9-6-88

Accession Number 406386-21

DATA EVALUATION RECORD

1. **CHEMICAL:** MON 7200/MON 15151.

2. **TEST MATERIAL:** MON 7200/MON 15151; 91.5% purity; a yellowish, crystalline solid.

3. **STUDY TYPE:** Avian Dietary LC50 Test.
   Species Tested: (Anas platyrhychos)

4. **CITATION:** Grimes, J. and Jaber, M. 1987. MON 7200: A Dietary LC50 Study with the Mallard. Prepared by Wildlife International Ltd., Easton, Maryland. Submitted by Monsanto Company, St. Louis, Missouri. Study Numbers 139-234 & 139-234A/WL-87-85. Accession Number 406386-21.

5. **REVIEWED BY:**

   Prapimpan Kosalwat, Ph.D.
   Staff Toxicologist
   KBN Engineering and
   Applied Sciences, Inc.

   Signature: P. Kosalwat
   Date: 7-30-88

6. **APPROVED BY:**

   James R. Newman, Ph.D.
   Project Manager/
   Principal Scientist
   KBN Engineering and
   Applied Sciences, Inc.

   Signature: James R Newman
   Date: 8/4/88

for Henry T. Craven
Supervisor, EEB/HED
USEPA

Signature: Richard m. Lee
Date: 9/6/88

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for an avian dietary LC50 test. With an LC50 value greater than 5620 ppm a.i., MON 7200 is considered practically non-toxic to mallard ducks (Anas platyrhynchos). The NOEC was determined to be 3160 ppm a.i.

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

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9. BACKGROUND:

10. DISCUSSION OF INDIVIDUAL TESTS: This report contains two tests. The first test was conducted between May 14 and May 22, 1987. Analysis of the diet showed an apparent lack of homogeneity at the 5620 ppm a.i. concentration. Therefore, the test for the 5620-ppm treatment level was repeated (with acetone added to the diet preparation) from September 17 to September 25, 1987 using the same test conditions and the same number of control birds.

11. MATERIALS AND METHODS:

A. Test Animals: All mallards (Anas platyrhynchos) were 10 days of age and appeared to be in good health at initiation of the study. One-day old birds were obtained from Whistling Wings, Hanover, Illinois. The birds were pen-reared and phenotypically indistinguishable from wild birds. All birds were acclimated to the caging and facilities from the day of receipt until initiation of the study. During acclimation, all birds were observed daily. Birds exhibiting abnormal behavior or physical injury were not used.

B. Test System: During acclimation and testing, all birds were housed indoors by test group in batteries of commercial brooding pens. Birds were assigned to pens by random draw. Each pen had floor space that measured approximately 72 x 90 cm. Ceiling height was approximately 24 cm. External walls, ceilings and floors were constructed of galvanized steel wire and sheeting. During the test the temperature in the brooding compartment of the pens was 31°C ± 3°C (SD). Average ambient room temperature for this study was 24°C ± 3°C (SD) with a relative humidity of 62%. The photoperiod (maintained by a time clock) was sixteen hours of light per day during acclimation and throughout the study. The birds received approximately twelve footcandles of illumination.

Throughout acclimation and testing, all test birds were fed a game bird ration (the diet formulation was included in the report). Water from the town of Easton and feed were provided ad libitum during acclimation and during the test. The birds received no form of antibiotic medication during acclimation or the study. The test diets were prepared by mixing the test substance into the diet with corn oil. The concentration of corn oil in the treated and control

diets was 2%. An amount of diet sufficient to last the five day exposure period was presented to the birds at initiation of the study. All dietary test concentrations were adjusted to 100% active ingredient based on the reported purity of the test substance. Therefore, all dietary concentrations and the LC50 value were reported as parts per million of the active ingredient in the diet.

C. Dosage: Eight-day Dietary LC50 test. The nominal dietary concentrations were 562, 1000, 1780, 3160, and 5620 parts per million (ppm) active ingredient (a.i.).

D. Design: Groups of ten mallard ducklings were assigned to each of the treatment and control groups by random draw. The birds used in this study were too immature to differentiate by sex. The test consisted of a geometric series of five test concentrations (see Section 11.C) and five control groups. The dietary concentrations were established based upon known toxicity data. Each group was fed the appropriate test or control diet for five days. During the exposure period the control group received an amount of the carrier in their diet equivalent to the greatest amount used in the treated diets. Following the five day exposure period all groups were given untreated feed for three days.

There were three phases of the study: acclimation, 9 days; exposure, 5 days; and post-exposure observation, 3 days. Following test initiation and continuing until termination, all birds were observed at least twice daily. A record was maintained of all mortality, signs of toxicity, or abnormal behavior. Body weights by group were measured at initiation of the study, on Day 5, and at termination of the test on Day 8. Average estimated feed consumption was determined for each test concentration group and control group for the exposure period (Days 0-5), and for the observation period (Days 6-8). Feed consumption was measured accurately, but was presented as an estimate due to the unavoidable wastage by the birds.

E. Statistics: The mortality pattern in the study was not conducive to calculating the LC50 value. Therefore, an estimation of the LC50 value was made by a visual inspection of the mortality data.

12. REPORTED RESULTS: There were no mortalities in the control group and in any of the concentrations tested (Tables 1 & 2 and 1A & 2A). All birds were normal in appearance and behavior for the duration of the study.

When compared to the controls, there appeared to be a slight reduction in body weight gain at the 5620 ppm concentration during the exposure period (Days 0-5). There was no effect on feed consumption at any of the concentrations tested.

The repeated test for the 5620-ppm treatment level yielded a comparable result to the original test.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES: Under the conditions of the study, the dietary LC50 for MON 7200 in mallard ducks was greater than 5620 ppm. The NOEL was considered to be 3160 ppm based on a slight reduction in body weight gain at the higher concentration.

The study was conducted so as to conform with Good Laboratory Practices (Federal Register, Volume 48, No. 230, November 29, 1983). The study was examined and the final report was signed by the Quality Assurance Unit of Wildlife International Ltd.

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

A. Test Procedure: The test procedures are generally in accordance with the SEP guidelines, except for some minor deviations as the following:

o The test was conducted at 31 $\pm$ 3^{o}C, instead of at 35^{o}C as recommended by the guidelines.

o No gross necropsy was performed at test termination.

B. Statistical Analysis: Statistical analysis was not needed due to the lack of mortalities in any treatments.

C. Discussion/Results: The results of both tests strongly confirm that the LC50 value of MON 7200 for mallard ducks was greater than 5620 ppm a.i. Therefore, MON 7200 is considered practically non-toxic to mallard ducks. Based on body weight gain during the exposure period, the NOEC was determined to be 3160 ppm a.i.

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D. Adequacy of the Study:

(1) Classification: Core.

(2) Rationale: N/A.

(3) Repairability: N/A.

15. COMPLETION OF ONE-LINER: Yes, July 11, 1988.