6-13-89
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DATA EVALUATION RECORD

1. Chemical: RE-45601 (Clethodim)

2. Test Material: RE-45601 Technical (SX-1688) 82.2% purity.

3. Study Type: Avian Dietary LC_{50}
   Species Tested: Mallard duck (Anas platyrhynchos)

4. Study ID: Hinken, C.,J. Grimes, and M. Graber. 1986. RE-45601 Technical (SX-1688): A Dietary LC_{50} Study With the Mallard. Prepared by Wildlife International Ltd., Easton, MD (Project No. 162-167). Study Sponsor: Chevron Environmental Health Center, Inc., Richmond, CA. EPA Accession No. 409745-27.

   With Addendum:

   Slagowski, J.L. 1986. Addendum to Eight Day Dietary LC_{50} Study in Mallard Ducks With RE-45601 Technical (SX-1688) Wildlife Project No. 162-167, Ortho Test No. S-2831: Diet Analyses. Chevron Chemical Company (Laboratory Project Identification S-2831-A).

5. Reviewed By: David Warburton
   Wildlife Biologist
   EEB/EFED
   Signature: Dave Warburton
   Date: 6/13/89

6. Approved By: Douglas J. Urban
   Supervisory Biologist
   EEB/EFED
   Signature: Douglas J. Urban
   Date: 6/13/89

7. Conclusions:

The submitted study is scientifically sound and documents a dietary LC_{50} >3978 ppm for mallard ducks exposed to RE-45601 technical. The study fulfills the Agency's Pesticide Assessment Guidelines requirement for avian dietary toxicity testing of RE-45601 (clethodim) on a waterfowl species only for an LC_{50} value of up to 3978 ppm.

8. Recommendations:

If regulatory criteria identify a need for a documented LC_{50} value greater than 3978 ppm in order to complete a hazard assessment, the study will need to be repeated at higher dosage levels to establish an LC_{50} value and corresponding 95% confidence intervals or to document an LC_{50} greater than 5000 ppm, as per Guidelines requirements.

9. Background:

The study was submitted to support, in part, a proposed Experimental Use Permit for Select 2EC herbicide to control annual and perennial grasses in cotton (EPA Record No. 238236).

10. Discussion of Individual Test: N/A.

11. Materials and Methods (Excerpted in part from submission):

a. Test Animals - Mallard ducklings (Anas platyrhynchos) were obtained from Whistling Wings, Hanover, Illinois. All mallards were 10 days of age and appeared to be in good health at initiation of the study. All birds were pen-reared and phenotypically indistinguishable from wild birds. The ducklings were too immature to differentiate by sex. All birds were acclimated to the caging and facilities from the day of receipt until initiation of the study.

b. System - During acclimation and testing, all birds were housed indoors by test group in batteries of brooding pens (Beacon Steel Products Co. Model No. B735). Average ambient room temperature was 86° ±2°F (SD) with a relative humidity of 77%. The photoperiod was 17 hours of light per day (Chroma 50 fluorescent lights; approximately 12 footcandles of illumination). Throughout acclimation and testing all birds were fed a game bird ration formulated to Wildlife International Ltd.'s specifications. Well water and feed were provided ad libitum during acclimation and during the test. Housing and husbandry practices were based upon the "Guide for the Care and Use of Laboratory Animals," 1978 DHEW Publications No. (NIH) 78-23.

c. Dose - 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%. Diets were prepared on the day of study initiation. An amount of diet sufficient to last two days of exposure was presented to the birds at initiation of the study. The remaining diet was placed in the freezer in labeled opaque bags until presented to the birds on Day 3. Dietary concentrations were not adjusted for purity of the test substance. Therefore all dietary concentrations and the LC_{50} value are reported as parts per million of the test substance as received. Nominal dietary test concentrations used in were 600, 1290, 2750, and 6000 ppm. Each group was fed the appropriate test or control diet for five days. Following the five day exposure period all groups were given untreated feed for three days.

Samples of the control diet and a test diet were collected immediately after mixing to assess homogeneity and initial concentration. Approximately one-half of each of the diets was

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presented to the birds on Day 0 and the remaining diet was stored frozen until presented to the birds on Day 2. Samples of the frozen diet were collected on Day 2 prior to presentation to the birds. Samples of control diet and test diet were taken from the feeders on Day 2 and Day 5 to assess stability during presentation. Samples were frozen immediately after collection and shipped to Chevron Chemical Company for analysis of the active ingredient.

d. Design - Birds were assigned to four test groups and three control groups. Each test or control group contained 10 ducklings. Birds were assigned to pens by random draw. 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. Individual body weights 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 0-2 and Days 3-5, and for the observation period, Days 6-8. Feed consumption was measured accurately, but is presented as an estimate due to the unavoidable wastage by birds.

e. Statistics - The mortality pattern in this study was not conducive to calculating the LC_{50} value. Therefore, an estimation of the LC_{50} value was made by a visual inspection of the mortality data.

12. Reported Results (Excerpted in part from submission):

There were no mortalities in the control group. All birds were normal in appearance and behavior throughout the test period. There were no mortalities or overt signs of toxicity at any concentration. All birds were normal in appearance and behavior throughout the test period. There was no apparent effect on body weight gain at the 600 ppm, 1290 ppm and 2750 ppm concentrations during the exposure period (Days 0-5) when compared to the controls. At 6000 ppm, there was a slight reduction in body weight gain during the exposure period and a reduction in feed consumption during the first two days of the study.

Since the median lethal concentration of RE-45601 technical was greater than 6000 ppm, only the 6000 ppm samples of diet were analyzed for active ingredient concentration. The average active ingredient concentrations (from duplicate samples) for each sample type were: 4660 ppm RE-45601 in the freshly prepared sample, 3690 ppm in the sample after 2 days in the hopper, 4480 ppm from the sample frozen for 2 days, and 3080 ppm from the sample after 3 days in the hopper following 2 days frozen.

13. Study Author's Conclusions/QA Measures:

The mallard dietary LC_{50} value of RE-45601 technical for this study was determined to be greater than 6000 ppm, the highest concentration tested. The no-observed-effect concentration was 2750 ppm, based upon a reduction in body weight and feed consumption at 6000 ppm.

The study was examined for conformance with Good Laboratory Practices as published by the U.S. Environmental Protection Agency, Office of Pesticide Programs. The final report was determined to be an accurate reflection of the data obtained.

14. Reviewer's Discussion and Interpretation of Study:

a. Test Procedures - The study was conducted according to Agency recommended procedures, except that the brooder temperature during the test was not reported.

b. Statistical Analysis - Not required due to mortality pattern.

c. Discussion/Results - Based on the results of the diet analysis, the average highest concentration of technical RE-45601 that the birds were exposed to was 3978 ppm. Section 71-2 of the Pesticide Assessment Guidelines, Subdivision E - Hazard Evaluation: Wildlife and Aquatic Organisms states: "Satisfactory data should establish that the 8-day dietary...LC_{50} is greater than 5000 ppm or establish an LC_{50} value and corresponding 95 percent confidence intervals." Therefore, because results of this study indicate only that the LC_{50} value for mallards exposed to RE-45601 technical in the diet is greater than 3978 ppm, the Guidelines requirement will be considered fulfilled only for toxicity testing up to 3978 ppm in the diet. Should a regulatory hazard assessment ever require an LC_{50} value greater than that documented by this study, the study will have to be repeated at higher dosage levels in order to establish an LC_{50} value and corresponding 95% confidence intervals or to document an LC_{50} greater than 5000 ppm. Results of this study (i.e., mallard LC_{50} >3978) may be used in a hazard assessment where appropriate.

d. Adequacy of Study -

1) Classification - Core for RE-45601 technical (Clethodim) up to 3978 ppm in the diet.
2) Rationale - Conducted according to Agency protocol; however, actual dosage levels tested were less than those identified in the Guidelines requirements.
3) Reparability - Study should be repeated as discussed only if the documented LC_{50} value (3978 ppm) is considered inadequate for use in a

regulatory hazard assessment.

CLETHODIM

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