DATA EVALUATION RECORD

1. Chemical: Triforine
MRID No. 122589

2. Test Material: Triforine technical a.i. 99.2%

3. Study Type: Avian oral LD_{50} test
Test species: Bobwhite quail (Colinus virginianus)

4. Study ID: Final report Acute oral LD_{50} in Bobwhite Quail. Project No. 920-102. Performed by Hazleton Laboratories 9200 Leesburg Turnpike, Vienna, VA 22180 for E.M. Laboratories, Inc., Elmsford, NY.

5. Reviewed By: Nimish Vyas
Biologist
EEB/EFED
Signature: Nimish Vyas
Date: 3/11/91

6. Approved By: Norman Cook
Head, Section II
EEB/EFED
Signature: Norman J. Cook
Date: 3.11.91

7. Conclusion: The LD_{50} was reported as greater than 5000 mg/kg body weight for bobwhite quail. This study is classified as core. According to this study, Triforine technical is classified as practically non-toxic to bobwhite quail. However, male ducks gained less weight (lost weight in certain cases) than female ducks.

8. Recommendations: N/A

9. Background Information: This study was reviewed in response to Phase 4 Reregistration (List B).

10. Discussion of Individual Tests: N/A

11. Materials and Methods:

a. Test Animal: Quail were hatched at Truslow Farms, Inc, Chestertown, MD and were raised at Robert Patey Farm. They were brooded indoors, under a controlled environment until they were of suitable age for placement in outside pens. The birds were phenotypically indistinguishable from wild birds and were at least 16 weeks of age. The initial body weights ranged from 177 to 236 g for males and 175 to 234 g for females.

b. Test System: Birds were acclimated to their test facilities for 17 days. All birds were caged in groups by treatment level and sex. Pens were located in a building with a controlled photoperiod of 17h L/7h D and average temperature and humidity of 22°C and 35%, respectively.

c. Study Design: Ten birds were exposed to each of the following treatment levels: vehicle control, 312.5, 625.0, 1250.0, 2500.0, 5000.0 mg/kg triforine. Triforine technical was prepared as a solution of 0.5% methylcellulose. Birds underwent an overnight fast prior to dosing. Feed and water were available ad libitum after dosing. Quail were observed for mortality, signs of toxicity and pharmacologic effects at one and four hours after dosing and once daily thereafter for fourteen days. All birds were weighed at the initiation, days 3, 7, and at termination of the study. Food consumption was determined weekly.

d. Statistics: No methodology on statistical analysis was presented.

12. Reported Results: No mortality occurred. All birds maintained a normal appearance throughout the 14 day observation period. A dose-related decrease in body weight gain was noted at 2500 and 5000 mg/kg.

13. Study Author's Conclusions/ Quality Assurance Measures:

The acute oral LD_{50} is estimated to be greater than 5000 mg/kg.

Quality Assurance and Good Lab Practices Statements were not included in the report.

14. Reviewer's Discussion and Interpretation of the Results:

a. Test Procedure: The study is scientifically sound and is classified as core. It meets the guidelines requirements with the following exceptions:

a. The guidelines require a 10 hour Light/ 14 hour Dark photoperiod, not a 17h L/7h D photoperiod.
b. Food consumption should have been reported as average daily consumption per treatment not as weekly consumption/treatment.
c. The method use for statistical analysis was not cited.

b. Statistical analysis: The LD_{50} analysis was not conducted because no mortality occurred. Body weight was analyzed using analysis of covariance.

c. Discussion/Results: The LD_{50} was reported as greater than 5000 mg/kg body weight for bobwhite quail. Dose related effects on body weight gain were not evident when analysis of covariance was conducted on body weight, as suggested by the author. However, male ducks gained less weight (lost weight in certain cases) than female ducks.

d. Adequacy of the Study:

(1) Classification: Core

(2) Rationale: N/A.

(3) Repairability: N/A

(4) Descriptive Conclusion: This study is classified as core. According to this study, Triforine technical is classified as practically non-toxic to bobwhite quail.