

US EPA ARCHIVE DOCUMENT

(9-2-92)

MRID No. 416100-02

DATA EVALUATION RECORD

- 1. **CHEMICAL:** Monosodium Methane Arsonate (MSMA).
Shaughnessey Number: 013803.
- 2. **TEST MATERIAL:** Arsonate liquid Blend; Notebook No. 20338-96-37; 51% purity; a clear liquid.
- 3. **STUDY TYPE:** Avian single dose oral LD₅₀ Test.
Species Tested: Bobwhite quail (Colinus virginianus).
- 4. **CITATION:** Campbell, S., K. A. Hoxter, and G. J. Smith. 1990. MSMA: an acute oral toxicity study with the northern bobwhite. Study performed by Wildlife International Ltd., Easton, Maryland. Laboratory study No. 296-104. Submitted by MSMA/DSMA Research Task Force Three, Luxembourg Industries (Pamol) Ltd., Tel Aviv, Israel. MRID No. 416100-02.

5. **REVIEWED BY:**

Rosemary Graham Mora, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: *Rosemary Graham Mora*
Date: *4/29/91*

6. **APPROVED BY:**

Michael Whitten, M.S.
Wildlife Toxicologist
KBN Engineering and
Applied Sciences, Inc.

Signature: *Michael L. Whitten*
Date: *4/30/91*

Henry T. Craven, M.S.
Supervisor, EEB/HED
USEPA

Signature: *Henry T. Craven*
Date: *8/12/92*

- 7. **CONCLUSIONS:** The study is scientifically sound and meets the requirements for an avian oral LD₅₀ test. With an LD₅₀ of 425.2 a.i. mg/kg, the test material is considered to be moderately toxic to bobwhite quail. The NOEL could not be determined.

*actually LD₅₀ = 834 mg/kg
for formulated product*

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

- 9. **BACKGROUND:**

6 hrs

10. DISCUSSION OF INDIVIDUAL TESTS: N/A.**11. MATERIALS AND METHODS:**

- A. Test Animals:** The birds used in the study were 18 week old bobwhite quail (Colinus virginianus), obtained from Fritts Quail Farm, Phillipsburg, New Jersey. Each treatment group and the control group contained five males and five females. All birds were acclimated to the facilities for 6 weeks prior to initiation of the test. Birds exhibiting abnormal behavior or physical injury during acclimation were not used in the study.
- B. Test System:** All birds were housed indoors in pens constructed of galvanized wire and galvanized sheeting. Pen dimensions were 78 cm x 51 cm x 20-25 cm high. Fluorescent lights provided 8 hours of light per day. The average temperature was $25^{\circ}\text{C} \pm 1^{\circ}\text{C}$ (SD). The average relative humidity was $27\% \pm 1\%$ (SD).
- C. Dosage:** 14-day single dose oral LD₅₀ test. Based upon known toxicity data, nominal dosages selected for the study were 292, 486, 810, 1350, and 2250 milligrams of MSMA (51% active ingredient) per kilogram of body weight. Dosages were not adjusted to 100% active ingredient. Therefore, all dosages and the LD₅₀ value are reported as milligrams of whole test substance per kilogram of body weight (mg/kg).
- D. Design:** Groups of ten birds (five males and five females) were randomly assigned to each of five treatment groups and one control group. Each dosage group was assigned two pens. One pen contained five males and the other contained five females. All birds were fed Wildlife International Ltd.'s game bird ration. Food and water were supplied ad libitum during acclimation and during the test, except during a 15-hour period prior to dosing, when all birds were fasted.

The test substance in diluent (distilled water) was orally intubated directly into the crop or proventriculus of each bird using a stainless steel cannula. Each bird was individually weighed and dosed on the basis of milligrams of test substance per kilogram of body weight. The control birds were administered with the corresponding volume of the diluent only.

All birds were observed at least twice daily for

mortalities, signs of toxicity, and abnormal behavior. The birds were individually weighed at test initiation and by group on days 3, 7, and 14. Group food consumption was determined for days 0-3, 4-7, and 8-14.

E. **Statistics:** The LD₅₀ and 95% confidence limits were calculated by the binomial probability method using the computer program of C.E. Stephan (1978).

12. **REPORTED RESULTS:** There were no mortalities in the control group. All birds appeared and behaved normally throughout the test period.

No mortality was observed in the 292 mg/kg group. Signs of intoxication were noted on day five to day six.

Ten percent and 30% mortality was observed in the 486 mg/kg and 810 mg/kg dosage groups, respectively. In the 1350 and 2250 mg/kg groups 100% mortality was observed on day 10 and day 4, respectively (attached Table 1).

Signs of toxicity in the test groups included reduced reaction to external stimuli, wing droop, loss of coordination, loss of righting reflex, ruffled appearance, lower limb weakness, and lethargy.

When compared to the control group, body weight was reduced in all test groups during the first 3 days of the study (Table 2, attached). Reduced food consumption was noted for this same period (Table 3).

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

The acute oral LD₅₀ for bobwhite exposed to MSMA was 834 mg/kg, with a 95% confidence interval of 671 to 1036 mg/kg. The no mortality level was 292 mg/kg. The NOEL was less than 292 mg/kg.

The report stated that the study was conducted in conformance with Good Laboratory Practice regulations "...with the following exception: Samples of the dosing solutions were not taken for confirmation of the test concentrations, homogeneity or stability." This statement was signed by representatives of Wildlife International Ltd. and a representative of the study sponsor. The Quality Assurance Statement was signed by the Quality Assurance Officer.

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

- A. Test Procedure: The test procedures were in accordance with Subdivision E and SEP guidelines with the following exceptions:

Necropsies were not performed.

Test material was a formulated product. Dosages were not adjusted to reflect percent active ingredient.

- B. Statistical Analysis: The reviewer used EPA's Toxanal computer program to calculate LD₅₀ values using two sets of dosage values. Printout #1 (attached) derived from the authors' dosage levels (not adjusted for percent active ingredient) shows an LD₅₀ of 834 mg/kg, the same value as reported by the author. Using dosage values adjusted for the 51% active ingredient, the LD₅₀ was 425 mg a.i./kg (printout #2, attached).

- C. Discussion/Results: With an LD₅₀ of 425.2 mg a.i./kg, the test material is considered to be moderately toxic to bobwhite quail. Food consumption and body weight were reduced at all treatment levels.

The study is scientifically sound and meets the requirements for an avian oral LD₅₀ test.

- D. Adequacy of the Study:

- (1) Classification: Core.
- (2) Rationale: N/A.
- (3) Repairability: N/A.

15. COMPLETION OF ONE-LINER: Yes; March 29, 1991.

DER / MSMA / MRID 4161002

Page _____ is not included in this copy.

Pages 5 through 7 are not included in this copy.

The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
 - Description of the product manufacturing process.
 - Description of quality control procedures.
 - Identity of the source of product ingredients.
 - Sales or other commercial/financial information.
 - A draft product label.
 - The product confidential statement of formula.
 - Information about a pending registration action.
 - FIFRA registration data.
 - The document is a duplicate of page(s) _____.
 - The document is not responsive to the request.
-

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Printout # 1

ROSEMARY GRAHAM MORA MSMA COLINUS VIRGINIANUS 03-29-91

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
2250	10	10	100	9.765625E-02
1350	10	10	100	9.765625E-02
810	10	3	30	17.1875
486	10	1	10	1.074219
292	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 486 AND 1350 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 910.1809

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
4	.1144044	799.3418	625.9575	1017.22

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
8	.2858571	1	.4539316

SLOPE = 7.44304
95 PERCENT CONFIDENCE LIMITS = 3.463574 AND 11.42251

LC50 = 833.6845
95 PERCENT CONFIDENCE LIMITS = 670.9624 AND 1035.634

LC10 = 562.8242
95 PERCENT CONFIDENCE LIMITS = 333.577 AND 693.1878

PRINT OUT # 2

ROSEMARY GRAHAM MORA MSMA COLINUS VIRGINIANUS 03-29-91

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
1147.5	10	10	100	9.765625E-02
688.5	10	10	100	9.765625E-02
413.1	10	3	30	17.1875
247.9	10	1	10	1.074219
148.9	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 247.9 AND 688.5 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 464.1926

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
4	.1144044	407.6738	319.2406	518.8027

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
14	.2859283	1	.4541533

SLOPE = 7.444571
95 PERCENT CONFIDENCE LIMITS = 3.46379 AND 11.42535

LC50 = 425.1904
95 PERCENT CONFIDENCE LIMITS = 342.2128 AND 528.1828

LC10 = 287.0709
95 PERCENT CONFIDENCE LIMITS = 170.1463 AND 353.5501

Haughnessy No. 013803

Chemical Name MSMA

Chemical Class _____

Page 1 of 1

Study/Species/Lab/
Accession _____
4-Day Single Dose Oral LD50

Chemical
X a.i.

Results

Reviewer/
Date _____
Valida
Stat _____

Species 511
Colinus virginianus
ab Wildlife International
cc. MRID 416100-02

LD50 = $\frac{425.2}{\text{mg/kg}}$ ($\frac{95\% \text{ C.L.}}{342.2, 528.2}$) Contr. Mort. (X) = 0%
Slope = 7.4 # Animals/Level = 10 Age (Days) = 126
Sex = ♂/5
14-Day Dose Level mg/kg/(% Mortality)
1147.7 (100%), 688.5 (100%), 413.1 (30%), 247.9 (10%), 148.9 (0%)
Comments: DOSAGE NOT ADJUSTED TO REFLEX MSMA active ingredient
were

RGM
3/29/91
Core

4-Day Single Dose Oral LD50

LD50 = $\frac{\text{mg/kg.}}{(\quad)}$ ($\frac{95\% \text{ C.L.}}{(\quad)}$) Contr. Mort. (X) = _____

Species _____

Slope = _____ # Animals/Level = _____ Age (Days) = _____
Sex = _____

ab _____

14-Day Dose Level mg/kg/(% Mortality)
(), (), (), (), ()

cc. _____

Comments: _____

8-Day Dietary LC50

LC50 = $\frac{\text{ppm}}{(\quad)}$ ($\frac{95\% \text{ C.L.}}{(\quad)}$) Contr. Mort. (X) = _____

Species _____

Slope = _____ # Animals/Level = _____ Age (Days) = _____
Sex = _____

ab _____

8-Day Dose Level ppm/(% Mortality)
(), (), (), (), ()

cc. _____

Comments: _____

8-Day Dietary LC50

LC50 = $\frac{\text{ppm}}{(\quad)}$ ($\frac{95\% \text{ C.L.}}{(\quad)}$) Contr. Mort. (X) = _____

Species _____

Slope = _____ # Animals/Level = _____ Age (Days) = _____
Sex = _____

ab _____

8-Day Dose Level ppm/(% Mortality)
(), (), (), (), ()

cc. _____

Comments: _____

48-Hour LC50

LC50 = $\frac{\text{pp}}{(\quad)}$ ($\frac{95\% \text{ C.L.}}{(\quad)}$) Contr. Mort. (X) = _____
Sol. Contr. Mort. (X) = _____

Species _____

Slope = _____ # Animals/Level = _____ Temperature = _____

ab _____

48-Hour Dose Level pp/(% Mortality)
(), (), (), (), ()

cc. _____

Comments: _____

96-Hour LC50

LC50 = $\frac{\text{pp}}{(\quad)}$ ($\frac{95\% \text{ C.L.}}{(\quad)}$) Con. Mor. (X) = _____
Sol. Con. Mor. (X) = _____

Species _____

Slope = _____ # Animals/Level = _____ Temp. = _____

ab _____

96-Hour Dose Level pp/(% Mortality)
(), (), (), (), ()

cc. _____

Comments: _____

96-Hour LC50

LC50 = $\frac{\text{pp}}{(\quad)}$ ($\frac{95\% \text{ C.L.}}{(\quad)}$) Con. Mort. (X) = _____
Sol. Con. Mort. (X) = _____

Species _____

Slope = _____ # Animals/Level = _____ Temp. = _____

ab _____

96-Hour Dose Level pp/(% Mortality)
(), (), (), (), ()

cc. _____

Comments: _____