

DATA EVALUATION RECORD

1. **CHEMICAL:** Sodium Methyldithiocarbamate. PM 10 100
Shaughnessey No. 039003.
2. **TEST MATERIAL:** BAS 005 00 N Metam-Sodium (Fluid) 510 g/L.
3. **STUDY TYPE:** Freshwater Invertebrate Static Acute Toxicity Test. Species Tested: Waterflea (Daphnia magna).
4. **CITATION:** Bias and Merz. 1985. Determination of the Acute Toxicity of BASF 005 00 N METAM SODIUM 510 g/L to the Waterflea Daphnia magna Straus. Registration Document No. 85/0497. Prepared by BASF Aktiengesellschaft, Department of Emissionsüberwachung und Ökologie/Wasser, Ludwigshafen, West Germany. Submitted by BASF Corporation Chemicals Division, Parsippany, NJ. EPA MRID No. 411062-03.
5. **REVIEWED BY:**

Louis M. Rifici, M.S. Associate Scientist II KBN Engineering and Applied Sciences, Inc.	Signature: <i>Louis M. Rifici</i> Date: 5/1/91
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6. **APPROVED BY:**

Pim Kosalwat, Ph.D. Senior Scientist KBN Engineering and Applied Sciences, Inc.	Signature: <i>P. Kosalwat</i> Date: 5/6/91
Henry T. Craven, M.S. Supervisor, EEB/HED USEPA	Signature: <i>Henry T. Craven</i> Date:
7. **CONCLUSIONS:** This study is scientifically sound but does not meet the guideline requirements for a toxicity test with freshwater invertebrates. The percent of active ingredient present in the formulation was not given in the report and the daphnids were tested in total darkness. Under the conditions of the test, the 48-hour EC₅₀ of Metam-Sodium for Daphnia magna was 2.36 mg/L (based on nominal concentrations). Therefore, Metam-Sodium is classified as moderately toxic to Daphnia magna. The NOEC, based on the absence of sublethal effects, was 0.98 mg/L (nominal).
8. **RECOMMENDATIONS:** See Section 14.D.(3).

9. **BACKGROUND:**10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A11. **MATERIALS AND METHODS:**

- A. **Test Animals:** The daphnids (*Daphnia magna*) used in the test were obtained from in-house cultures originally obtained from the Institut National de Recherche Chimique Appliquee, France. The adult daphnids were fed Brewer's yeast after each water change and washed green algae once per day. Daphnids were not fed on weekends and holidays. The culture conditions were described as a total hardness of 2.50 ± 0.25 mmol/L ($1 \text{ mmol CaCO}_3/\text{L} = 100 \text{ mmol CaCO}_3/\text{L}$), an oxygen content greater than 2 mg/L, a temperature range of 292.0 to 294.0°K (18.9°-20.9°C), a 16-hour light/8-hour dark photoperiod, and a light intensity of approximately 5 $\mu\text{Einstein}/(\text{m}^2 \cdot \text{s})$.

The daphnids chosen for the test were 6-24 hours old.

- B. **Test System:** The test chambers were 250-mL beakers containing 200 mL of test solution. The test vessels were maintained in total darkness (except when determining swimming ability) at a temperature of 292.0-294.0 K (18.9°-20.9°C). Filtered ($6 \mu\text{m}$) dechlorinated tap water blended with deionized water was used as dilution water. Characteristics of the water include a hardness of 2.5 ± 0.25 mmol/L, a pH of 7.7-8.3, and a conductivity of 500-650 $\mu\text{Siemens}/\text{cm}$ ($1 \mu\text{Siemens}/\text{cm} = 1 \mu\text{mhos}/\text{cm}$). The dilution water was aerated with oil-free air and allowed to stand for 24 hours before use.

The test concentrations were prepared by serial dilution of a 62.5 mg/L stock solution.

- C. **Dosage:** Forty-eight-hour static test. Ten nominal concentrations (0.122, 0.244, 0.488, 0.976, 1.95, 3.9, 7.81, 15.6, 31.2, and 62.5 mg/L) and a dilution water control were used.
- D. **Design:** Five daphnids were placed in each test beaker, four beakers per test level. All chambers were observed once every 24 hours. The ability of the daphnids to swim was used as the measure of toxicity.

The dissolved oxygen (D.O.) and pH in replicate 1 of each test level were monitored every 24 hours.

E. **Statistics:** The 48-hour median effective concentration (EC_{50}) and 95% confidence interval (C.I.) were calculated using the moving average method.

12. **REPORTED RESULTS:** The responses of *Daphnia magna* are given in Table 4 (attached). The 48-hour EC_{50} based on nominal concentrations was 2.34 mg/L (95% C.I. = 1.83-2.85 mg/L). The no-observed-effect concentration (NOEC) was given as 0.976 mg/L (the EC_0 value).

The hardness and conductivity at the beginning of the test were given as 2.6 mmol/L and 520 μ mhos/cm, respectively. The D.O. of the test solutions ranged from 8.29 to 8.6. The pH values ranged from 7.84 to 8.10. The temperature at test initiation was given as 19.9°C.

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

The authors presented no conclusions.

No Quality Assurance Statement or Good Laboratory Practice Statement were included in the report. A supplement was included which stated that the study did not have to meet the Good Laboratory Practice requirements of 40 CFR 160.

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

A. **Test Procedure:** The test procedures were generally in accordance with protocols recommended by the guidelines, but deviated as follows:

The report did not state the percentage of active ingredient in the formulation or if the concentrations used in the test were based on the percent active ingredient or total product.

The test beakers were kept in total darkness during the test period. A 16-hour light/8-hour dark photoperiod is recommended.

The hardness of the dilution water, 2.5 mmol/L (250 mg/L), was higher than recommended (no greater than 200 mg/L).

A mixture of dechlorinated tap water and deionized water was used as dilution water in the test. Using dechlorinated water is not recommended in the SEP.

The test material was not identified by lot or batch numbers.

Observations of the daphnid cultures such as adult mortality, stress, and the presence of ephippia were not given in the report.

The daphnids used in tests should be from the fourth or later broods of a given parent. The authors did not state which brood was the source of the test daphnids.

Each nominal concentration was approximately 50% of the next highest concentration. The guidelines recommend that each concentration be at least 60% of the next highest concentration.

The period of time between test solution preparation and test initiation was not given in the report. Daphnids should be placed into the test solutions within 30 minutes of solution preparation.

The report does not state if the daphnids were fed during the test.

The system used to control temperature was not described in the report.

Temperature must be monitored continuously or at least every 6 hours (if the test vessels are located in a water bath). No raw temperature data were provided.

- B. **Statistical Analysis:** The reviewer used EPA's Toxanal program to calculate the 48-hour EC_{50} value and obtained similar results (see attached printout).
- C. **Discussion/Results:** Numerous deviations from the guidelines weaken this study. Two points are especially important. The percent of active ingredient present in the formulation is essential for determining the actual concentration of Metam-Sodium the daphnids were exposed to. The authors tested the daphnids in the dark. Since the toxicity endpoint was the inability to swim, what effect does 48 hours of total darkness have on Daphnia magna swimming ability? If there is a benefit to this method over presently accepted methods (16:8 photoperiod), the authors did not state it. Before this study can be classified as "Core", additional information and evidence that

complete darkness does not modify the response of the daphnids needs to be submitted.

Under the conditions of the test, the 48-hour EC_{50} of 2.36 mg/L classifies Metam-Sodium as moderately toxic to Daphnia magna. The slope of the concentration-response curve was 4.17. The NOEC, based on the lack of sublethal effects, was 0.98 mg/L (nominal concentration).

D. Adequacy of the Study:

- (1) **Classification:** Supplemental.
- (2) **Rationale:** 1) The percent of active ingredient in the formulation was not provided; 2) the daphnids were tested in total darkness.
- (3) **Repairability:** The registrant should submit the percent of active ingredient in the formulation, whether the test concentrations were based on the percent active ingredient or total product, and data supporting the testing of daphnids in total darkness.

15. COMPLETION OF ONE-LINER FOR STUDY: Yes, 03-21-91.

Table 4

Animals able to swim

Conc. [mg/l]	Animals able to swim after		
	0 h	24 h	48 h
.122	20	20	20
.244	20	20	20
.488	20	20	20
.976	20	20	20
1.95	20	20	9
3.9	20	20	6
7.81	20	20	0
15.6	20	18	0
31.2	20	20	0
62.5	20	5	0
0.	20	20	20

SUMMARY OF RESULTS AFTER 24h

EC 50 [mg/l] = -

CI 95% [mg/l] = - - -

EC 0 [mg/l] = 31.2

EC 100 [mg/l] = >62.5

SUMMARY OF RESULTS AFTER 48h

EC 50 [mg/l] = 2.34

CI 95% [mg/l] = 1.83 - 2.85

EC 0 [mg/l] = .976

EC 100 [mg/l] = 7.81

85/0497 0012

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LOUIS M. RIFICI SODIUM METHYLDITHIOCARBAMATE DAPHNIA MAGNA 2-21-91

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
62.5	20	20	100	9.536742E-05
31.2	20	20	100	9.536742E-05
15.6	20	20	100	9.536742E-05
7.81	20	20	100	9.536742E-05
3.9	20	14	70	5.765915
1.95	20	11	55	41.19014
.976	20	0	0	9.536742E-05
.488	20	0	0	9.536742E-05
.244	20	0	0	9.536742E-05
.122	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT .976 AND 7.81 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 1.862895

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS
9	5.135012E-02	2.435389	1.732418 3.377615

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
8	.1092803	1	.6062385

SLOPE = 4.170241
 95 PERCENT CONFIDENCE LIMITS = 2.79166 AND 5.548821

LC50 = 2.355277
 95 PERCENT CONFIDENCE LIMITS = 1.902176 AND 2.916716

LC10 = 1.168162
 95 PERCENT CONFIDENCE LIMITS = .7655737 AND 1.500907

Shaughnessy No. 039003

Chemical Name Sodium
Methyldithiocarbamate

Chemical Class _____

Page 6 of 1Study/Species/Lab/
AccessionChemical
X a.i.

Results

Reviewer/
DateValidation
Status14-Day Single Dose Oral LD₅₀LD₅₀ = mg/kg (95% C.L.) Contr. Mort.(X) =

Species _____

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

Lab _____

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

Acc. _____

Comments:

14-Day Single Dose Oral LD₅₀LD₅₀ = mg/kg. (95% C.L.) Contr. Mort.(X) =

Species _____

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

Lab _____

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

Acc. _____

Comments:

8-Day Dietary LC₅₀LC₅₀ = ppm (95% C.L.) Contr. Mort.(X) =

Species _____

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

Lab _____

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

Acc. _____

Comments:

8-Day Dietary LC₅₀LC₅₀ = ppm (95% C.L.) Contr. Mort.(X) =

Species _____

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

Lab _____

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

Acc. _____

Comments:

48-Hour LC₅₀LC₅₀ = 2.36 ppm * 95% C.L. Probit
(1.90 - 2.92) Contr. Mort.(X) = 0Species Daphnia magna

Slope = 4.17 # Animals/Level = 20 Sol. Contr. Mort.(X) = N/A

Lab BASF Aktiengesellschaft
Nest Germany48-Hour Dose Level ppm/(X Mortality)
0.122 (0) , 0.244 (0) , 0.488 (0) , 0.976 (0) , 1.95 (55) , 3.9 (70) , 7.8 (100) ,
15.6 (100) , 31.2 (100) , 62.5 (100)Acc. MRID 411062-03Comments: Nominal Concentrations96-Hour LC₅₀LC₅₀ = pp (95% C.L.) Con. Mort.(X) =

Species _____

Slope = # Animals/Level = Sol. Con. Mort.(X) =

Lab _____

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

Acc. _____

Comments:

96-Hour LC₅₀LC₅₀ = pp (95% C.L.) Con. Mort.(X) =

Species _____

Slope = # Animals/Level = Sol. Con. Mort.(X) =

Lab _____

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

Acc. _____

Comments: