6-1-94

DATA EVALUATION RECORD

1. **CHEMICAL:** Endothall Technical
Shaughnessey No. 038901

2. **TEST MATERIAL:** Endothall Technical; Batch No. B44-26-3; 83.16% active ingredient expressed as Endothall Acid equivalent; chemical name: 7-oxabicyclo-[2.2.1] heptane-2,3-dicarboxylic acid; CAS Reg. No. 145-73-3; off-white crystalline solid.

3. **STUDY TYPE:** 71-2. Avian Dietary LC_{50} Test. Species Tested: Mallard Ducklings (*Anas platyrhynchos*).

4. **CITATION:** Petersen, C.A. and A.M. Solatycki. 1994. Endothall Technical: 8-Day Acute Dietary LC_{50} Study in Mallard Ducklings. Project No. BLAL No. 106-015-02. Performed by Bio-Life Associates, Ltd. N6230 County Road G, Neillsville, WI 54456. EPA MRID No. 43167701.

5. **REVIEWED BY:**

Joanne S. Edwards, M.S.
Entomologist
Ecological Effects Branch
Environmental Fate and
Effects Division (7507C)

Signature: Joanne S. Edwards
Date: 5/31/94
Joan Edwards

6. **APPROVED BY:**

Leslie W. Touart, Ph.D.
Supervisory Biologist
Ecological Effects Branch
Environmental Fate and
Effects Division (7507C)

Signature: L W T
Date: 6-1-94

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirement for an avian dietary LC_{50} toxicity test. Based on nominal concentrations, the 8-day LC_{50} of endothall technical for mallards is >5000 ppm. Therefore, this compound is classified as practically non-toxic to mallards.

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

9. **BACKGROUND:** This data was submitted in support on endothall acid (technical) as required in a Reregistration DCI.

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

Awl

11. MATERIALS AND METHODS:

A. **Test Animals:** One hundred sixty mallard ducklings (*Anas platyrhynchos*) were obtained from Whistling Wings, Inc., Hanover, IL. The birds were from the same hatch, and were phenotypically indistinguishable from wild birds. Eighty of the birds were placed on an 2-day quarantine period to determine suitability for test and to acclimate them to the caging and facilities. The birds were 4 days of age at test initiation. All birds were fed Purina® Game Bird Startena® during the quarantine period and were fed well water *ad libitum*. During acclimation, the birds were observed daily.

B. **Test System:** The birds were housed indoors in thermostatically controlled brooders. Individual brooders measured 28" wide x 36" long x 11" high. Room lighting was provided by 24-hr natural daylight spectrum lighting. The average room temperature and relative humidity during the quarantine period, five day test period and three day recovery period was: 23°C/64%; 23°C/69%; and 22°C/69%, respectively. The average temperature and relative humidity in the brooders during the quarantine period, five day test period and three day recovery period was: 36°C/35%, 25°C/40%, and 36°C/36%, respectively.

The test diets were prepared by mixing appropriate amounts of the test substance with Purina® Game Bird Startena® and blending in a Hobart H-600-DT mixer. The diets were prepared at test initiation and enough was made to last throughout the exposure period. The birds were offered water and feed *ad libitum* throughout the study.

C. **Dosage:** Eight-day dietary LC_{50} test. Dietary levels selected for the study were 312, 625, 1250, 2500, and 5000 ppm. Birds were fed for a period of five days, followed by a three-day recovery period. The dietary concentrations were not corrected for the percent active ingredient of the test material.

D. **Design:** Ten ducklings per test level and in each of two controls were randomly assigned to pens. Birds were of indeterminate sex. Signs of toxicity, abnormal behavior, and mortality were assessed daily. Birds were fed test diet for five consecutive days beginning April 16, 1993 (age of birds was 4 days). Birds were fed untreated diet for the three day recovery period. Body weights by group were measured just prior to test initiation, and on day 8 (termination) of the test.

Average feed consumption by group was recorded during the last day of the quarantine period, at the end of the five day test period and at the end of the three day recovery period. Four arbitrarily selected birds each of the test groups and two arbitrarily selected birds from each of the controls were subjected to gross pathological examinations at the end of the test.

Samples of the test diets were taken for homogeneity and stability verification.

E. **Statistics:** Visual assessment of the data was made due to the lack of mortality in this study.

12. **REPORTED RESULTS:**

Two deaths were recorded during the quarantine period. They occurred on day two of the quarantine period.

No mortality or abnormal effects were observed in the control or in the treatment groups during the study.

Reductions in body weight gain and feed consumption during the study were noted (Tables 1 & 2, attached). Small reductions in average body weights and body weight gains were noted in the 625 and 1250 ppm test groups when compared to the controls on day 8. The authors did not consider these to be related to the test substance. Marked reductions in both body weight gains and average body weight gains were noted in the 2500 and 5000 ppm test groups as compared to the controls on day 8. The authors considered these to be related to the test substance. Reduced feed consumption was noted in the 2500 and 5000 ppm test groups as compared to the controls during the test days 1 through 5.

Gross pathological examinations revealed abnormal findings in two of the 24 birds: both were in the 5000 ppm group. The birds were noted as having pale livers.

The no-observed-effect concentration was considered to be 1250 ppm.

The percent recovery of nominal from the definitive study diets (homogeneity testing) ranged from 50.8 to 132%, and the percent recovery of the nominal from the stability samples ranged from 87 to 130%. Results are noted in Table 4. Based on the homogeneity data, the highest dose level (4151 ppm a.i. nominal) contained an average of 3813 ppm a.i. actual based on feed analysis (91.8% of nominal). Based on the stability data, the

highest dose level (4151 ppm a.i. actual) contained an average of 4795 ppm a.i. actual (116% of nominal).

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

Statements of adherence to Quality Assurance resulting in conformance to Good Laboratory Practice standards (40 CFR Part 160) were included in the report. Feed and water used for the test system were analyzed periodically to ensure that contaminants known to be capable of interfering with the study and reasonably expected to be present in such feed and water were not present in levels above those considered to be safe. These routine analyses were not conducted under GLPs.

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

A. **Test Procedure:** The test procedures were in accordance with Subdivision E, ASTM, and SEP guidelines with the following exceptions:

Group weights were used during the study. Individual body weights of the birds are recommended for monitoring weight gain or loss.

ASTM Guideline E 857-87 recommends that homogeneity testing, stability testing, and testing to confirm test substance concentrations in the diet at the beginning of the test be performed. Homogeneity testing was performed. Stability testing (i.e. testing of samples at the end of the five day exposure period to verify stability of the test substance) was not performed. Testing to confirm test substance concentrations in the diet at the beginning of the test was performed (Table 4/"Stability Data").

The test birds were four days old at study initiation, not five as reported (hatch date was 4/12/93 and study initiation date was 4/16/93). Five day old birds are preferred.

B. **Statistical Analysis:** Since a dose response was not evident by the end of the testing period, an LC_{50} value and 95% confidence limits could not be obtained.

C. **Discussion/Results:**

The EEB concurs overall with the reported results and conclusions of the study authors, with one exception. Reporting of a no-observable-effect concentration is inappropriate for this type of study.

This study is scientifically sound and meets the guideline requirements for an avian dietary LC_{50} toxicity test. Based on nominal concentrations, the 8-day LC_{50} value of endothall technical for mallard ducklings is >5000 ppm. This compound is classified as practically non-toxic to mallard ducks.

D. **Adequacy of the Study:**

(1) **Classification:** Core.

(2) **Rationale:** N/A.

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

15. **COMPLETION OF ONE-LINER:** Yes, 5-12-94.

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