DATA EVALUATION RECORD

1. **CHEMICAL:** Nuosept 95.
Shaughnessey No. 107001.

2. **TEST MATERIAL:** Nuosept 95; Batch No. 129593; 50% purity; a clear pale yellow liquid.

3. **STUDY TYPE:** Avian Dietary LC_{50} Test. Species Tested: Bobwhite quail (*Colinus virginianus*).

4. **CITATION:** Hakin, B., M. Rodgers, A. Anderson, and I.S. Dawe. 1990. Nuosept 95: LC_{50} to Bobwhite Quail. HRC Report No. NDX 9/901288. Performed by Huntingdon Research Center Ltd., Cambridgeshire, UK. Submitted by Hüls America Inc., Piscataway, NJ. EPA MRID No. 416848-01.

5. **REVIEWED BY:**

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Signature: Mark Mossler
Date: 6/25/92

6. **APPROVED BY:**

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Signature: Daniel Rieder 7-7-92
Date:

7. **CONCLUSIONS:** This study is scientifically sound but does not meet the guideline requirements for an avian dietary LC_{50} toxicity test. The test material was administered via drinking water rather than food. The LC_{50} for Nuosept 95 to bobwhite quail was determined to be greater than 5200 ppm ai (10400 ppm as total product), which classifies this compound as practically non-toxic to bobwhite quail. The NOEC was 1541 ppm ai (3082 ppm as total product).

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

9. **BACKGROUND:**

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

5.5 hrs

6

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Bobwhite quail (*Colinus virginianus*) were obtained from a supplier in Cambridgeshire, UK. The birds were one-day old when received and were phenotypically indistinguishable from wild birds. All birds were in apparent good health at the beginning of the pre-treatment period (day -3). The birds were 13 days of age at test initiation.

B. **Test System:** The birds were housed indoors in wooden boxes. Lids were constructed of wire mesh and each box contained a drinker and feeding tray. During the test, the mean daily temperature in the building was 26-29°C. The average relative humidity was 64%. A continuous photoperiod was used throughout the study.

The test material was administered in the drinking water of the birds. Solutions were prepared by adding the test substance to tap water. The test material was prepared daily during the exposure period (days 0-5).

The birds were offered water and feed (standard chick diet) *ad libitum* throughout the study. A list of the ingredients in the feed was given in the report and it appeared to be free of antibiotics and growth promoters.

C. **Dosage:** Acute dietary LC_{50} test. Dosage levels selected for the study were 1541, 2311, 3467, and 5200 ppm active ingredient (ai). The amount of test material added to the water was corrected for purity (50%).

D. **Design:** Ten quail per test level and in each of three controls were assigned to each pen. Signs of toxicity, abnormal behavior, and mortality were assessed daily. Group mean body weights were measured at initiation and on days 5, 8, and 9. Average feed and water consumption was determined by group for days 0-1, 1-2, 2-3, 3-4, 4-5, (the exposure period) and 6-9 (the observation period).

Samples of the drinking water were taken immediately after preparation for analysis (concentration) of the test substance by gas chromatography. Stability analyses were performed on samples collected after 24 hours in the test room.

A post-mortem examination was conducted on all birds in the highest test group and on the birds which died during the study.

E. **Statistics:** The LC_{50} value was estimated by visual assessment of the data due to the mortality pattern in this study.

12. **REPORTED RESULTS:** All birds in the three control groups and the lowest test concentration group were healthy throughout the test period.

One mortality occurred in the 2311 ppm ai group on day 5 of the study. A single mortality was noted on each of test days 4 and 6 for the 3467 ppm ai group. Two mortalities occurred in the highest concentration group (5200 ppm ai) on day 4. The only bird showing clinical symptoms was from the 3467 ppm ai group. This bird was quiet and unsteady prior to death on day 4.

A reduction in bodyweight increase and feed consumption was observed in the two highest treatment groups during the exposure period (Tables 2 & 3, attached). During the observation period, similar bodyweight increases were observed in all groups and feed reduction increased in the three highest treatment groups in comparison to the control birds.

Water consumption was variable between treatment groups. There was no evidence of a treatment-related effect (Table 4, attached).

The two mortalities in the 5200 ppm ai group and one of the two mortalities in the 3467 ppm ai group were found to have dark intestines. The other mortality in the 3467 ppm ai group had brown gas-filled intestines. No abnormalities were detected in any of the other birds examined by post-mortem necropsy.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The authors concluded that it was not possible to determine the LC_{50} of Nuosept 95 to the bobwhite quail. This value must lie in excess of 5200 ppm ai, the maximum dose level tested. The no-effect-level was determined to be 1541 ppm ai.

A Quality Assurance Unit and Good Laboratory Practice Statement was included in the report indicating that the

study conformed with Good Laboratory Practice regulations as set forth in 40 CFR Part 160.

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:

Body weights were measured by group. Individual body weights are recommended.

The temperature in the pens (26-29°C) was less than recommended (35°C).

The birds were not distributed randomly.

It was not stated if the test material was technical or a formulated product.

The test material was administered in the drinking water rather than in the food.

B. Statistical Analysis: Since a dose-related mortality response greater than 50% did not occur during the testing period, an LC_{50} value and 95% confidence interval could not be obtained.

C. Discussion/Results: The report stated that chicks were distributed in a manner that would equilibrate the mean weight of each test group. If the chicks were weighed and put in a group on the basis of weight, they were not distributed randomly. However, the reviewer believes that the distribution was adequate for testing purposes.

A report on the analysis of the test material in the water was included in the main report. The study verified that the test material was present at the desired levels at both 0 and 24 hours after preparation (Addendum Tables 1 & 2, attached). The nominal concentrations acceptably estimate the actual concentrations to which the birds were exposed.

The study is scientifically sound and adequately determines the LC_{50} of the test material in the drinking water of bobwhite quail. However, the intended end-point of the guidelines is a determination of the LC_{50} in food. Chemical uptake from the gut, as well as chemical fate (e.g., hydrolysis in water) may be

different when comparing between test material in water vs. food. Inter-chemical comparisons require the use of LC_{50} values for a single medium (food). Therefore, this study does not meet the guideline requirements for an avian dietary LC_{50} toxicity test. The LC_{50} for Nuosept 95 to bobwhite quail was determined to be greater than 5200 ppm ai (10400 ppm as total product), which classifies this compound as practically non-toxic to bobwhite quail. The no-observed-effect concentration (NOEC) was 1541 ppm ai (3082 ppm as total product) based on mortality observed in the 3211 ppm ai group.

D. Adequacy of the Study:

(1) **Classification:** Supplemental.

(2) **Rationale:** The test material was administered via drinking water rather than food.

(3) **Repairability:** No.

15. COMPLETION OF ONE-LINER: Yes, 5-26-92.