 CFR Part 160) guidelines was included in the analytical report from ABC Laboratories.

14. **Reviewer's Discussion and Interpretation of the Study:**

A. **Test Procedure:** The test procedures were in accordance with Subdivision E - Hazard Evaluation: Wildlife and Aquatic Organisms, ASTM, and SEP guidelines except for the following deviations:

Eggs were stored at a temperature of 13.5 ±1.0°C; 16°C is recommended.

Eggs were candled on day 21 to determine embryo survival; day 18 is recommended.

Eggs were set at 37.5°C and 56% relative humidity; 39°C and 70% relative humidity are recommended.

Hatchlings were removed from the incubator on day 25 or 26; day 24 is recommended.

The adults were maintained at 22.5°C and 62% relative humidity; 21°C and 55% are recommended.

Eight hours of light, not seven as recommended, was provided during the first seven weeks of the study.

Behavioral observations of offspring were not reported.

Observations on food palatability were not reported.

B. **Statistical Analysis:** Statistical analyses of reproductive parameters were performed by the reviewer using analysis of variance (ANOVA) following square-root transformation of the count data and arcsine square-root transformation of the ratio data. The comparison between control data and data from each treatment level was made using multiple comparison tests. The computer program used is based on the EEB Birdall program, with an exception that the count data were square-root transformed before the ANOVA. The significance level was $p \leq 0.05$.

Analyses of reproductive parameters were verified (attached printouts) and found to match those reported by the authors, with the following exceptions: adult males at 500 ppm gained significantly more weight than controls, and food consumption at 25 ppm was significantly lower than controls. These differences were not considered to be treatment-related.

C. **Discussion/Results:** This study is scientifically sound and fulfills the guideline requirements for an avian reproduction study. There were no treatment-related effects on mortality, weight gain, feed consumption, or reproduction at any concentration tested. The NOEC was 500 ppm (nominal concentration).

D. **Adequacy of the Study:**

(1) **Classification:** Core.

(2) **Rationale:** Deviations from protocols were minor and did not affect the validity of the study.

(3) **Repairability:** N/A.

15. **COMPLETION OF ONE-LINER:** Yes; 02/22/93.

PERMETHRIN

Page_____ is not included in this copy.

Pages 9 through 16 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

DATABASE ENTRY FORM
FOR ACUTE OR CHRONIC TOXICITY STUDIES

1. **Chemical** Permethrin **Shaughnessy** 109701
2. **Common Name Of Organism Tested** Bobwhite quail
3. **Scientific Name** Colinus virginianus
4. **Age Of Organisms** 20 weeks
5. **Guideline No.** 71-4
6. **Type Of Dosing Method Or Study (Circle One)**

   1. Oral 2. Dietary (3. Reproduction) 4. Static
   5. Static Renewal 6. Flowthrough 7. Acute Contact
   8. Other _____

7. **% AI Of Test Substance** 95.2
8. **Study Duration (Hrs Or Days)** 20 wks (140 days)
9. **Dose Type (Circle One)** A. LD50 B. LC50 C. EC50 D. MATC
10. **Toxicity Level** A. mg/kg (B. ppm) C. mg/l D. µg/l E. ng/l F. µg/bee G. Other
11. **95% C.L.s** N/A
12. **Curve Slope** N/A
13. **NOEL** 500 ppm
14. **Study Date (YEAR)** 1992
15. **Study Review Date (YEAR)** 1993
16. **Category (Circle One)** (CORE) SUPPLEMENTAL INVALID
17. **MRID Or Accession Number** 423229-01
18. **Laboratory** Wildlife International, Ltd.
19. **Reviewer** Charles G Nace Jr.
20. **For Reproductive Studies (avian or aquatic) Indicate Which Parameter Affected At What Toxicity Level.**

    Eggs Laid _____ % Cracked _____ % Viable _____
    % Live Embryos _____ % Eggs hatched _____ 14D Survivors _____
    Growth Effected at _____ Other Effects _____