To: Tom Myers  
Product Manager 51  
Special Review and Reregistration Division (H7508W)

From: Anthony F. Maciorowski, Chief  
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File #: 039003-010182  
Chemical Name: Sodium N-methylthiocarbamate (SNMDC)  
Type Product: Microbiocide  
Product Name: SNMDC  
Company Name: Metam Task Force  
Purpose: Submission of avian dietary studies in support of reregistration of List B, Case No. 2390.

Action Code: 627  
Date Due: 12/27/93  
Reviewer: A. Vaughan  
Date In: 09/29/93

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EEB Guideline/MRUD Summary Table: The review in this package contains an evaluation of the following:

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#Acceptable (Study satisfied Guideline)/Concur  
#Partial (Study partially fulfilled Guideline but additional information is needed)  
#Supplemental (Study provided useful information but Guideline was not satisfied)  
#Unacceptable (Study was rejected)/Nonconcur
Please review the following ecotox studies for the chemical metam-sodium:

Gdln 71-2(a) Acute Avian Dietary - Quail  MRID 42914002
Gdln 71-2(b) Acute Avian Dietary - Duck  MRID 42914001

No evaluation is written for this data package.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *
MEMORANDUM

SUBJECT: Data Review for SNMDC: Avian Dietary Studies. DP Barcode 195347; Case 2390

FROM: Anthony F. Maciorowski, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (7507C)

TO: Tom Myers, PM 51
Accelerated Reregistration Branch
Special Review and Reregistration Division (7508W)

The Metam Task Force submitted two avian dietary studies (MRID’s 429140-01 and 429140-02) in support of reregistration of SNMDC. The studies were conducted with a 43% ai test material, which represents the technical pesticide. The dietary LC₅₀ was greater than 5000 ppm ai in both studies. The studies (EEB reviews attached) fulfill the guideline requirements for avian dietary testing.

The Agency has already determined that testing for ecological effects is interchangeable for PNMD and SNMD. Thus, the requirements for avian dietary testing have been fulfilled for PNMD as well as SNMD.

EEB is providing updated data tables (attached) for both chemicals. As noted in the tables, all the data requirements for these two chemicals have been fulfilled.

Any questions or comments on this memo should be referred to Allen Vaughan at 305-6464.
DATA EVALUATION RECORD

1. CHEMICAL: Sodium Metaphosphate, Metam Sodium.
   Shaughnessy Number: 039003.

2. TEST MATERIAL: Metam Concentrate; Sodium N-
   methyldithiocarbamate; CAS No. 137-42-8; Lot No. 650; 43% purity: a brownish-orange liquid with a sulfide odor.

   Species Tested: Mallard duck (Anas platyrhynchos).


5. REVIEWED BY:

   Nicole U. Jurczyk, M.S.
   Associate Scientist
   KBN Engineering and
   Applied Sciences, Inc.

   Signature: Maria M. Janitz
   Date: 12/16/93

6. APPROVED BY:

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

   James J. Goodyear, Ph.D.
   Project Officer, EEB/HED
   USEPA

   Signature: Michael L. Whitten
   Date: 12/16/93
   [Signature: Allen W. Vaughan 01/06/94]
   Date: 1/6/94

7. CONCLUSIONS: The study is scientifically sound and fulfills the requirements for an avian dietary LC₅₀ test using a formulated product. The dietary LC₅₀ was greater than 5000 ppm a.i. nominal, the highest concentration tested. This classifies the test material as practically non-toxic to the mallard duck. A no-observed-effect-concentration was not achieved in this study. * Tech. Metam sodium = 43% a.i. ppm

8. RECOMMENDATIONS: N/A

   Look like NOEL = 1250 ppm - see study authors Comments. KBN
   1/6 strikes again!
9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

   A. **Test Animals:** The birds used in the study were 7-day old mallard ducklings (*Anas platyrhynchos*) obtained from Whistling Wings, Hanover, Illinois. All birds were from the same hatch, pen-reared and phenotypically indistinguishable from wild birds. The birds were acclimated to the facilities for four days. One death was recorded on day 1 of the quarantine period, but all other birds were normal and active during the four day period.

   B. **Test System:** Ten birds per pen were housed indoors in 28 x 36 x 11 inch brooder units. The construction material for the brooder units was not described. Natural daylight spectrum lighting provided 24 hours of light per day. The average temperature in the brooder units was 37°C during the quarantine period, 36°C during the test period, and 36°C during the recovery period. The brooder humidity during the quarantine, test, and recovery periods averaged 36%, 37%, and 35%, respectively. The average ambient room temperature was 22°C, with an average relative humidity of 58% during the quarantine period, 62% during the test period, and 60% during the recovery period.

   C. **Dosage:** Ten-day dietary LC₅₀ test. Nominal dietary concentrations were 312, 625, 1250, 2500, and 5000 parts per million of active ingredient (ppm a.i.).

   D. **Design:** Groups of ten birds were assigned arbitrarily to each of five control groups and five treatment groups. All birds were fed Purina Game Bird Startena. Food and well water were supplied *ad libitum* during acclimation, test, and recovery periods. "There were no known or suspected contaminants in the well water which is analyzed periodically for organophosphates, chlorinated insecticides, and PCBs."

The test diets were prepared daily for five consecutive days and were offered to the birds on the same day they were mixed. The 5000 ppm a.i. test diet was prepared by mixing 7.90 kg of Purina Game Bird Startena with 93.02 grams of Metam Concentrate. The diet was blended for 15 minutes in a Hobart H-600-DT mixer.
The 2500 ppm a.i. test diet was prepared by mixing equal amounts (4.00 kilograms each) of the 5000 ppm a.i. test diet with untreated feed. Each successively lower test level diet was prepared in a similar manner by using the next highest test level diet mixed with untreated feed (the serial dilution method). All test diets were mixed for 15 minutes in a Hobart H-600-DT mixer.

The birds were fed the appropriate dietary concentrations for five days, and then given untreated food during a five-day recovery period. Samples of the diets were taken at 0 hour (when the birds were fed) on test days 1 and 5. One hundred-gram samples were collected in duplicate for concentration verification, and to confirm the stability and homogeneity of the test substance in the diets. The samples were not analyzed. They are being kept frozen at Bio-Life Associates, Ltd. in case they are needed for analysis.

Observations were made daily for mortalities, abundance of feed and water, signs of toxicity, and abnormal behavior. Birds were weighed by group at test initiation and at test termination (day 10). Group food consumption was recorded during the last two days of the quarantine period, daily during the five-day test period, and following the five-day recovery period. The one bird that died during the study was subjected to a gross pathological examination. In addition, four control birds and four birds from each test group were arbitrarily selected for pathological examination at the termination of the project.

E. Statistics: Due to the occurrence of only one death in the treatment groups, the LC_{50} was not calculated.

12. REPORTED RESULTS: There were no mortalities in the control groups. One death was recorded on test day 6 in the 5000 ppm a.i. test group.

No clinical signs of toxicity were noted in the control, 312, 625, or 1250 ppm a.i. test birds throughout the investigation. Clinical signs noted in the 2500 ppm a.i. test birds included inactivity, moving only when gently prodded, and crawling when attempting to walk. In addition to the above clinical signs, the 5000 ppm a.i. test birds exhibited clinical signs including instability, hunching in a corner, huddling, and death. Complete remission of all clinical signs was achieved in survivors by study termination (day 10).
Reduced body weights were noted in the four highest treatment groups when the test birds were compared to the control birds at the completion of the study (day 10) (Table 3A, attached). During the five-day test period, reduced food consumption was noted in all the test groups, as compared to the control groups. During the five-day recovery period, the four highest treatment groups continued to feed at a lower consumption rate.

Gross pathological examination of the one 5000 ppm a.i. bird that died during the investigation revealed gaseous intestines and a dark red-colored liver. Of the 24 other birds that were arbitrarily selected for pathological examination, abnormal findings were revealed in six birds. The abnormal findings were in birds from the 625, 2500, and 5000 ppm a.i. test groups. The abnormalities included gizzards that were devoid of feed, gaseous intestines, and pale colored livers and intestines. "Due to inconsistency and lack of dose-related pathological observations, the abnormal findings were attributed to factors other than the test material."

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The dietary LC₅₀ was greater than 5000 ppm a.i. nominal, the highest concentration tested. One death was recorded in the 5000 ppm a.i. test group during day 6 of the study. A no-observed-effect-concentration was not achieved in this study.

Quality Assurance and Good Laboratory Practice statements were included in the report indicating (with minor deviations) conformance with GLP regulations as set forth in 40 CFR Part 160.

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

A. **Test Procedure:** The test procedures were in accordance with Subdivision 6, ASTM, and SEP guidelines except for the following deviations:

Body weights were measured by group. Individual body weights should have been measured.

The brooder compartment floor dimensions (reported as 28" x 36"; approx. 71 cm x 91 cm = 6461 cm²) were slightly smaller than the recommended dimensions (70 cm x 100 cm = 7000 cm²).

The birds were not randomly assigned to pens. Instead, they were assigned by "arbitrary selections."
The concentration of the test substance in the diet was not confirmed by chemical analysis. This is recommended, but not required.

B. **Statistical Analysis:** Due to the limited mortality during the test (one death), the $LC_{50}$ could not be calculated. Based on nominal concentrations, the $LC_{50}$ was greater than 5000 ppm a.i.

C. **Discussion/Results:** The study generally conforms to the recommended procedures, except for the deviations listed above. The lack of data concerning the verification of actual concentrations administered, and stability of the compound during the course of the day leads to some uncertainty that the birds did receive the full doses reported here. The use of the "serial dilution method" would mean that all test diets would be incorrect if the initial 5000 ppm a.i. nominal test diet was mixed incorrectly. It would have been prudent to at least check some of the diets for Metam Concentrate levels each day that the diets were prepared.

The birds were assigned to brooders arbitrarily, but to an objective reader, the control birds appear to be somewhat lighter than the test birds. The average weight for the control birds was approximately 84 grams while the average weight for the test birds was approximately 90 grams. Although the results of this study were probably not altered by the method of assignment, the registrant should enact procedures in future tests that provide random assignment to groups.

Table 3A (attached) lists the average body weight and feed consumption data from the study. On day five of the test period, when the Metam Concentrate was still being administered, the feed consumption increased markedly in the 5000 ppm a.i. test group. The estimated feed consumption for the group was 147 grams, while the day before it had been just 63 grams total. It is interesting that the average feed consumption per bird in this test group was almost three times as high on day five, when compared to that on day four (Table 3B, attached).

The purity of the test chemical was 43%. Thus, the reviewer assumes that the test was conducted with a formulated product. The study is scientifically sound and meets the requirements of an $LC_{50}$ study using a formulated product. Based on nominal concentrations, the $LC_{50}$ was greater than 5000 ppm a.i., which
classifies it as practically non-toxic to the mallard duck.

D. Adequacy of the Study:

(1) Classification: Core for a formulated product.

(2) Rationale: N/A

(3) Repairability: N/A

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.
DATA EVALUATION RECORD

1. **CHEMICAL**: SNMDC, Metam Sodium. Shaughnessey Number: 039003.

2. **TEST MATERIAL**: Metam Concentrate; Sodium N-methylldithiocarbamate; CAS No. 137-42-8; Lot No. 650; 43% purity: a brownish-orange liquid with a sulfide odor.

3. **STUDY TYPE**: 71-2. Avian Dietary LC\(_{50}\) Test. Species Tested: Bobwhite Quail (*Colinus virginianus*).


5. **REVIEWED BY**:
   - Nicole U. Jurczyk, M.S.
   - Associate Scientist
   - KBN Engineering and Applied Sciences, Inc.

6. **APPROVED BY**:
   - Michael L. Whitten, M.S.
   - Wildlife Toxicologist
   - KBN Engineering and Applied Sciences, Inc.

   - James J. Goodyear, Ph.D.
   - Project Officer, EEB/HED USEPA

   **Signature**: [Signature]
   **Date**: 12/16/93

7. **CONCLUSIONS**: The study is scientifically sound and fulfills the requirements for an avian dietary LC\(_{50}\) test of a formulated product. The dietary LC\(_{50}\) was greater than 5000 ppm a.i. nominal, the highest concentration tested. This classifies the test material as practically non-toxic to bobwhite quail. The no-observed-effect-concentration (NOEC) was 312 ppm a.i. nominal. *Tech. metam sodium is 43% a.i.*

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 14-day old bobwhite quail (*Colinus virginianus*) obtained from Sand Prairie Quail Farm, Maquoketa, Iowa. All birds were from the same hatch, pen-reared and phenotypically indistinguishable from wild birds. The birds were acclimated to the facilities for thirteen days. Fourteen of the original 130 birds were found dead during the acclimation period. Only three of the deaths occurred during the three day period prior to testing. All other birds were normal and active during the acclimation period.

   B. **Test System:** Ten birds per pen were housed indoors in 28 x 36 x 11 inch brooder units. The construction material for the brooder units was not described. Natural daylight spectrum lighting provided 24 hours of light per day. The average temperature in the brooder units was 38°C during the acclimation, test, and recovery periods. The average brooder humidity during the acclimation period was 36%. During the test and recovery periods the brooder humidity averaged 32%. The average ambient room temperature was between 22°C and 23°C, with an average relative humidity of between 48% and 54% during the acclimation, test, and recovery periods.

   C. **Dosage:** Eight-day dietary LC₅₀ test. Nominal dietary concentrations were 312, 625, 1250, 2500, and 5000 parts per million of active ingredient (ppm a.i.).

   D. **Design:** Groups of ten birds were assigned arbitrarily to each of five control groups and five treatment groups. All birds were fed Purina Game Bird Startena. Food and well water were supplied *ad libitum* during acclimation, test, and recovery periods. "There were no known or suspected contaminants in the well water which is analyzed periodically for organophosphates, chlorinated insecticides, and PCBs."

   The test diets were prepared daily for five consecutive days and were offered to the birds on the same day they were mixed. The 5000 ppm a.i. test diet was prepared by mixing 7.90 kilograms of Purina Game Bird Startena with
93.02 grams of Metam Concentrate. The diet was blended for 15 minutes in a Hobart H-600-DT mixer.

The 2500 ppm a.i. test diet was prepared by mixing equal amounts (4.00 kilograms each) of the 5000 ppm a.i. test diet with untreated feed. Each successively lower test level diet was prepared in a similar manner by using the next highest test level diet mixed with untreated feed (the serial dilution method). All test diets were mixed for 15 minutes in a Hobart H-600-DT mixer. The untreated control diets were also mixed in a Hobart H-600-DT mixer for a period of 15 minutes.

The birds were fed the appropriate dietary concentrations for five days, and then given untreated food during a three-day recovery period. Samples of the diets were taken on test days 1 and 5. Samples were collected for dose verification, homogeneity, and 24-hour animal room stability. The samples were not analyzed. They are being kept frozen at Bio-Life Associates, Ltd. in case they are needed for analysis.

Observations were made daily for mortalities, abundance of feed and water, signs of toxicity, and abnormal behavior. Birds were weighed by group at test initiation and at test termination (day 8). Group food consumption was recorded during the last two days of the acclimation period, daily during the five-day test period, and following the three-day recovery period. The one bird that died during the study was subjected to a gross pathological examination. In addition, four control birds and four birds from each test group were arbitrarily selected for pathological examination at the termination of the study.

E. **Statistics:** Due to the occurrence of only one death in the treatment groups, the LC₅₀ was not calculated.

12. **REPORTED RESULTS:** There were no mortalities in the control groups. One death was recorded on test day 5 in the 5000 ppm a.i. group.

The 5000 ppm a.i. test group was the only group for which clinical signs were reported. On test day 5, one 5000 ppm a.i. bird was found dead and the remaining 5000 ppm a.i. test birds were moving slowly. Complete remission of all clinical signs was achieved in survivors by test day 6.

Reduced body weights were noted on test day 8 in the four highest treatment groups (625, 1250, 2500, and 5000 ppm
a.i.). During the five-day test period, reduced feed consumption was noted in the four highest test groups (Table 3A, attached). The 5000 ppm a.i. group was the only group that continued to feed at a reduced rate during the three-day recovery period.

Gross pathological examination of the one 5000 ppm a.i. bird that died during the study revealed no abnormal findings. Abnormal pathological findings were revealed in four of the 24 birds examined at study termination. The abnormal findings were in birds from the 312 and 5000 ppm a.i. test groups. The 312 ppm a.i. bird and one of the 5000 ppm a.i. birds had pale livers. Two 5000 ppm a.i. birds had gaseous intestines. One of these birds also had a crop which was void of feed and the other had a friable liver. "Due to inconsistency and lack of dose-related pathological observations, the abnormal findings were attributed to factors other than the test material."

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:
The dietary LC₅₀ was greater than 5000 ppm a.i. nominal, the highest concentration tested. One death was recorded in the 5000 ppm a.i. test group during day 5 of the study. The NOEC was determined to be 312 ppm a.i. nominal.

Quality Assurance and Good Laboratory Practice statements were included in the report indicating (with minor deviations) conformance with GLP regulations as set forth in 40 CFR Part 160.

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:

Body weights were measured by group. Individual body weights should have been measured.

The relative humidity in the brooders ranged from 21% to 43%. A considerable number of humidity values were below 30%. The guidelines state that relative humidity should not be less than 30%.

The average temperature in the brooder units was 38°C. The protocol for brooder temperature was amended to have this temperature instead of the recommended 35°C. No explanation was given for this change to the protocol.
The birds were not randomly assigned to pens. Instead, they were assigned by arbitrary selections.

The concentration of the test substance in the diet was not confirmed by chemical analysis. This is recommended, but not required.

B. **Statistical Analysis:** Due to the limited mortality during the test (one death), the \( LC_{50} \) could not be calculated. Based on nominal concentrations, the \( LC_{50} \) was greater than 5000 ppm a.i.

C. **Discussion/Results:** The study generally conforms to the recommended procedures, except for the deviations listed above. The lack of data concerning the verification of actual concentrations administered, and stability of the compound during the course of the day leads to some uncertainty that the birds did receive the full doses reported here. The use of the "serial dilution method" would mean that all test diets would be incorrect if the initial 5000 ppm a.i. test diet was mixed incorrectly. It would have been prudent to at least check some of the diets for Metam Concentrate levels each day that the diets were prepared.

The purity of the test chemical was 43%. Thus, the reviewer assumes the test was conducted with a formulated product. The study is scientifically sound and meets the requirements of an \( LC_{50} \) study using a formulated product. Based on nominal concentrations, the \( LC_{50} \) was greater than 5000 ppm a.i. This classifies the test material as practically non-toxic to bobwhite quail. The NOEC was determined to be 312 ppm a.i.

D. **Adequacy of the Study:**

1. **Classification:** Core for a formulated product.
   - \( \checkmark \)

2. **Rationale:** N/A

3. **Repairability:** N/A

15. **COMPLETION OF ONE-LINER:** Yes; December 15, 1993.
Metham - Sodium

Page 17 is not included in this copy.

Pages ____ through ____ 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.
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3. Study was performed with PNMDC.

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