3-27-92

MRID No. 420553-11.

DATA EVALUATION RECORD

1. **CHEMICAL**: NTN 33893
   Shaughnessy No. ~~129059~~ 129099

2. **TEST MATERIAL**: Technical NTN 33893, 94.8%

3. **STUDY TYPE**: Avian Dietary LC50, Mallard duck (Anas platyrhynchos).

4. **CITATION**: Toll, P. A. 1990. "Technical NTN 33893: Subacute Dietary LC50 With Mallard Ducks." Mobay Corporation, Agricultural Chemicals Division Research and Development Department, Biochemistry/Ecological Effects, 17745 South Metcalf, Stilwell, Kansas 66085-9104. Report Number 100238. Submitted by Mobay Corporation, P.O. Box 4913, Kansas City, Missouri 64120-0013. USEPA MRID No. 420553-11.

5. **REVIEWED BY**:

   Dana Lateulere, Biologist
   Ecological Effects Branch
   Environmental Fate and
   Effects Division

   Signature: Dana Lateulere
   Date: 3/27/92

6. **APPROVED BY**:

   Ann Stavola, Section Head, 5
   Ecological Effects Branch
   Environmental Fate and
   Effects Division

   Signature: Ann Stavola
   Date: 3/27/92

7. **CONCLUSIONS**: This study is scientifically sound and fulfills guideline requirements. The LC50 for Technical NTN 33893 on juvenile mallard ducks is >4797 ppm based on the lack of mortality at that concentration. The NOEC is 69 ppm based on significant decreases in body weight for all exposure levels. The LOEC is 150 ppm based on body weight data. Based on the LC50 NTN 33893 Technical is classified as practically non-toxic to mallard ducks.

8. **RECOMMENDATIONS**:

9. **BACKGROUND**: This study is submitted as part of a data package for an EUP and for registration requirements.

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

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11. **MATERIALS AND METHODS:**

A. **Test Animals:** One hundred fifty five mallard ducks were obtained from Whistling Wings, Hanover, Il. They were one day old upon arrival. The ducklings were housed for acclimation for 9 days prior to being randomized into test groups. Less than 5% mortality was noted during the three days immediately prior to test initiation.

B. **Test System:** The ducklings were housed in stainless steel brooders maintained at an internal temperature gradient from approximately 100°F down to room temperature (range of 66° to 86°F) for the acclimation period and throughout the test. Humidity within the room averaged 46% for the same time period. Room lighting was maintained under 16/8 hours light/dark cycle. Brooder bedding was changed at least weekly. Food and water were available ad libitum prior to and during the study.

Ninety ducklings were randomized into each of seven treatment groups and two control groups. Birds were given feed containing technical grade NTN 33893 for five days, then were given a "clean" diet for a three day observation period. The two control groups received untreated diet containing an equal amount of carrier and solvent as was used to prepare the treated diet.

C. **Dosage:** Based on results from a range finding study the NTN 33893 nominal dietary concentrations were set at 78, 156, 312.5, 625, 1250, 2500 and 5000 ppm. Appropriate amounts of technical grade NTN 33893, corn oil and acetone were combined in an Erlenmeyer flask then added to the feed while mixing in a Hobart mixer. Compensation was made for the NTN 33893 purity in calculating the diet concentration. Measured concentrations in the diet at initiation to be 69, 150, 270, 622, 1228, 2474, and 4797 ppm; a range of 86-100% of nominal.

D. **Design:** Body weights were recorded at test initiation, day 5, and termination (day 8). Feed consumption for each group was recorded daily. Observations for mortality and clinical signs of intoxication were recorded .5, 1, 2 and 4 hours post-initiation, then twice daily throughout the remainder of the study except on weekends when only one observation per day was made. At the end of the study all surviving birds were

sacrificed by CO_2 asphyxiation and examined for gross lesions.

E. **Statistics**: The acute oral LD50 was calculated using a computer program which estimated the LD50 using one of three statistical techniques: moving average, binomial probability, or probit. The appropriate method was determined on the basis of data characteristics. For parametric procedures, body weight and feed consumption days for all treatment levels were subject to a standard one-way analysis of variance.

12. **REPORTED RESULTS**: The initial stability analysis showed significant declines in active ingredient over the five day feeding period. Since this information was atypical relative to other stability information available, a new analytical method was developed using methanol as the extraction solvent. This second method was used when the bobwhite quail study was conducted (Mobay Study No. N3721702; MRID No. 420553-10) and showed NTN 33893 to be stable in the diet with Day 5 values ranging from 88 to 104% of the initial samples after being exposed to study conditions for five days. Since the Day 5 measured concentrations did not reflect true values, the initial measured concentrations will be used for all subsequent discussions.

No mortalities occurred at any of the test concentrations. One bird at the 2474 ppm concentration and four birds at 4797 became ataxic during the exposure phase of the study. Symptoms at the 2474 ppm concentration were observed only on day 4, while the four birds at 4797 ppm were ataxic on days 4 and 5.

Control groups were combined for subsequent statistical analyses. A statistically significant decrease in body weight was noted on day 5 in all exposure groups $\geq$150 ppm when compared to the controls. Depressed weights were apparent in these same groups on day 8. The growth data showed these same trends from initiation to day 5; however, the data showed that birds exposed to $\geq$622 ppm gained significantly more weight than the controls after they were returned to the toxicant free feed, indicating recovery was occurring.

Feed consumption data support the noted body weight effects. Exposure groups $\geq$150 ppm NTN 33893 consumed significantly less feed during the exposure period with marked increases in feed consumption occurring when they were offered the NTN

33893-free feed. This data would suggest treated feed unpalatability.

Postmortem examinations of those birds sacrificed at study termination are presented in Table 5. Observations noted included pale liver, pale spleen, pale kidneys and pale pancreases. These examinations are often seen in young birds and were not considered to be treatment-related or compound related effects.

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

The subacute dietary LC50 of technical grade NTN 33893 in mallard ducks is greater than 4797 ppm. Based on body weight and feed consumption effects the highest no-observed-effect concentration (NOEC) was 69 ppm. The lowest-observed-effect concentration (LOEC) was 150 ppm.

Quality Assurance Inspection was conducted for compliance verification by the Quality Assurance Unit. It was also stated that this study was conducted in compliance with the Good Laboratory Practice Standards.

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

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

- Acetone should be completely evaporated before feeding.

- Pretreatment feed consumption should be recorded.

B. **Statistical Analysis:** Due to the nature of the data and reported values, statistical analysis could not be performed.

C. **Discussion/Results:** The measured concentrations taken on day 5 were significantly lower than those taken at initiation. However, after reviewing the referenced study on the bobwhite quail, the reviewer agrees with the study author that the day 5 measurements are inaccurate and using the initiation measurements is acceptable. The LC50 for Technical NTN 33893 on juvenile mallard ducks is >4797 ppm based on the lack of mortality at that concentration. The NOEC is 69 ppm based on significant decreases in body weight for all exposure levels. The LOEC is 150 ppm based on body

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weight data. Based on the LC50 NTN 33893 Technical is classified as practically non-toxic to mallard ducks.

D. **Adequacy of the Study:**

(1) **Classification:** Core.

(2) **Rationale:**

(3) **Repairability:**

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