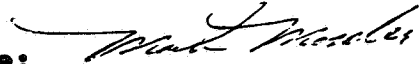
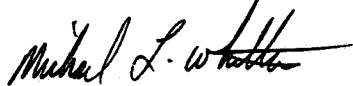
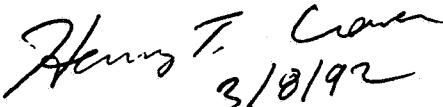


US EPA ARCHIVE DOCUMENT

DATA EVALUATION RECORD

1. **CHEMICAL:** Amitraz.
Shaughnessey No. 106201.
2. **TEST MATERIAL:** Technical BTS 27271.HCl (BTS 27271); Batch No. CR 19621/1; 99.1% active ingredient; a pale pink powder.
3. **STUDY TYPE:** Avian Dietary LC₅₀ Test. Species Tested: Mallard duck (*Anas platyrhynchos*).
4. **CITATION:** Hakin, B. and A.J. Johnson. 1991. W138 Amitraz: Technical BTS 27271.HCl: Subacute Dietary Toxicity (LC₅₀) to Mallard Duck. Lab. Proj. ID No. TOX 90558. Performed by Huntingdon Research Center, Huntingdon, Cambridgeshire, UK. Submitted by NOR-AM Chemical Co., Wilmington, DE. EPA MRID No. 421246-06.
5. **REVIEWED BY:**

Mark A. Mossler, M.S. Associate Scientist KBN Engineering and Applied Sciences, Inc.	Signature:  Date: 1/30/92
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6. **APPROVED BY:**

Michael Whitten, M.S. Wildlife Toxicologist KBN Engineering and Applied Sciences, Inc.	Signature:  Date: 1/30/92
Henry T. Craven, M.S. Supervisor, EEB/EFED USEPA	Signature:  Date: 3/10/92
7. **CONCLUSIONS:** This study is scientifically sound but does not meet the guideline requirements for a dietary avian acute test. The results of the homogeneity, stability, and concentration verification tests were not included in the report. The LC₅₀ was >5,200 ppm (based on nominal concentrations) which classifies BTS 27271.HCl as practically non-toxic to mallard ducklings. The NOEC was 81 ppm.
8. **RECOMMENDATIONS:** See Section 14 D-3.

9. **BACKGROUND:** Data submitted to support conditional registration on cotton.
10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.
11. **MATERIALS AND METHODS:**

- A. **Test Animals:** Mallard ducklings (*Anas platyrhynchos*) were obtained from a supplier in Kent, UK. The birds were one-day old when received. All birds were acclimated to the caging and facilities for 3 days. The birds weighed between 66 and 68 g at the beginning of the acclimation period and were 10 days of age at test initiation. The birds were phenotypically indistinguishable from wild birds and were in apparent good health at the start of acclimation.
- B. **Test System:** The birds were housed indoors in floor pens measuring 1.5 x 1.25 m. Each pen contained a drinker and feeding tray covered with wire mesh to minimize spillage of the diet. During the test, the mean daily temperature in the building was 25-29°C. The average relative humidity was 53 ±6.7%. A continuous photoperiod was used throughout the study.

The test diets were prepared by adding the test substance into the diet (standard chick diet in meal form) to form a pre-mix from which the final diets were prepared. The diets were prepared immediately prior to use and the remainder of the premix was frozen until needed.

The birds were offered water and feed *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 unfamiliar ingredients and medications.

- C. **Dosage:** Acute dietary LC₅₀ test. Dosage levels selected for the study were 81, 163, 325, 650, 1,300, 2,600, and 5,200 ppm.
- D. **Design:** Ten ducklings were used per test level and in each of two controls. Birds were assigned to treatment groups by body weight so that all treatment groups would have similar initial body weight means. Groups were assigned to treatments using a random allocation system. Signs of toxicity, abnormal behavior, and mortality were assessed daily. Group body weights were measured at initiation, day 5, 8, and 10 of the test. Average feed consumption was determined by group for days 1, 2, 3, 4,

and 5 (the exposure period), 5-8 and 8-10 (the observation period).

Samples of the test diet were taken from a trial mix (81 and 5,200 ppm) for homogeneity and stability determinations. Samples were taken from the actual test diets (all concentrations) for test substance concentration verification.

A post-mortem examination was conducted on the surviving birds in the highest test group, five control birds, and on all birds that died during the study.

E. **Statistics:** Due to the pattern of mortality, the LC_{50} was estimated by visual inspection of the data.

12. **REPORTED RESULTS:** One mortality occurred in the second highest concentration test group (2,600 ppm) on day 6. There were three mortalities (1 each on days 4, 5, and 7) in the 5,200 ppm test concentration group (Table 1, attached).

Clinical signs of toxicity including subdued behavior and unsteadiness of gait were observed at 325 ppm and above. The amount of excreta produced was reduced at 1,300 ppm and above.

There were reductions in body weight gain observed in the 163 through 1,300 ppm test groups and a loss of bodyweight in the 2,600 and 5,200 ppm test groups over the exposure period. Bodyweight gain was slightly lower than the controls during the observation period. Food consumption was reduced at 325 ppm and above during the exposure period and remained reduced in the 2,600 and 5,200 ppm test groups throughout the recovery period (Tables 2 & 3, attached).

No abnormalities were detected in any of the birds examined by post-mortem necropsy.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:**
The authors concluded that BTS 27271.HCl was of low subacute dietary toxicity to the mallard duck since the LC_{50} was greater than 5,200 ppm.

Good Laboratory Practice and Quality Assurance Unit Statements were included in the report indicating that the study conformed with Good Laboratory Practice standards published by the U.S. Environmental Protection Agency (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 should have been measured.

The results from the analyses conducted to verify the stability, homogeneity, and concentration of test substance were not included in the report.

The birds were not randomly assigned to groups.

- B. Statistical Analysis: Upon review of the mortality data, the reviewer concurs that the LC₅₀ was greater than 5,200 ppm.

- C. Discussion/Results: The birds were assigned to groups on the basis of body weight, after which the groups were randomly assigned to a particular treatment. Although this method of assignment probably did not affect the results of the test, it is not the same as random assignment to pens. A fundamental requirement of statistical analysis is that sampling of individuals be at random. The risk of non-random sampling is that the results may be biased in some way. For this reason, ASTM and the SEP guidelines specify that birds be randomly assigned to pens. The SEP actually states that birds "must be" randomly assigned to pens. The report stated that body weights were used to make assignments to groups in order to achieve similar initial bodyweight means in all groups. However, if birds were of the same age and from the same hatch, random assignment should produce similar initial body weights among groups. Although the method of assignment probably did not affect the results of the test, the registrant should enact procedures in future tests that provide random assignments to groups.

In contrast to what was reported by the authors, food consumption appeared to be reduced in the 1,300, 650, and 325 ppm treatment groups as well as the 2,600 and 5,200 groups during the observation period.

This study is scientifically sound but does not meet the guideline requirements for a dietary avian acute test since the results of the homogeneity, stability, and

concentration verification tests were not included in the report. The LC_{50} was $>5,200$ ppm which classifies BTS 27271.HCl as practically non-toxic to mallard ducklings. The NOEC was determined to be 81 ppm, based on reduced body weight gain during the exposure period.

D. Adequacy of the Study:

- (1) **Classification:** Supplemental.
- (2) **Rationale:** The results of the homogeneity, stability, and concentration verification tests were not included in the report.
- (3) **Repairability:** This study can be upgraded to "core" upon satisfactory submission of dietary analyses.

15. **COMPLETION OF ONE-LINER:** Yes, 1-10-92.