11/19/93

MRID No. 423229-02

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: Mallard duck (*Anas platyrhynchos*).

4. **CITATION:** Beavers, J.B., J.W. Foster, S.P. Lynn, and M. Jaber. 1992. Permethrin: A One-Generation Reproduction Study with the Mallard (*Anas platyrhynchos*). Project No. 104-167. Conducted by Wildlife International Ltd., Easton, MD. Submitted by FMC Corporation, Philadelphia, PA. EPA MRID No. 423229-02.

5. **REVIEWED BY:**

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

Signature: M J Whitten For C.G. Nace
Date: 3/12/93

6. **APPROVED BY:**

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

Signature: Michael L. Whitten
Date: 3/12/93

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

W. Linton, 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. At 25 and 125 ppm, no treatment-related effects were observed. At 500 ppm, slightly decreased food consumption and egg production were noted, and at terminal necropsy there was an increase in the number of females with a regressing ovary. No other reproductive parameters were affected. The no-observed-effect concentration (NOEC) was 125 ppm.

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

9. **BACKGROUND:**

36 hours

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Pen-reared mallard ducks (*Anas platyrhynchos*) were purchased from Whistling Wings, Hanover, IL. All birds were from the same hatch and were phenotypically indistinguishable from wild birds. The birds were acclimated to the facilities for 7 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 23 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 compositions of the diets were 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. Permethrin analyses were conducted using gas-liquid chromatography with an electron-capture detector.

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 - 7 weeks.
2. Pre-photostimulation - 8 weeks.
3. Pre-egg laying (with photostimulation)- 1 week.
4. Egg laying - 10 weeks.
5. Post-adult sacrifice (final incubation, hatching, 14-day offspring rearing period) - 5 weeks.

D. **Pen Facilities:** Adult birds were housed indoors in pens constructed of galvanized wire grid and sheeting. The pens measured approximately 75 x 90 x 45 cm. The average temperature in the adult study room was 22.1 ±2.1°C with an average relative humidity of 72 ±13%.

The photoperiod during acclimation and during the first 8 weeks of the study was 8 hours of light per day. The photoperiod was increased to 17 hours of light per day at the beginning of week 9 and was maintained at that level until sacrifice of adult birds. The birds were exposed to approximately 443 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 washed to prevent pathogen contamination. The eggs were then stored at 13.7 ±1.2°C and 65 ±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 14 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 24. The average temperature in the hatcher was 37.2 ±0.0°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 27 or 28 of incubation. The average body weight of the hatchlings by pen was then determined. Hatchlings were wing banded for identification by pen of origin and placed in brooding pens until 14 days of age. Each brooding pen measured 62 x 92 x 26 cm high, and was constructed of vinyl coated wire mesh and stainless steel sheeting. Temperatures in the brooding compartments were approximately 38°C until the birds were 5 to 7 days of age. At that time, the temperature was adjusted to approximately 26°C. The average ambient room temperature was 22.1 ±2.5°C. 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 90 ±3.1% (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 four incidental mortalities, two in the control group, and one each at 25 and 125 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. One female at 125 ppm had a prolapsed cloaca during week 13. The prolapse was reduced, and the bird appeared normal thereafter. Incidental clinical signs were noted in various groups during the course of the study (i.e., head lesions, feather loss). 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 25 and 125 ppm (Table 2, attached). When compared to the control group, food consumption showed a slight, but not significant decrease at 500 ppm throughout the study. This difference may have been related to treatment. The decrease was significant during weeks 6, 12, 14, and 19, when compared to the control.

D. **Reproduction:** When compared to the control group, there were no significant differences or apparent treatment-related effects in reproductive parameters at 25 and 125 ppm (Tables 3 & 3A, attached). However, while not significant, there appeared to be a slight reduction in the number of eggs laid by hens at 500 ppm during the last two weeks of egg production. During terminal necropsy, this reduction in egg production was correlated with an increase in the number of hens with a regressing ovary at 500 ppm.

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 and there were no apparent treatment related effects upon body weight at any of the concentrations tested or feed consumption at the 25 and 125 ppm test concentrations. At test concentrations of 25 and 125 ppm there were no effects upon any reproductive parameter. At the 500 ppm test concentration there appeared to be a slight decease in feed consumption during the test period. During the last two weeks of egg production there appeared to be a slight numerical decrease in egg production, however the overall decrease in egg production was very slight and was not statistically significant. Correlated with the reduction in egg production in the final two weeks of the study, in the 500 ppm treatment group at

terminal necropsy, there also was an apparent increase in the number of hens noted with a regressing ovary. Based upon a possible reduction in egg production during the last two weeks of egg laying, the no observed effect level in this study for mallards exposed to permethrin in the diet was at least 125 ppm and may have been as high as 500 ppm."

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 13.7 ±1.2°C; 16°C is recommended.

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

The adults were maintained at 22.1°C and 72% relative humidity; 21°C and 55% are recommended.

Eight hours of light, not seven as recommended, was provided during the first eight 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, body weight, feed consumption, and hatchling weight and survival were verified (see attached printouts) and found to match those reported by the authors.

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, or hatchling weight and survival. There were slight, but not significant decreases in food consumption and egg production at 500 ppm. At terminal necropsy, a regressing ovary was noted in eight females at 500 ppm, compared to two females with a regressing ovary in the control group. These differences were considered to be treatment-related. No other reproductive parameters were affected. The NOEC was 125 ppm.

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; 02/26/93.

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.

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____ Sales or other commercial/financial information.

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DATABASE ENTRY FORM
FOR ACUTE OR CHRONIC TOXICITY STUDIES

1. **Chemical** Permethrin **Shaughnessy** 109701
2. **Common Name Of Organism Tested** Mallard Duck
3. **Scientific Name** Anas platyrhynchos
4. **Age Of Organisms** 23 wks.
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** 125 ppm
14. **Study Date (YEAR)** 1992
15. **Study Review Date (YEAR)** 1993
16. **Category (Circle One)** (CORE) SUPPLEMENTAL INVALID
17. **MRID Or Accession Number** 423229-02
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 500 ppm % Cracked _____ % Viable _____
    % Live Embryos _____ % Eggs hatched _____ 14D Survivors _____
    Growth Effected at _____ Other Effects Regressing ovaries @ 500 ppm
    Food Consumption @ 500 ppm