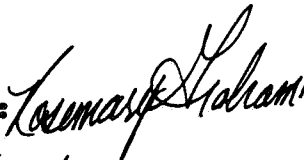
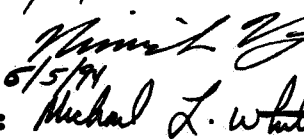
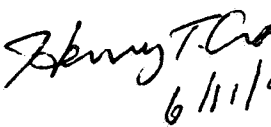


## DATA EVALUATION RECORD

JUN 18 1991

1. **CHEMICAL:** Sodium Methyldithiocarbamate (METAM-sodium).  
Shaughnessey Number: 039003.
2. **TEST MATERIAL:** METAM-sodium. Test Substance No. 85/232;  
Batch No. ZH 130 585 / April 1985; 42.2% METAM-sodium; an  
aqueous solution.
3. **STUDY TYPE:** Avian Dietary LC<sub>50</sub> Test.  
Species Tested: Bobwhite quail (Colinus virginianus).
4. **CITATION:** Munk, R., 1986. Avian Dietary LC<sub>50</sub> Test of  
METAM-SODIUM (Aqueous Solution) to the Bobwhite Quail.  
Project No. 31W0232/8580. Study performed by BASF  
Aktiengesellschaft, Agricultural Research and Development,  
Limburgerhof, West Germany. No. 86/0520. Submitted by BASF  
Corporation, Agricultural Chemicals, Research Triangle Park,  
North Carolina. MRID No. 414764-01.
5. **REVIEWED BY:**  
  
Rosemary Graham Mora, M.S.  
Associate Scientist  
KBN Engineering and  
Applied Sciences, Inc.  
  
Signature:   
Date: 4/12/91
6. **APPROVED BY:**  
  
Michael L. Whitten, M.S.  
Wildlife Toxicologist  
KBN Engineering and  
Applied Sciences, Inc.  
  
Signature:   
Date: 4-12-91  
  
Henry T. Craven, M.S.  
Supervisor, EEB/HED  
USEPA  
  
Signature:   
Date: 6/11/91
7. **CONCLUSIONS:** The study appears to be scientifically sound  
but does not meet the requirements for an avian dietary LC<sub>50</sub>  
study. The LC<sub>50</sub> could not be determined, since there was no  
treatment related mortality in the highest concentration  
tested (2110 ppm a.i.). The NOEC was 2110 ppm a.i. The  
test material was not stable in the diet therefore the  
actual concentrations to which the birds were exposed could  
not be determined.
8. **RECOMMENDATIONS:** N/A

9. BACKGROUND:

10. DISCUSSION OF INDIVIDUAL TESTS: N/A.

11. MATERIALS AND METHODS:

- A. Test Animals: The birds used in the study were 15-day old bobwhite quail (Colinus virginianus), hatched by BASF "from eggs of animals indistinguishable from wild birds."
- B. Test System: Each pen, located in building BASF - Z (an air conditioned room), was constructed of stainless steel (520 X 350 X 490 mm) with wire mesh (5 X 5 mm) flooring. Birds were exposed to fluorescent lighting for 16 hours daily. The test room temperature was 22°C and relative humidity was about 50%.
- C. Dosage: Acute dietary LC<sub>50</sub> test. Nominal dietary concentrations selected for the study were 62, 185, 556, 1667, and 5000 mg/kg diet (ppm, formulated test substance). These concentrations were not adjusted to reflect the percentage of active ingredient of the test substance used.
- D. Design: A group of ten birds were randomly assigned to a negative control group and five treatment groups. All birds were fed "Ssniff" experimental diet. The composition of the diet was included in the report. Food and water were supplied ad libitum before the study and throughout the test.

The test diets were prepared separately by "preparing a premix in a mixing bowl. These premixes were then mixed with meal form basal diet in a suitable laboratory mixer to make sufficient quantities of final diet mixtures for each test group for the whole study." The birds were fed ad libitum the appropriate dietary concentrations for five days, and then given untreated food for three days. The negative control birds received the basal diet throughout the study.

"As it was assumed that the test substance could not be sufficiently stable in the diet at higher temperatures the feed was cooled down to about 4°C before the test substance was added and the final mixtures were stored at about 4°C. Each day the feed in the hoppers was completely replaced by the respective mixtures stored in the refrigerator. To verify the stability of the substance in the feed under these storage conditions samples of the concentrations 62 and 5000 mg/kg diet

were taken at the end of the substance feeding period from the samples stored at about +4°C and transferred into a deep freezer and stored at about -20°C until analysis." Samples were also taken for analysis of homogeneity and verification of treatment concentrations.

Observations for mortality, and signs of toxicity and other abnormal behavior were made daily for the duration of the study, except for Day 4 when (for technical reasons) no observations were made. Birds were weighed by group at test initiation and on Days 5 and 8. Daily mean food consumption per bird was determined based upon the group food consumption per day. Means were determined for Days 0-5 and Days 6-8.

Birds were weighed individually on Days 0, 5, and 8. The mean body weight was calculated for each cage.

E. Statistics: The statistical evaluation of the body weight was performed followed by Dunnet's test.

12. REPORTED RESULTS: No mortality occurred in the negative control and no symptoms were detected throughout the test period.

Twenty percent mortality was demonstrated in the 1667 ppm nominal concentration (Table 1, attached). This mortality was "caused by injuries induced by aggressive individuals" and "was not substance related." No signs of toxicity were demonstrated by any of the test birds. Some birds demonstrated injured beaks and apathy in three of the test concentrations. These clinical signs were "due to aggressive behavior of some individual chicks."

"No substance- or concentration- related reduction in feed consumption was observed" (Table 2, attached).

"No substance- or concentration- related reduction in body weight gain occurred" (Table 3, attached)

A post-mortem macroscopic examination of all birds was conducted and "no substance related effects could be observed."

Results of analyses of test substance stability, homogeneity and concentration were presented (Tables A, B, and C, attached). The stability of the test compound in the diet was limited as expected.

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

The LC<sub>50</sub> based on nominal concentrations of METAM-sodium in the test diets was greater than 5000 ppm formulated test substance. Based on the analysis of actual test concentrations, the LC<sub>50</sub> was 4700 ppm (beginning of test) to 3400 ppm (end of Day 5). The NOEC based on the nominal concentration was 5000 ppm, since no substance-related mortality and no toxic signs were observed in any concentration.

The report included the following Good Laboratory Practices statement: "This study was conducted prior to the effective date of 40 CFR part 160 for studies of this nature. Therefore there is no Sponsor or Study Director of record for signature of this compliance statement." The statement was signed by a BASF representative. A Quality Assurance Statement was included in the report. The report was also signed by the study Director and other representatives of the BASF toxicology department.

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 except for the following deviations:

Food consumption for each group was not monitored for the period of pretreatment.

Birds were 15 days old. The recommended age is 10 to 14 days old.

- B. **Statistical Analysis:** The reviewer could not determine the LC<sub>50</sub> value since no substance related mortality was observed.

- C. **Discussion/Results:** The LC<sub>50</sub> value (> 5000 ppm) presented by the author did not reflect the percentage of active ingredient of the test substance. The test concentrations based on percentage active ingredient were 26.2, 78.1, 234.6, 703.5, and 2110 ppm a.i. Guidelines require that the LC<sub>50</sub> must be established or else shown to be > 5000 ppm. This test does not fulfill that requirement, since the highest nominal concentration tested was 2110 ppm a.i., and since the test compound was not stable in the diet (Table A, attached).

Chemical analysis for stability of the test diets was performed on samples which had been stored at 4°C during the five-day substance administration period.

Since the author "assumed that the test substance could not be sufficiently stable in the diet at higher temperatures," the actual stability of the test substance was not reflected in the data presented, and the concentrations to which the birds were exposed cannot be determined.

Nominal test concentrations were presented as "mg/kg diet." The reviewer assumes this to be milligrams of test substance per kilogram of feed (or parts per million).

Although the percentage body weight gain from Day 0 to 5 was considerably lower in the two highest concentrations (703.5 and 2110 ppm a.i.) than in the control, the treatment values fall within the normal range of body weight gain for 15 day-old bobwhite quail.

The age of test birds (15 days versus required 10 to 14 days) probably had no bearing on the outcome of the test. ~~The study is in accordance with the guidelines.~~

The study appears to be scientifically sound but does not meet the requirements for an avian dietary LC<sub>50</sub> study.

**D. Adequacy of the Study:**

- (1) **Classification:** Supplemental.
- (2) **Rationale:** An LC<sub>50</sub> was not established or shown to be greater than 5000ppm, and the actual concentrations to which the birds were exposed cannot be determined.
- (3) **Repairability:** No.

15. **COMPLETION OF ONE-LINER:** Yes; April 12, 1991.

TABLE 1.

Group No.	Concentration (mg/kg diet)	Time of death (cumulative mortality)								
		Substance feeding period						Post-exposure period		
		Day						Day		
		0	1	2	3	4	5	6	7	8
0	0 (untreated control)	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10
1	62	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10
2	185	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10
3	556	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10
4	1667	0/10	0/10	0/10	0/10	0/10	1/10	1/10	1/10	2/10
5	5000	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10

4.2.

LC--

31W0232/8580

## 4.4. Feed consumption

No substance - or concentration - related reduction in feed consumption was observed.

Group mean feed consumption (g/bird/day)\*

TABLE 2

Group mean feed consumption (g/bird/day)*	Group No. (concentration mg/kg)					
	0 (untreated control)	1 (62)	2 (185)	3 (556)	4 (1667)	5 (5000)
Day						
1	4.9	4.9	4.7	4.0	4.1	4.0
2	5.6	5.8	5.5	5.3	4.4	5.0
3	6.1	6.3	5.8	5.5	5.0	5.6
4	7.2	7.2	6.7	6.7	6.4	6.4
5	6.1	5.8	5.3	5.4	5.1	5.4
mean (days 1 - 5; exposure period)	6.0	6.0	5.6	5.4	5.0	5.3
6	7.7	7.6	7.4	7.6	7.5	8.3
7	6.1	5.9	6.1	6.2	6.0	6.6
8	5.6	5.5	5.4	5.3	6.3	6.2
mean (days 6 - 8; post-exposure period)	6.5	6.3	6.3	6.4	6.6	7.0

\* The birds that were found dead in their cages on the respective day of the determination of the feed consumption are not included in the calculations and thus in the feed consumption figures.

86/0520 0025

TABLE 3

BASF TOXICOLOGY  
PROJECT NUMBER 31W0232/8580 LC50 BOBWHITE QUAIL (CHICKS)

GROUP MEANS

BODYWEIGHT

PRINT DATE 15-APR-86

M A L E S	day 0	day 5	day 8	TOTAL %A (Day 0-8)
GROUP 0	BODYWT G	BODYWT G	BODYWT G	
0 MG/KG	M 28.4 SD 2.3 N 10	39.4 3.4 10	48.0 4.0 10	71%
GROUP 1				
62 MG/KG (26.2)	M 26.7 SD 3.4 N 10	48.1 6.2 10	49.5 7.6 10	85%
GROUP 2				
185 MG/KG (28.1)	M 28.1 SD 2.2 N 10	39.5 3.6 10	48.6 4.6 10	72.9%
GROUP 3				
556 MG/KG (234.6)	M 28.9 SD 2.7 N 10	38.8 4.5 10	47.8 4.8 10	65%
GROUP 4				
1667 MG/KG (403.5)	M 27.7 SD 3.2 N 10	34.6 6.1 9	41.7 8.9 8	50%
GROUP 5				
5000 MG/KG (2110)	M 29.6 SD 2.6 N 10	36.4 4.5 10	47.2 5.4 10	59.6%

(Statistical unit = animal)

Statistics: Anova + Dunnett tests \* p&lt;0.05 \*\* p&lt;0.01 two sided

86/0520

0034



4.8.1. Stability

TABLE A

Nominal concentration (mg/kg diet)	Analytically detected concentration (mg/kg diet)	% of nominal concentration
62	69.2 mean 34.6 6.8	56
5000	3452 mean 3407 3361	68

4.8.2. Homogeneity

TABLE B

Nominal concentration (mg/kg diet)	Analytically detected concentration (mg/kg diet)	% of nominal concentration
62	28.3 49.8 35.4 37.0 25.3 50.4	46 80 57 60 41 81
mean	37.7	61
5000	4846 4929 4578 4443 5215 4259	97 99 92 89 104 85
mean	4712	94

20440

TABLE C

4.8.3. Concentration control

Nominal concentration (mg/kg diet)	Analytically detected concentration (mg/kg diet)	% of nominal concentration
62	mean 37.7*	61
185	177, 172 mean 175	95
556	509, 512 mean 511	92
1667	1868, 1735, mean 1802	108
5000	mean 4712*	94

Shaughnessey # 039003

Chemical Name METAM - Sodium

Chemical Class \_\_\_\_\_ Page    of   

Study/Species/Lab/Chemical  
MRID # \_\_\_\_\_ % a.i. \_\_\_\_\_  
Results \_\_\_\_\_  
Reviewer/Validation  
Date \_\_\_\_\_ Status \_\_\_\_\_

14-Day Single Oral LD<sub>50</sub>

LD<sub>50</sub> - \_\_\_\_\_ mg/kg ( 95% C.L. ) Control Mortality (%) - \_\_\_\_\_

Species \_\_\_\_\_ Slope - \_\_\_\_\_ # Animals/Level - \_\_\_\_\_ Age (Days) - \_\_\_\_\_

Lab \_\_\_\_\_ Sex - \_\_\_\_\_

MRID # \_\_\_\_\_  
14-Day Dose Level mg/kg/(% Mortality)  
(    ), (    ), (    ), (    ), (    )

Comments:

8-Day Dietary LC<sub>50</sub>

42.2% LC<sub>50</sub> - ND pp ( 95% C.L. ) Control Mortality (%) - 0%

Species

Colinus virginianus  
Lab \_\_\_\_\_

Slope - — # Animals/Level - 10 Age (Days) - 15

Sex - ND

BASF

MRID # \_\_\_\_\_  
8-Day Dose Level pp / (% Mortality)  
26.2 (0%), 78.1 (0%), 234.6 (0%), 703.5 (20%), 2110 (0%)

Comments:

0 414764-01

Supplemental  
4/12/91