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: Bobwhite Quail (*Colinus virginianus*).

4. **CITATION:** Petersen, C.A. and A.M. Solatycki. 1994. Endothall Technical: 8-Day Acute Dietary LC_{50} Study in Bobwhite Quail. Project No. BLAL No. 106-011-01. Performed by Biolife 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 L Touart
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 bobwhite quail is >5000 ppm. Therefore, this compound is classified as practically non-toxic to bobwhite quail.

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

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

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** One hundred eighty bobwhite quail (*Colinus virginianus*) were obtained from Sand Prairie Quail Farm, Maquoketa, IA. The birds were from the same hatch, and were phenotypically indistinguishable from wild birds. Ninety of the birds were placed on an 11-day quarantine period to determine suitability for test and to acclimate them to the caging and facilities. The birds were 11 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. During the quarantine period the average room temperature and relative humidity was 21°C/63%; for the five day test period, 23°C/69%; and for the three day recovery period, 22°C/69%. During the quarantine period the average temperature and relative humidity in the brooders was 38°C/36%; for the five day test period, 38°C/37%; and for the three day recovery period, 38°C/36%.

The test diets were prepared by mixing 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 chicks 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. 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 from each of the test groups and two arbitrarily selected birds from each of the control groups 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:**

Fourteen deaths were recorded during the quarantine period. Two occurred during the last three days.

No mortality or abnormal effects were observed in the control or in the treatment groups during the study. There were no reductions in either body weight gain or feed consumption during the study (Tables 1 & 2, attached).

Gross pathological examinations revealed abnormal findings in five of the 24 birds: one in the 1250 ppm group; two in the 2500 ppm group; and two in the 5000 ppm group. The five birds were noted as having gaseous intestines.

The no-observed-effect concentration was considered to be in excess of 5000 ppm. ??

The percent recovery of nominal from the definitive study diets ranged from 50.8 to 132%, and the percent recovery of the nominal from the definitive study stability samples ranged from 87 to 130% (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 (91.8% of nominal). Based on the stability data, the highest dose level (4151 ppm a.i. actual) contained as 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.

The fourteen deaths that occurred during the quarantine period should have been subjected to gross pathological examinations.

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 eleven days of age at study initiation, not twelve as reported by the authors (if hatch date was 4/5/93 and study was initiated 4/16/93).

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 bobwhite quail is >5000 ppm. Therefore, this compound is classified as practically non-toxic to bobwhite quail.

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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