United States Environmental Protection Agency
Office of Prevention, Pesticides And Toxic Substances (7508W)
EPA 738-R-95-035 January 1996

Reregistration Eligibility Decision (RED)

Nabam

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case Nabam which includes the active ingredient Disodium ethylene bisdithiocarbamate. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredient to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the receipt of this letter. The second set of required responses are due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Jean Holmes at (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative Venus Eagle at (703) 308-8045.

Sincerely yours,

Lois Rossi, Division Director
Special Review
and Reregistration Division

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

Nabam

LIST A

CASE 0641

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

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NABAM REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

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Frank Hernandez	Economic Analysis Branch
Phyllis Johnson	LUIS

Environmental Fate and Effects Division

Silvia Termes	Environmental Fate and Groundwater Branch
Conchi Rodriguez	Ecological Effects Branch
Mary Powell	Science Analysis and Coordination Staff

Health Effects Division

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Byron Backus	Toxicology Branch II
Winston Dang	Occupational and Residential Exposure Branch
Hugh Pettigrew	Science Analysis Branch
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Carol Glasgow	Registration Support Branch

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Steve Shapiro

Special Review and Reregistration Division

Venus Eagle	Reregistration Branch
Judy Coombs	Reregistration Branch
Walt Waldrop	Reregistration Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA) The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration
NPDES	National Pollutant Discharge Elimination System

GLOSSARY OF TERMS AND ABBREVIATIONS

NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
FAO/WHO	Food and Agriculture Organization/World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

Background

This Reregistration Eligibility Decision (RED) document addresses the reregistration eligibility of the pesticide nabam, disodium ethylene bisdithiocarbamate.

Nabam was first registered in 1948 as a broad spectrum fungicide used to prevent crop damage by fungi, to protect harvested products from deterioration, and as an industrial microbiocide. Nabam and the other ethylene bisdithiocarbamate (EBDC) pesticides mancozeb, maneb, and metiram, have been the subject of two Special Reviews based on the presumption that the EBDCs and their common metabolite, ethylene thiourea (ETU), posed potential risks to human health and/or the environment in the following areas: carcinogenicity, developmental toxicity, and acute toxicity to aquatic organisms. Three additional areas of concern that were identified were thyroid toxicity, mutagenicity, and skin sensitization.

As a result of the Special Reviews on nabam, all food uses were voluntarily cancelled except one FDA-regulated food use on sugar mill grinding, crusher and/or diffuser systems. Pesticides added to sugar mill processing water systems to control microorganisms is an indirect food additive and, therefore falls under FDA jurisdiction. All other uses of nabam are as an industrial biocide in paper mills, water cooling systems, drilling mud and packer fluids and secondary oil recovery water systems.

The first Registration Standard for nabam, issued in 1987, required further data to evaluate the environmental and human risks associated with the use of nabam. Prior to the issuance of the Registration Standard, the Agency had also issued five separate Data Call-Ins for nabam. The Agency has now completed its review of the nabam target data base including the data submitted from the Registration Standard and five Data Call-Ins.

Reregistration Eligibility

The Agency has determined that all currently registered uses of nabam will not cause unreasonable risk to humans or the environment and are eligible for reregistration provided the risk mitigation measures and other changes specified in this document are implemented. Risk mitigation measures, being imposed include requiring that the liquid formulations be applied into water cooling systems by a pump metering system or a closed loading/application delivery system and requiring that all solid/dry formulations of nabam be marketed in water soluble packaging.

Health Effects

To assess the cancer risks associated with nabam uses, the Agency used estimates of exposure to ETU based on exposure to nabam, and used the unit risk for ETU. ETU is present in nabam as a contaminant, metabolite, and the main degradation product. ETU is classified as a probable human carcinogen (Group B2) with a Q_1^* of 6.01×10^{-2} $(mg/kg/day)^{-1}$ based on studies which show that it induced an increased incidence of thyroid adenomas and adenocarcinomas in rats and hepatomas in mice. A RfD (reference dose) has not been established for nabam at this time since the intended uses (industrial microbicide) of this chemical are classified as non-food applications.

Occupational and Residential Exposure

The toxicological endpoints of concern for occupational and residential exposure to nabam is systemic toxicity based on a rabbit developmental study and from exposure to ETU. The calculated Margins of Exposure (MOE = NOEL/exposure) for nabam represent acceptable margins of exposure (greater than 100) for most uses. Exposures to handlers using open pour liquid formulations in cooling water systems (e.g. towers) and open pour solid formulations to drilling muds & packing fluids and secondary & tertiary oil recovery water systems are unacceptable (less than 100) without the additional risk mitigation requirements imposed in this RED.

Environmental Fate and Ecological Effects

The Agency requires only a limited set of ecotoxicology and environmental fate studies for microbiocides. While the hazard to aquatic organisms from nabam has been characterized, a quantitative risk assessment has not been conducted. Risks to aquatic organisms resulting from the discharge of effluent containing nabam is regulated under the NPDES permitting program of the Agency's Office of Water. The Agency currently requires that labels for all nabam products require that discharges to aquatic environments comply with an NPDES permit.

Existing studies show that nabam was found to be practically nontoxic to birds on an acute oral and subacute dietary basis and practically nontoxic to bees. Available data indicate that nabam is slightly to moderately toxic to both cold and warm water fish and moderately toxic to freshwater invertebrates. Additionally, nabam ranged from being highly toxic to practically nontoxic to estuarine/marine organisms. Ecological effects testing of ETU previously had been required; however, because of the current limited uses of nabam, these tests are not required at this time.

Before reregistering the products containing nabam, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include

product chemistry and acute toxicity testing for each registration. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of nabam. The document consists of six sections. Section I is the introduction. Section II describes nabam, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for nabam. Section V discusses the reregistration requirements for nabam. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient(s) are covered by this Reregistration Eligibility Decision:

- **Common Name:** Nabam
- **Chemical Name:** Disodium ethylene bisdithiocarbamate
- **Chemical Family:** Ethylene bisdithiocarbamate (EBDC)
- **CAS Registry Number:** 142-59-6
- **OPP Chemical Code:** 014503
- **Empirical Formula:** $C_4H_6N_2Na_2S_4$
- **Trade and Other Names:** AMA-9, AMA-30, AMA-31, Alcotreat MOS, Alcotreat LOS, Aquatreat DNM-30, Aquatreat DN-30, Aquatreat DNM-9, Aquatreat DNM-360, Aquatreat DNM-25E, Aquatreat DNM-25L, Aquatreat DNM-80, Amersperse 280
- **Basic Manufacturer:** Alco Chemical Division of the National Starch & Chemical Co. and Vinings Industries, Inc.

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of these uses of nabam is in Appendix A.

For nabam:

Type of Pesticide: Microbiocide/Microbiostat (slime-forming bacteria, fungi, and algae), Antifoulant.

Use Sites: AQUATIC NON-FOOD INDUSTRIAL:

Air Washer Water Systems
Commercial/Industrial Water Cooling Systems (includes shipboard seawater cooling systems)
Evaporative Condenser Water Systems
Oil Recovery Drilling Muds/Packer Fluids*
Pulp/Paper Mill Water Systems
Secondary Oil Recovery Injection Water

INDOOR NON-FOOD:

Fuels/Oil Storage Tank Bottom Water Additive
Oil Recovery Drilling Muds/Packer Fluids*
Pasteurizer/Warmer/Cannery Cooling Water Systems
Specialty Industrial Products (flue gas desulfurization thickeners)

INDOOR FOOD:

Food Processing Water Systems (cane and beet sugar mill processing water - regulated by FDA)

TERRESTRIAL NON-FOOD CROP:

Oil Recovery Drilling Muds/Packer Fluids*

*Registrants must specify on labels, as per Section V of this document, whether the product is used on off-shore and/or terrestrial sites.

Target Pests: Slime-forming bacteria, fungi, and algae, *Flavobacterium capsulatum, Aerobacter aerogenes, Bacillus cereus, Bacillus subtilis, Pseudomonas sp., Pseudomonas flourescens, Desulfovibrio desulfuricans, Aspergillus niger,*

Penicillium expansum, *Fusarium oxysporium*, *Trichoderma sp.*, barnacle larvae.

Formulation Types Registered:

Soluble concentrate/liquid, soluble concentrate/solid.

Method and Rates of Application:

TYPES OF TREATMENT:

Water treatment (recirculating system), Water treatment (once-through system-shipboard seawater cooling systems only), Water treatment, Additive treatment, Preservative treatment.

EQUIPMENT:

Feed system (eductor), Feed system (gravity), Chemical pump, Metering pump.

RATES OF APPLICATION:

Aquatic non-food industrial
1.5 ppm active ingredient for shipboard seawater cooling systems (once-through system).
2.4 to 210 ppm active ingredient for all other uses.

Indoor Non-Food
2.4 to 210 ppm active ingredient.

Indoor Food
1.5 to 3 ppm active ingredient for beet and cane sugar mill processing water.

Terrestrial Non-Food Crop
12 to 210 ppm active ingredient.

Timing: Initial, Subsequent/maintenance, Continuous feed (initial), Continuous feed (subsequent), Intermittent feed (initial), Intermittent feed (subsequent), Intermittent (slug) (initial),

Intermittent (slug) (subsequent), Not specified on label (registrant must specify on labeling).

C. Estimated Usage of Pesticide

Of all the nabam sites listed in the use profile, only one in-house source from the late 1980's showed relatively low levels of annual usage. According to that proprietary data base, nabam has a relatively minor share of the biocide market in the paper industry.

D. Data Requirements

Data requested in the 1987 Nabam Registration Standard included product chemistry, toxicology, ecological effects, environmental fate, and residue chemistry studies. These data were required to support the uses listed in the Registration Standard. Data required in five separate Data Call-In Notices issued prior to the Registration Standard are outlined in the Regulatory History section below. Appendix B of this RED document includes all data requirements identified by the Agency for currently registered uses needed to support reregistration of nabam.

E. Regulatory History

Nabam was first registered in the United States in 1948 for use as a broad spectrum fungicide used to prevent crop damage by fungi, to protect harvested products from deterioration, and as an industrial microbiocide. Nabam and the other EBDC pesticides, mancozeb, maneb and metiram have been the subject of two Special Reviews based on the presumption that the EBDCs and their common metabolite, ETU, posed potential risks to human health and/or the environment in the following areas: carcinogenicity, developmental toxicity, and acute toxicity to aquatic organisms. Three additional areas of concern identified were thyroid toxicity, mutagenicity, and skin sensitization.

Upon conclusion of the first Special Review which was initiated in 1977 and concluded in 1982, the Agency issued a Final Position Document (PD 4) that required risk reduction measures to prevent unreasonable adverse effects pending development of additional data needed to better assess the risks. An additional label statement was required to warn users of hazards to fish and additional protective clothing was required to mitigate potential risks of developmental and thyroid effects to applicators. Additional exposure data were required to address mutagenic effects but it was determined that the skin sensitization effect did not ultimately meet the criteria for a Special Review. Following the first Special Review, the Agency classified ETU as a Group B2 carcinogen shortly after the classification system was established in 1986.

During the second Special Review, which was initiated in 1987, all food uses of nabam were voluntarily cancelled (December 1989). At the close of the second Special Review in 1992, the Agency concluded that industrial uses of nabam could be retained including one FDA-regulated food use on sugar mill grinding, crusher and/or diffuser systems. Therefore, the EPA does not require food use data since this use pattern falls under the purview of the FDA (see 36 FR 24234 dated 12/22/71).

In the Registration Standard for nabam issued in April 1987 (NTIS #PB88-192745) the Agency reported its evaluation of the studies submitted as a result of the 1985 Data Call-In (DCI). It required further data to evaluate the environmental and human risks associated with the uses of nabam. This RED document reflects a reassessment of all data that were submitted in response to the Registration Standard. The following data were required in the DCI Notices issued for nabam:

1. January 17, 1983 - This notice required the submission of the metabolism, dermal penetration and mutagenicity data identified in the 1982 Special Review Decision Document.

2. July 25, 1984 - This notice advised registrants of the Agency's concern about the existence of pesticides in ground water and the designation of a number of chemicals, including nabam, which may have the potential to contaminate ground water. The chemicals were designated based on such factors as chemical structure, solubility, and use patterns. The notice required submission of certain environmental fate and product chemistry data for agricultural uses only.

3. October 19, 1984 - This notice required dietary exposure, product chemistry and toxicology (subchronic feeding and inhalation) data.

4. March 20, 1985 - This notice required registrants of pesticide products containing nabam to submit all outstanding data requirements as outlined under 40 CFR 158 regulations for disciplines including product chemistry, toxicology, wildlife and aquatic organisms, and environmental fate.

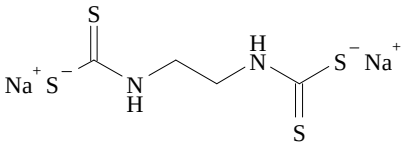
5. April 30, 1985 - This notice required additional data, not identified in the October 1984 Data Call-In Notice, considered necessary to the reassessment of the chemicals. These data included additional toxicological (subchronic feeding and inhalation - ETU) and residue data for ETU as well as nabam.

The data required by these Data Call-In Notices to support the continued registration of nabam products have been received and considered by the Agency in its evaluation of nabam reregistration eligibility.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Nabam [(disodium ethylene bis(dithiocarbamate)] is an EBDC pesticide registered for non-food industrial uses, and FDA-regulated food uses in sugar mill grinding, crusher, and or diffuser systems (21 CFR 173.320(b)(3)). The Agency does not consider this use to be a food-use for its own regulatory purposes.



Empirical Formula:	$C_4H_6N_2Na_2S_4$
Molecular Weight:	256.3
CAS Registry No.:	142-59-6
Shaughnessy No.:	014503

IDENTIFICATION OF ACTIVE INGREDIENT

Technical nabam is not commercially produced. Nabam is produced as a 30% manufacturing-use product (MP) or end-use product (EP). Nabam products containing 30% nabam are yellow to amber aqueous solutions. Nabam is soluble in water (40 g/100 mL). The purified or dried nabam is a solid with a melting point of 200 C.

MANUFACTURING-USE PRODUCTS

There is a single nabam manufacturing-use product (MP) registered to Alco Chemical Division, the 30% FI (formulation intermediate) (EPA Reg. No. 31910-7). All of the registered end-use products (EPs) contain nabam in combination with sodium dimethyldithiocarbamate (SDDC). Of the three nabam registrants, only Alco and Vinings Industries, Inc., which together comprise the Nabam Task Force, manufacture nabam.

The Agency has concluded that data submitted for the Alco pure active ingredient (PAI) can support both the Alco and Vinings nabam products. The Agency notes that, due to Vinings EPs manufacturing system, data are only required on the isolated TGAI at this time.

Data concerning the presence of nitrosamines in nabam products were required by the Agency; however, in response to a request by the registrants to waive the data requirement, the Agency concluded in 1994 that analysis would no longer be required for nabam because nitrites are not involved in the manufacturing process. The Agency also waived a product chemistry data requirement for analytical methods capable of distinguishing nabam per se from other EBDCs and CS_2-producing impurities.

The current status of the product chemistry data requirements for the Alco and Vinings MP and TGAI products is presented in Appendix B of this RED document. Product chemistry data remain outstanding for both registrations.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base for nabam is adequate and will support reregistration eligibility.

a. Acute Toxicity

Table 1. Acute Toxicity Data

TEST	RESULTS	CATEGORY
Oral LD_{50} - rat * MRID No. 00097093	LD_{50} = 1.4 g/kg	III
Dermal LD_{50} - rabbit * MRID No. 00159774	LD_{50} >2.0 g/kg	III
Inhalation LC_{50} - rat MRID No. 00159770	supplementary study	
Eye irritation - rabbit** MRID No. 00159775	not irritating	IV
Dermal irritation - rabbit** MRID No. 00159776 & 40024201	not irritating	IV
Dermal sensitization - human** (open literature)	dermal sensitizer	Sensitizer

* The test material was Aquatreat DN-30 (containing approximately 30% nabam in aqueous solution).
** Note: Data pertaining to acute eye irritation, dermal irritation, and dermal sensitization are not required to support the reregistration of the TGAI. These data are presented for informational purposes.

In the acute inhalation toxicity study with rats, the LC_{50} was reported to be greater than 2.19 mg/L (no mortalities following a 4-hour exposure). The study is currently classified as supplementary because the report does not specifically state what substance (e.g. the active ingredient, the 30% solution, Aquatreat DN-30) was tested and it is not evident how this value was calculated. This classification can be upgraded with additional information. In the April 1987 Registration Standard for nabam it was noted that a study in the open literature reported that a sensitization reaction in humans occurred following exposure to a 19% nabam solution. This finding adequately demonstrates that nabam is a skin sensitizer and no further dermal sensitization data are required.

b. Subchronic Toxicity

In a 21-day dermal toxicity study, groups of 5 male and 5 female Sprague-Dawley rats were dermally exposed to 0, 46, 457, 1525 or 3050 mg Aquatreat DN-30/kg/day (equivalent to 0, 15, 150, 500 and 1000 mg nabam/kg/day) 5 days/week over a 21-day period for a total of 15 six-hour occluded exposures. At termination, the highest-dose females showed a significant decrease in T4, and the value (2.6 µg/dL) was below the diurnal range (3 to 7 µg/dL) stated to be normal for Sprague-Dawley rats. The systemic NOEL was 1525 mg DN-30/kg/day (=500 mg nabam/kg/day) for females (based on the decrease in T4) and 3050 mg DN-30/kg/day (=1000 mg nabam/kg/day) for males. The NOEL for dermal effects was 46 mg Aquatreat DN-30/kg/day (=15 mg nabam/kg/day) and the LEL for dermal effects (slight to moderate erythema of the treatment site in some animals) was 457 mg Aquatreat DN-30/kg/day (=150 mg nabam/kg/day). No other systemic effects and no other dermal effects were found (guideline 82-2; MRID 42791602).

In a combined subchronic neurotoxicity study and 90-day subchronic oral toxicity study, Aquatreat DN-30 (31.1% nabam) was administered by gavage to male and female Sprague-Dawley rats at 0, 0.08, 0.8, 8.0, 80 or 260 mg/kg/day. These doses were equivalent to 0, 0.025, 0.25, 2.49, 24.9 and 80.86 mg of nabam/kg/day. In the subchronic neurotoxicity study, no treatment-related changes were noted in either the Functional Observational Battery or locomotor evaluations. No statistically significant differences in the brain weights and dimensions were noted between the control and treated animals. Additionally, no treatment-related histopathological lesions were observed in the central or peripheral nervous systems. The subchronic neurotoxicity NOEL was 260 mg Aquatreat DN-30/kg/day (=80.86 mg

nabam/kg/day), the highest dose tested (guideline 82-7; MRID 42751601).

In the subchronic oral toxicity study, body weights and body weight gains were decreased in 80 mg Aquatreat DN-30/kg/day males and 260 mg Aquatreat DN-30/kg/day males and females, but these decreases were judged to be minimal (<10%) and not of physiological and/or toxicological importance. Absolute and relative thyroid weights were increased at 80 mg/kg/day (females only) and at 260 mg/kg/day (both sexes). Decreases in thyroxine (T4) levels were observed at 80 and 260 mg/kg/day in both sexes; increases in TSH were observed in 260 mg/kg/day males. Macroscopic examination revealed an enlarged thyroid in one high-dose male; microscopic examination revealed mild hypertrophy of the follicular epithelium in the thyroid glands of 3/10 high-dose (260 mg/kg/day) males. The systemic LOEL was established at 80 mg Aquatreat DN-30/kg/day (=24.9 mg nabam/kg/day) in males (decreased T4) and females (decreased T4 and increased thyroid weight). The systemic NOEL was 8.0 mg Aquatreat DN-30/kg/day or 2.49 mg nabam/kg/day (guideline 82-1; MRID 42751601).

c. Chronic Toxicity and Carcinogenicity

No chronic studies exist for nabam. However, chronic and carcinogenicity studies exist for ethylene thiourea (ETU), a metabolite of nabam. ETU is currently classified as a B2 carcinogen, with a revised (Feb. 24, 1995) unit risk Q_1^*(mg/kg/day)$^{-1}$ of 6.01 x 10^{-2} in human equivalents.

d. Developmental Toxicity

Two developmental studies were conducted with New Zealand white rabbits. In the first study (MRID 40873301), groups of 18 pregnant females were orally dosed with 0, 10, 100 or 200 mg/kg/day of test material (Aquatreat DN-30, approximately 30% nabam in aqueous solution) from days 7 through 19 of gestation. The maternal LEL (based on a weight loss occurring during days 7-13) was 100 mg/kg/day. For fetal malformations, there was a dose-related increased incidence of hydrocephaly (fetal incidences: 0/98, 3/102, 8/95 and 10/55; with litter incidences of 0/14, 2/16, 4/16 and 5/8 at 0, 10, 100 and 200 mg/kg/day, respectively). Also, there were 7 additional fetuses (not included among the 55 indicated above) which did not reach term (late resorptions or abortions) at 200 mg/kg/day which had findings suggestive of hydrocephaly. Hydrocephaly was also present in a fetus

that was aborted in the 10 mg/kg/day group and one that was aborted at 100 mg/kg/day. In addition, there was a dose-related trend for soft spot and/or domed cranium (fetal incidences: 0/98, 2/102, 4/95 and 6/55; litter incidences: 0/14, 2/16, 3/16 and 4/8). Among developmental variations, there was a trend involving incomplete ossification of the frontals of the cranium (fetal incidences: 0/98, 4/102, 8/95, and 9/55; litter incidences: 0/14, 4/16, 4/16 and 5/8). In general, the increased incidences were statistically significant at 100 and 200 mg/kg/day. While the incidence of hydrocephaly in the 10 mg/kg/day fetuses was not statistically significant, the report noted that: "hydrocephaly was not seen in any of the control rabbits in this study, nor has it been observed previously in control rabbits utilized by this laboratory." The developmental toxicity NOEL in this study was below 10 mg/kg/day (lowest dose tested). The maternal NOEL was 10 mg/kg/day; the LEL (weight loss days 7-13) was 100 mg/kg/day.

In the second rabbit developmental study (MRID 42437701) groups of 20 inseminated females were orally dosed with 0, 1, 8 or 100 mg/kg/day of test material (Aquatreat DN-30, approximately 30% nabam in aqueous solution) from days 7 through 19 of gestation. The maternal LEL (based on a statistically significant inhibition of weight gain during the first 6 days of dosing and the occurrence of elevated - in excess of 0.4 grams - thyroid weights in 2 females at termination) was 100 mg/kg/day. Fetal incidences of hydrocephaly were 0/98, 1/117, 3/134 and 3/114 (litter incidences: 0/16, 1/18, 1/18 and 3/18) at 0, 1, 8 and 100 mg/kg/day respectively. Two hydrocephalic fetuses at the median dose and one at the high dose also had cleft palate. Hydrocephaly had been previously observed in this laboratory, but cleft palate had not. The developmental toxicity NOEL in this study was 1 mg/kg/day (= 0.328 mg nabam/kg/day); the LEL was 8 mg/kg/day (= 2.62 mg nabam/kg/day) based on the occurrence of hydrocephaly in association with cleft palate and/or carpal flexure. The maternal NOEL was 10 mg/kg/day; the LEL (weight loss days 7-13) was 100 mg/kg/day.

The two studies (MRID 40873301 and MRID 42437701) satisfy the guideline requirement (83-3) for a developmental toxicity study in rabbits.

e. Mutagenicity

Nabam, tested as a 30% aqueous solution, did not induce a mutagenic response at the histidine locus in Salmonella typhimurium

strains TA98, TA100, TA1535, or TA1537 either in the absence or presence of rat-derived S9 (strains TA100, TA1535 and TA1537 were also tested in the presence of mouse S9, with no indication of any mutagenic response). The combination of studies (MRIDs 00152701, 42387101) satisfies the guideline requirement for an Ames assay (84-2).

In an initial Chinese Hamster Ovary/hprt assay (MRID 00153559) there was no indication of an increased mutation frequency at the hprt locus in cells exposed at up to 10 µg nabam/mL in the absence of S9, or at up to 20 µg nabam/mL in the presence of mouse S9. The next higher doses (20 µg nabam/mL without S9, and 30 µg/mL with mouse S9) were not evaluated, as there was considerable cytotoxicity (less than 10% relative plating efficiency). In the presence of rat S9, there was a statistically significant increase in mutation frequency at the hprt locus following exposure to 300 µg/mL (highest dose tested), but not at lower doses (60 - 150 µg nabam/mL). While the rat S9 significantly detoxified the nabam, the mouse S9 did not. In a subsequent CHO/hprt assay (MRID 41089901), conducted only in the presence of rat S9, there were statistically significant increases in mutant frequencies at the two highest doses (0.2 and 0.3 mg/mL) in a first trial, and also (with no evidence of a dose-related trend within the comparatively narrow concentration range of 0.1 to 0.3 mg/mL) in a second trial. The combination of studies (MRIDs 00153559, MRID 41089901) satisfies the guideline requirement (84-2) for an in vitro gene mutation assay in a mammalian cell line.

In an in vivo cytogenetics assay (MRID 41177201) there was no indication of an increased incidence of chromosomal aberrations in male and female Sprague-Dawley rats which received a single oral dose of up to 1200 mg/kg Aquatreat DN-30 (approximately 30% nabam) and were sacrificed 6, 18 or 30 hours following dosage. There were no indications of an increased incidence of chromosomal aberrations in another in vivo cytogenetics assay (MRID 00160516) in which groups of 10 male Fischer 344 rats received five doses of 0 (vehicle control) or 400 mg "nabam"/kg/day (from the wording of the report it was assumed they received 400 mg Aquatreat DN-30/kg/day) for 5 consecutive days, with sacrifice 6 hours after the final dose. From the reported toxicity (two rats died following dosing on day 3, and all animals had diarrhea) the highest dose was adequate. The study, MRID 41177201, satisfies the guideline requirement for an in vivo chromosomal aberration assay (84-2); MRID 00160516 is also acceptable, and the negative findings are consistent with what was observed in the other study.

In a single UDS (Unscheduled DNA Synthesis) study (MRIDs 00151954, 41174601) rat hepatocytes were exposed to concentrations of 0.1, 0.5, 1.0, 5.0 and 10.0 µg/mL (it is uncertain whether these values refer to concentrations of Aquatreat DN-30, or to concentrations of nabam). No cells survived treatment with 50 or 100 µg/mL. In the initial review, it was noted that there were increases in mean nuclear grain counts following exposure to nabam at doses from 0.1 to 1 µg/mL, suggestive of a dose-related effect, although these increases were not statistically significant. At the 5 µg/mL dose, there was good relative survival (95%) and a statistically significant increase in mean net nuclear grain counts. At 10.0 µg/mL there was a drop in relative survival (to 34%) and an increase (but not significantly so) in mean net nuclear grain counts. Subsequent evaluation of individual cell grain counts (MRID 41174601) showed that at doses of 1.0, 5.0 and 10.0 µg/mL the incidences of nuclei with ≥20 net grains were significantly elevated, indicating a positive response at these dose levels. The studies, MRID nos. 00151954 and 41174601, are acceptable and satisfy guideline 84-4, Other Genotoxic Effects.

There have been two SCE (Sister Chromatid Exchange) studies, both with positive findings. In the first study, (MRID 00160517), slight (statistically non-significant) increases in sister chromatid exchanges in CHO were observed under non-activated conditions; significant increases (with a dose-related trend) were observed at all dose levels (1000-5000 µg/mL) in the presence of mouse S9 and at the two highest dose levels (4000 and 5000 µg/mL) in the presence of rat S9. In the second SCE study (MRID 42303601), conducted under non-activated conditions only, there were increased incidences of SCE in CHO cells correlating with increasing exposure levels to Aquatreat DN-30 (first assay: significant increases following exposure to 16.7 and 50.1 µg/mL Aquatreat DN-30; second assay: significant increases following exposure to 16.7, 50 and 100 µg/mL). The two studies (MRIDs 00160517 and 42303601) are acceptable and satisfy guideline 84-4, Other Genotoxic Effects.

There have been two cell transformation assays. In the first assay, (MRID 00151955), there was no evidence of an increase in cell transformation under nonactivated conditions following exposure to concentrations ranging from 0.1 to 0.8 µg/mL. At 0.8 µg/mL there was 18% survival. In the second assay (MRID 41221201), conducted with activation only (rat S9 was used) there were no indications of an increased rate of cell transformation at the highest doses (127, 115, and 127 µg/mL) evaluated in 3 trials, with doses higher than these showing

excessive toxicity. The studies, MRID 00151955 and 41221201, are acceptable and satisfy guideline requirement 84-4, Other Genotoxic Effects.

f. Metabolism

In an acceptable metabolism study (MRID 00160125, with additional information and clarifications in MRID 00161804) radiolabelled nabam was administered to male and female rats by both oral and intravenous routes. Group A rats each received a single intravenous injection at 4.5 mg/kg; group B rats each received a single oral dose of 4.5 mg/kg. Each group C rat was dosed with 4.5 mg unlabelled nabam/kg/day, and then received 4.5 mg labelled nabam/kg on day 15. Each group D rat received a single dose of 100 mg labelled nabam/kg. For each group, most of the recovered radioactivity was in the urine (percentages ranged from 56.92 in group D males to 91.82 in group A females), with most of the remainder in the feces. Although the amount of radiolabelling in thyroids tended to be relatively low in terms of total administered ^{14}C (0.001% to 0.008%) concentrations were relatively high (10X to 31X) relative to carcass values. ETU was present in urine (11.7 to 36.6% of total ^{14}C present in the urine, with the highest percentages occurring in group D rats). No ETU was detected in the feces from group A animals; but 65.3% of the ^{14}C in the feces of group D males was from ETU; the value for group D females was 47.5%. This study is acceptable and satisfies guideline requirement 85-1.

g. Dermal Absorption

In a dermal absorption study (MRID 40317901) male rats received 10-hour occluded exposures to 0.2%, 2% and 20% (equal to 0.013, 0.13 and 1.3 mg/cm^2 respectively) radiolabelled nabam in aqueous solutions; there was absorption of 0.24%, 0.05% and 0.08% of the label, respectively. Corresponding values for the amounts remaining on the skin (and presumably available for absorption) were 15.68%, 3.66%, and 1.09% respectively. It is noted that in a dermal absorption study for ETU (MRID 40312001) "A significant portion of the dermal dose could not be washed off with soap and water and was subsequently absorbed." The study MRID 40317901 is acceptable and satisfies the data requirement for dermal absorption, guideline 85-2.

Based on this study the Agency has determined that a dermal absorption value of 16% (15.68% + 0.24%), should be used for risk assessment purposes.

h. Toxicity Endpoints

The following toxicity endpoints were selected for nabam and its metabolite ethylenethiourea (ETU):

A NOEL of 0.328 mg/kg/day from a rabbit developmental toxicity study (MRID 42437701) was the endpoint selected for the short and the intermediate-term occupational exposure assessment (Toxicology Endpoint Selection Document, 6/1/95). The LEL in the study was 2.62 mg/kg/day based on the occurrence of hydrocephaly in association with cleft palate and/or carpal flexure. These developmentally toxic effects occurred at doses that are not maternally toxic.

The carcinogenic potential of nabam has not been evaluated. To assess the cancer risks associated with nabam uses, the Agency recommended the estimation of exposure to ETU based on exposure to nabam, and using the unit risk for ETU (Comments on Calculation of Cancer Risk from Nabam, June 13, 1995). ETU is present in nabam as a contaminant, metabolite, and the main degradation product. ETU is classified as a Group B2 carcinogen with a Q_1^* of 6.01×10^{-2} $(mg/kg/day)^{-1}$ based on studies which show that it induced an increased incidence of thyroid adenomas and adenocarcinomas in rats and hepatomas in mice (51 CFR 33992, September 26, 1986).

The dermal absorption rate for nabam was calculated at 16 percent (Toxicology Endpoint Selection Document, May 30, 1995). The percentage of dermally absorbed nabam that is metabolically converted to ETU was calculated at 7.5 percent (Revision of EBDC Worker Exposure Assessment for Position Document Four, April 16, 1991). The dermal absorption rate for ETU was calculated at 30 percent (Exposure and Risk Assessment for Applicators of Nabam-Containing Microbiocides, Alco Chemical Corporation and Vinings Industries, May 5, 1988).

The OPP RfD Committee did not set an RfD for nabam at this time since the intended uses of this chemical are limited to non-food applications. Nabam's food uses (sugar mill grinding, crusher, and or/

diffuser systems) are regulated under the purview of FDA (21 CFR 173.320(b)(3)).

2. Exposure Assessment

a. Dietary Exposure

The uses of nabam under EPA's regulatory jurisdiction are limited to non-food applications. The food uses (sugar mill grinding, crusher, and or diffuser systems) fall under the purview of FDA (21 CFR 173.320(b)(3)). The EPA defers to FDA regarding dietary risk assessment. Dietary exposure to residues of nabam from EPA-regulated uses is not expected.

b. Occupational and Residential

Use Patterns

Nabam is applied by hand, open pouring, metering pump, and drip-feed devices. Applications are made continuously or as-needed.

Application rates range from 1.5 to 3.0 parts per million (ppm) in sugar processing; 7.2 to 170 ppm in pulp and paper processing; 2.4 to 60 ppm in water cooling towers, and 2.4 to 210 ppm for other industrial uses.

At this time, no end-use products containing nabam are intended for homeowner use. Many products containing nabam are labelled for "industrial use only" and are, therefore, intended for occupational use. None of the registered uses are likely to involve direct applications at residential sites.

Handler (Mixer/Loader/Applicator) Exposure

EPA has determined that there is potential for exposure to handlers during use-practices associated with nabam. Specifically, EPA is concerned about exposures to handlers at industrial sites. Data from the Chemical Manufacturer Association's (CMA) Antimicrobial Exposure Assessment study were used to complete the exposure assessment. The CMA study includes handlers who wear chemical resistant gloves, long pants and sleeves, shoes and socks. Alco Chemical Corporation and Vinings Industries were participants in the CMA study.

Based on the use pattern, several exposure scenarios are plausible as defined by the type of application equipment and procedures that may be employed by nabam handlers. The current labels indicate that two kinds of loading/application methods are available: open pouring (liquid and solid formulations) and pump metering system (liquid formulation in mechanical delivery system) applications. For those handlers using open pouring methods, there is the potential for respiratory, dermal, and eye exposure to nabam/ETU. Application via pump metering delivery systems would significantly reduce potential exposure.

The exposure scenarios are presented in Tables 2(a) through 4(c) along with the corresponding exposure and risk assessment for that scenario. For each of the loading/application methods, open-pour liquid, metering-pump liquid, and open-pour solid:

- Table "a" contains the exposure and risk estimates for short-term and intermediate-term exposures to nabam,
- Table "b" contains the average daily exposure estimates for ETU, and
- Table "c" contains the cancer risk estimates for ETU.

Two exposure settings are presented for open pouring application of the soluble concentrate liquid:

(1) industrial recirculating water cooling systems and
(2) drilling mud and packer fluids.

Four exposure settings are presented for meter-pump application of the soluble concentrate liquid:

(1) industrial recirculating water cooling systems,
(2) drilling mud and packer fluids,
(3) sugar mills processing water, and
(4) paper and pulp mill water systems.

Four exposure settings are presented for open pouring application of the soluble concentrate powder:

(1) industrial recirculating water cooling systems,
(2) drilling mud and packer fluids,
(3) paper and pulp mill water systems, and

(4) secondary and tertiary oil petroleum recovery. (Note that industry reports indicate that sugar mills and paper/pulp mills do not use the open-pouring application method).

Short and intermediate-term exposure to nabam was calculated as shown below. The body weight value for these nabam exposure calculations was 60 kg, the estimated weight of an average adult female in the United States, since the endpoint of concern is developmental toxicity.

- Actual Daily Exposure (ADE) (μg/kg/day) =

$$\frac{\text{Unit Exposure } (\mu\text{g/lb ai}) \times \text{Amount of A.I. Used (lb)}}{\text{Body Weight (60 kg)}}$$

- Adjusted Actual Daily Exposure (Adj.ADE) (μg/kg/day) = ADE (μg/kg/day) X Percent Dermal Absorption of Nabam (16)

Exposure to ethylenethiourea (ETU) was calculated as shown below. The body weight value for this exposure calculation was 70 kg, the estimated weight of an average person in the United States, since the chronic toxicological endpoints pertain to all persons, male and female.

1. ETU Exposure Calculations:

i. Average Daily Nabam Exposure (Nabam ADE) (μg/kg/day) =

$$\frac{\text{Unit Exposure } (\mu\text{g/lb ai}) \times \text{Amount of A.I. Used (lb)}}{\text{Body Weight (70 kg)}}$$

ii. Adjusted Nabam ADE (μg/kg/day) =

Nabam ADE (μg/kg/day) X Percent Dermal Absorption of Nabam (16%)

iii. Adjusted ETU ADE (μg/kg/day) =

Adj. Nabam ADE (μg/kg/day) X Percent Nabam Converted to ETU (7.5%)

2. ETU Exposure Calculations:

i. Average Daily ETU Exposure (ETU ADE) (μg/kg/day)

= Unit Exposure (μg/lb ai) X Amount (lb) of ETU Contaminate in Nabam Formulation Used (based on 0.5% ETU contaminate in nabam formulations) ÷ Body Weight (70 kg)

ii. Adjusted ETU ADE (μg/kg/day) =

ETU ADE (μg/kg/day) X Percent Dermal Absorption of ETU (30%)

3. Total Calculation of ETU Average Daily Exposure

Total ETU Adjusted Average Daily Exposure =

ETU ADE Converted (Table 2(c)) + Adj. ETU ADE (Table 3(b))

These calculations of daily exposure to nabam and ETU by handlers are used to assess the risk to those handlers.

Post-Application Exposure

EPA has determined there are possible exposures to persons working at industrial sites where nabam is applied, such as persons cleaning or maintaining the equipment. No post-application data are available to directly assess these exposures. However, post-application dermal exposures resulting from nabam use-patterns are likely to be minimal, since the exposures are to highly diluted nabam, not the concentrate, and the exposures are likely to be brief, since the post-application tasks do not involve prolonged contact with nabam-treated surfaces. Post-application inhalation exposures to nabam also are likely to be minimal, since nabam has very low vapor pressure and is, therefore, unlikely to generate sufficient vapor to cause a concern to workers performing post-application tasks.

3. Risk Assessment

a. Dietary

An assessment for human health risk from dietary exposure was not performed because nabam has no registered food uses under EPA purview.

b. Occupational and Residential

The Margin of Exposure (MOE) for nabam was calculated as follows:

Short and Intermediate-Term MOE =

$$\frac{\text{NOEL (328 } \mu\text{g/kg/day)}}{\text{Adj. Nabam ADE (}\mu\text{g/kg/day)}}$$

The cancer risk for ETU was calculated as follows:

1. Average Daily Dose Per Year (ADD) =

Total Adj ETU ADE (μg/kg/day) X [Exposure Frequency (EF) (days) ÷ 365 days/year)]

2. Lifetime Average Daily Dose (LADD) (μg/kg/day) =

ADD (μg/kg/day) X [40 work-years ÷ 75 years lifetime]

3. Cancer Risk =

LADD (μg/kg/day) X Q* (μg/kg/day)$^{-1}$

Risk From Handler (Mixers/Loaders/Applicators) Exposure

The Agency conducted an assessment of the risks associated with handler exposures to nabam and its contaminant ETU. The results are presented in Tables 2(a) through 4(c).

The margins of exposure (MOEs) associated with nabam are greater than 100 for all exposure scenarios, **EXCEPT** the following:

1. open-pour liquid applications in water cooling systems (MOE 4),

2. open-pour solid applications to drilling muds and packer fluids (MOE 43),
3. open-pour solid applications to secondary and tertiary oil recovery water systems (MOE 9.6).

The cancer risk associated with exposures to ETU are 1×10^{-5} or lower, except for open pour liquid applications in water cooling systems (cancer risk 3.9×10^{-5}).

Risk From Post Application Exposure

Since post-application dermal and inhalation exposures resulting from nabam use-patterns are likely to be minimal, no risk assessment is required.

TABLE 2: USING AQUATREAT DNM-360 SOLUBLE CONCENTRATE LIQUID WITH 18% OF ACTIVE INGREDIENT NABAM

Assumptions

For industrial recirculating water cooling systems: 1) 10.88 ounces of product per 1,000 gallons of water in the system (100 ppm) as initial dose, and 20,000 gallons of water per use for a total of 217.6 ounces of product used. 2) By weight, this is equal to: 217.6 ounces divided by 128 ounces per gallon X 9.8 lbs per gallon = 16.66 pounds of product added 3) 16.66 lbs X 0.18 = 3 lbs of active ingredient handled.

For drilling mud and packer fluids: 1) 4.17 gallons per 100 bbl. of mud (it can be used directly from the shipping container or pre-diluted with water, it can be put through the mud hopper or added to the pump suction) 2) By weight, 4.17 gallons of product is equal to: 4.17 gallons X 9.8 lbs per gallon = 40.87 pounds of product added. 3) 40.87 lbs X 0.18 = 7.36 pounds of active ingredient were used.

Table 2(a) - Short and Intermediate Term Occupational Exposure and MOEs for Nabam

OPEN POUR LIQUID						
Setting	UE* (μg/lb ai)	lb ai/ used	BW** (kg)	ADE*** (μg/kg/day)	Adj. ADE**** (μg/kg/day)	**MOE**
Cooling Water	10230	3	60	511.50	81.84	4
Drilling Mud/ Packer Fluid	140	7.36	60	17.17	2.75	119

* Unit Exposure, derived from CMA Study (Amended report, 1992) with gloves.
** Body Weight
*** Actual Daily Exposure (μg/kg/day) = (UE X lb ai/used) / BW
**** Adj. ADE (μg/kg/day) = ADE adjusted for 16% dermal absorption rate of nabam
NOEL = 0.328 mg/kg/day
MOE = NOEL/Adj. ADE

Table 2(b) - Average Daily Occupational Exposure To ETU (from metabolic conversion and 0.5 % contaminant).

OPEN POUR LIQUID					
Setting	Adj. ADE* μg/kg/day (Nabam)	ETU** μg/kg/day Converted	ADE (ETU)*** μg/kg/day Exposed (contaminant)	ADJ. ETU**** μg/kg/day Exposed (contaminant)	Total ETU ADE μg/kg/day
Cooling Water	69.95	5.25	12.18	3.65	8.90
Drilling Mud/ Packer Fluid	2.35	0.18	0.41	0.12	0.30

* Adjusted Average Daily Exposure (using 70 kg body weight)

** Based on 7.5% of absorbed nabam metabolically converted to ETU

*** Average Daily Exposure, based on 0.5% of ETU contaminant in the concentrate product

**** Adjusted Average Daily Exposure, based on the registrant's assumption of 30% dermal absorption of ETU

Table 2(c) - Cancer Risk Estimates.

OPEN POUR LIQUID					
Setting	Total ETU ADE μg/kg/day	EF/yr*	ADD** μg/kg/day	LADD*** μg/kg/day	**Risk**
Cooling Water	8.90	50	1.22	0.65	3.9×10^{-5}
Drilling Mud/ Packer Fluid	0.30	50	0.04	0.02	1.2×10^{-6}

* EF (Exposure Frequency), treatment is assumed once a week, 50 times per year

** Average Daily Dose (ADD) per year = ADE x EF/365

*** LADD (Lifetime Average Daily Dose) = ADD x 40/75 (40 working year of 75 year of lifetime

Cancer risk = LADD x Q_1*

Q_1* = Cancer Potency Factor = 6.01×10^{-2} $(mg/kg/day)^{-1}$

TABLE 3: USING AMA-30 SOLUBLE CONCENTRATE LIQUID (EPA REG. 9386-11), 15% OF ACTIVE INGREDIENT NABAM (SUGAR MILLS, PAPER/PULP AND COOLING SYSTEMS) AND AQUATREAT DNM-360, 18% OF ACTIVE INGREDIENT (DRILLING MUD & PACKER FLUIDS)

Assumptions:

For sugar mills processing water : 1) 4 gallons (39.2 pounds) of AMA-30 per 1,000 tons of beets sliced per 24 hours. 2) By weight, 39.2 pounds of AMA-30 X 0.15 = 5.88 lbs of active ingredient used.

For paper mill water: 1) 2 pounds of product per ton of finished paper and 100 tons of finished paper treated per use for a total of 200 pounds of product added. 3) By weight; 200 lbs X 0.15 = 30 lbs of active ingredient used.

For industrial recirculating water cooling systems: 1) 13.6 fluid ounces of product per each 1,000 gallons of water in the system (120 ppm) as the initial dose with the mechanical delivery metering pump 2) 20,000 gallons of water treated and 272 ounces of product used 3) One gallon of product is 9.6 lbs (label), and is equal to 128 fluid ounces, therefore, 272 ounces divided by 128 ounces = 2.13 gallons of product 4) By weight, 2.13 gallons of product X 9.6 lbs/gallon X 0.15 = 3.07 lbs of active ingredient used.

For drilling mud and packer fluids: 1) 4.17 gallons of AQUATREAT DNM-360 (18% ai) per 100 bbl. of mud (it can be used directly from the shipping container or pre-diluted with water; or it can be put through the mud hopper or added to the pump suction) 2) By weight, 4.17 gallons of product X 9.8 lbs per gallon = 40.87 pounds of product added 3) 40.87 lbs X 0.18 = 7.36 pounds of active ingredient used

Table 3(a) - Short and Intermediate Term Occupational Exposure and MOEs for Nabam.

PUMP LIQUID (MECHANICAL DELIVERY SYSTEM)						
Setting	UE* (μg/lb ai)	lb ai/ used	BW** (kg)	ADE*** μg/kg/day	Adj. ADE**** μg/kg/day	**MOE**
Sugar Mills Processing Water	3.9	5.88	60	0.38	0.06	5,466
Paper/Pulp Water	3.9	30	60	1.95	0.31	1,058
Drilling Mud/ Packer Fluids	7.5	7.36	60	0.92	0.15	2,186
Cooling Water	90	3.07	60	4.61	0.74	443

* Unit Exposure, from CMA Study (Amended report, 1992) with gloves.
** Body Weight of 60 kg.
*** Actual Daily Exposure (μg/kg/day) = (UE X lb ai/used) / BW
**** ADE adjusted for 16% dermal absorption rate of nabam
NOEL = 0.328 mg/kg/day
MOE = NOEL/Adj. ADE

Table 3(b) - Average Daily Occupational Exposure To ETU (from metabolic conversion and 0.5 % contaminant)

PUMP LIQUID (MECHANICAL DELIVERY SYSTEM)					
Setting	Adj. ADE* μg/kg/day (Nabam)	ETU Converted** μg/kg/day	ADE (ETU)*** μg/kg/day Exposed	ADJ.ADE (ETU)**** μg/kg/day Exposed	Total ETU ADE μg/kg/day
Sugar Mills Processing Water	0.05	0.004	0.0108	0.0033	0.0073
Paper/Pulp Water	0.27	0.02	0.056	0.0168	0.0368
Drilling Mud/ Packer Fluid	0.13	0.01	0.026	0.0078	0.0178
Cooling Water	0.63	0.05	0.13	0.039	0.089

* Adjusted Average Daily Exposure (using 70 kg body weight)

** Based on 7.5% of absorbed nabam metabolically converted to ETU

*** Average Daily Exposure, based on 0.5% of ETU contaminant in the concentrate product

**** Adjusted Average Daily Exposure, based on the registrant's assumption of 30% absorption rate for ETU

Table 3(c) - Cancer Risks.

PUMP LIQUID (MECHANICAL DELIVERY SYSTEM)					
Setting	Total ETU ADE μg/kg/day	EF/yr*	ADD** μg/kg/day	LADD*** μg/kg/day	**Risk**
Sugar Mills Processing Water	0.0073	26	0.00052	0.00028	1.7×10^{-8}
Paper/Pulp Water	0.0368	26	0.00262	0.0014	8.4×10^{-8}
Drilling Mud/ Packer Fluids	0.0178	26	0.00127	0.00067	4.1×10^{-8}
Cooling Water	0.089	50	0.0122	0.0065	3.9×10^{-7}

* Exposure Frequency

** Average Daily Dose per year = ADE x EF/365

*** Lifetime Average Daily Dose = ADD x 40/75 (40 working year of 75 year of lifetime

Cancer risk = LADD x Q_1*

Q_1* = Cancer Potency Factor = 6.01×10^{-2} $(mg/kg/day)^{-1}$

TABLE 4: USING AQUATREAT DNM-80 POWDER, 40% ACTIVE INGREDIENT OF NABAM

Assumptions:

For cooling water systems: Based on the information from the label (EPA Reg. 31910-20, 2/1/95), 1 pound of product added into 1,000 gallons of water in the industrial recirculating water cooling tower and evaporative condensers as the initial dose. This dose may be repeated three times per week. If a system needs 5,000 gallons of water to treat each time, 5 lbs of AQUATREAT DNM-80 are added into the system = 2 lbs of active ingredient handled each time.

For pulp and paper mill water: Based on the information from the label (EPA Reg. 31910-20, 2/1/95), 0.75 pounds of AQUATREAT DNM-80 powder added per ton of hydropulper. Assuming that 1 ton of hydropulper is treated for each handled activity : 0.75 lbs X 0.4 = 0.3 lbs of a.i. added into the pulp system.

For drilling mud and packer fluids: Based on the information from the label (EPA Reg. 31910-20, 2/1/95), 15 pounds of AQUATREAT DNM-80, 40% a.i. of nabam powder added into 100 bbl of mud (300 ppm). A total of 15 lbs X 0.4 = 6 pounds of a.i. are handled.

For secondary and tertiary petroleum recovery water: Based on the information from the label (EPA Reg. 31910-20, 2/1/95), a total of 6.7 pounds of AQUATREAT DNM-80 powder are added per 100 bbl of water. Assuming that 1,000 bbl of water are treated per use, a total of 67 lbs X 0.4 = 26.8 lbs a.i. are handled.

Table 4(a) - Short and Intermediate Term Occupational Exposure and MOEs for Nabam.

OPEN POUR SOLIDS						
Setting	UE* (μg/lb ai)	lb ai/ used	BW** (kg)	ADE*** μg/kg/day	Adj. ADE**** μg/kg/day	**MOE**
Cooling Water	479	2	60	15.97	2.56	128
Paper/Pulp Water	479	0.3	60	2.40	0.38	863
Drilling Mud/ Packer Fluids	479	6	60	47.90	7.66	43
2° Oil Recovery Water	479	26.8	60	213.95	34.23	9.6

* Unit Exposure, derived from CMA Study (Amended report, 1992) with gloves.
** Body Weight of 60 kg.
*** Actual Daily Exposure (μg/kg/day) = (UE X lb ai/used) / BW
**** ADE adjusted for 16% dermal absorption rate for nabam
NOEL = 0.328 mg/kg/day
MOE = NOEL/Adj. ADE

Table 4(b) - Average Daily Occupational Exposure to ETU (from metabolic conversion and from 0.5 % contaminant).

OPEN POUR SOLIDS					
Setting	Adj. ADE* μg/kg/day (Nabam)	ETU** μg/kg/day Converted	ADE (ETU)*** μg/kg/day Exposed	ADJ.ADE ETU**** μg/kg/day Exposed	Total ETU ADE μg/kg/day
Cooling Water	2.19	0.16	0.17	0.05	0.21
Paper/Pulp Water	0.32	0.02	0.027	0.01	0.03
Drilling Mud/ Packer Fluid	6.55	0.49	0.51	0.15	0.64
2^0 Oil Recovery Water	29.26	2.19	2.28	0.68	2.87

* Adjusted Average Daily Exposure (using 70 kg body weight)

** Based on 7.5% of absorbed nabam metabolically converted to ETU

*** Average Daily Exposure, based on 0.5% of ETU contaminant in the concentrate product

**** Adjusted Average Daily Exposure, based on the registrant's assumption of 30% absorption rate for ETU

Table 4(c) - Cancer Risk Estimates.

OPEN POUR SOLIDS					
Setting	Total ETU ADE μg/kg/day	EF/yr*	ADD** μg/kg/day	LADD*** μg/kg/day	**Risk**
Cooling Water	0.21	50	0.03	0.02	1.2×10^{-6}
Paper/Pulp Water	0.03	26	0.0021	0.0011	6.8×10^{-8}
Drilling Mud/ Packer Fluid	0.64	26	0.05	0.03	1.8×10^{-6}
2^{o} Oil Recovery Water	2.87	26	0.20	0.11	6.6×10^{-6}

* Exposure Frequency

** Average Daily Dose per year = ADE x EF/365

*** Lifetime Average Daily Dose = ADD x 40/75 (40 working year of 75 year of lifetime

Cancer risk = LADD x Q_1*

Q_1* = 6.01×10^{-2} $(mg/kg/day)^{-1}$.

MOE = NOEL/ADD

C. Environmental Assessment

1. Ecological Toxicity Data

Nabam was found to be practically nontoxic to birds on an acute oral and subacute dietary basis and practically nontoxic to bees. Available data indicated that nabam is slightly to moderately toxic to both cold and warm water fish and moderately toxic to freshwater invertebrates. Additionally, nabam ranged from being highly toxic to practically nontoxic to estuarine/marine organisms. Ecological testing of ETU, a primary degradate of nabam, previously had been required; however, because of the current limited uses of nabam, these tests are not required.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

To establish the toxicity of nabam to birds, the following tests are required: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); one subacute dietary study (LC_{50}) on one species (preferably the mallard duck or bobwhite quail). The following tables show the results of these tests.

Avian Acute Oral Toxicity Findings (LD_{50})

Species	% A.I.	LD_{50} mg/kg	MRID/ Author(s)/Year	Toxicity Category	Fulfill Guideline Requirements
Northern Bobwhite Quail	30	>2250	159771 Beavers, 1986	Practically nontoxic	Yes

Avian Subacute Dietary Toxicity Findings (LC_{50})

Species	% A.I	LC_{50} ppm	MRID Author(s)\Year	Toxicity Category	Fulfill Guideline Requirement
Northern Bobwhite Quail	93	>5000	22923 Hill et al., 1975	Practically nontoxic	Yes
Mallard Duck	93	>5000	22923 Hill et al., 1975	Practically nontoxic	Yes

These results indicate that nabam is practically nontoxic to birds on an acute oral and subacute dietary basis. The guideline requirements are fulfilled (MRID #159771, 22923).

(2) Insects

A honey bee acute contact LD_{50} study is required if the proposed use will result in honey bee exposure. Nabam uses are aquatic non-food industrial and no honey bee acute testing is required for this use pattern. However, a study was submitted and reviewed. The following table shows the results.

Nontarget Insect Acute Contact Toxicity Findings

Species	% A.I.	LD_{50} μg/bee	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirements
Apis mellifera	tech	12.09	36935 Atkins et al. 1975	Practically nontoxic	Yes

There is sufficient information to characterize nabam as practically nontoxic to bees. The guideline requirement would be fulfilled (MRID #36935).

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

To establish the toxicity of a pesticide to freshwater fish, the minimum data required on the technical grade of the active ingredient is one freshwater fish toxicity study using either a coldwater fish (preferably the rainbow trout) or a warmwater fish (preferably the bluegill sunfish). The following table shows the results of these studies.

Freshwater Fish Acute Toxicity Findings					
Species	**% A.I.**	**LC_{50} ppm (product)**	**MRID/Accession NO. Author(s)/Year**	**Toxicity Category**	**Fulfill Guideline Requirements**
Rainbow trout	30	11	157611 McAllister & Bowman, 1985	Slightly Toxic	Yes[1]
Bluegill sunfish	30	28	157611 (same as above)	Slightly Toxic	Yes[1]
Rainbow Trout	30	1.73	104057 Allen, 1975	Moderately Toxic	Supplemental[2]
Bluegill sunfish	30	3.44	104057 Allen, 1975	Moderately Toxic	Supplemental[2]

1. Static test on 30% nabam.
2. Static test on 15% nabam and 15% sodium dimethyl dithiocarbamate. Supplemental studies provided useful information but did not fulfill guideline requirement.

The results of the two 96-hour acute toxicity studies indicate that nabam and nabam-containing products are slightly to moderately toxic to both cold and warm water fish. The guideline requirement for acute toxicity testing on freshwater fish is fulfilled (Accession #157611).

(2) Freshwater Invertebrates

The minimum testing required to assess the hazard of a pesticide to freshwater invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges. The following table shows the results of testing with *Daphnia magna*.

Freshwater Invertebrate Toxicity Findings					
Species	**% A.I.**	EC_{50} ppm (product)	**MRID No. Author/Year**	**Toxicity Category**	**Fulfills Guideline Requirements**
Daphnia magna	30	5.6	40164046 Forbis et al., 1985	Moderately Toxic	Yes[1]

1. Static test on 30% nabam.

There is sufficient information to characterize nabam as moderately toxic to aquatic invertebrates. The guideline requirement is fulfilled (MRID #40164046).

(3) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. The aquatic nonfood use of nabam may result in exposure to the estuarine environment.

The requirements under this category include a 96-hour LC_{50} for an estuarine fish, a 96-hour LC_{50} for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters. The following table shows the results of these studies.

Estuarine/Marine Acute Toxicity Findings					
Species	**% A.I**	**LC_{50} ppm (product)**	**MRID No. Author/Year**	**Toxicity Category**	**Fulfills Guideline Requirements**
Eastern oyster	30.83	0.96	40966801 Surprenant, 1989	Highly Toxic	Yes[1]
Easter Oyster embryo	30	4.61	97064 Union Carbide, 1985	Moderately Toxic	Yes[2]
Mysid Shrimp	30.2	0.17	40966701 Surprenant, 1989	Highly Toxic	Yes[1]
Grass Shrimp	30.2	0.179	107905 Conzelmann, 1982	Highly Toxic	Supplem.[2]
Grass Shrimp	30	5.22	97064	Moderately Toxic	Supplem.[3]
Sheepshead minnow	30.8	>11000	40961601 Surprenant, 1988	Practically Nontoxic	Yes[1]
Sheepshead minnow	30	0.14	107906 Conzelmann, 1982	Highly Toxic	Yes[2]

1. Flow-through conditions with 30% nabam.
2. Static conditions with 15% nabam and 15% sodium dimethyl dithiocarbamate. Supplemental studies provided useful information but did not fulfill guideline requirement.
3. 48-hr static with 15% nabam and 15% sodium dimethyl dithiocarbamate. Supplemental studies provided useful information but did not fulfill guideline requirement.

There is sufficient information to characterize nabam and nabam-containing products as highly to moderately toxic to estuarine/marine organisms. The guideline requirements are fulfilled (MRID #40966801, 40966701, 40961601).

c. Toxicity to Plants

Terrestrial and aquatic plant testing (seedling emergence and vegetative vigor) is not required for the currently registered uses of nabam. Those studies are required for herbicides with terrestrial nonfood/feed or aquatic nonfood (except residential) use patterns. However, if incidents or adverse effects to plants are reported to the Agency, these plant data may be required.

2. Environmental Fate

a. Environmental Fate Assessment

General Issues Related to Nabam-Containing Products

All of the manufacturing-use products and end-products containing nabam as an active ingredient require a National Pollutant Discharge Elimination System (NPDES) permit for discharge of treated effluents. In addition, the discharge of treated fuel tank bottom water is regulated under the Agency's Resource Conservation and Recovery Act (RCRA). The only data requirement that applies in this case is guideline 161-1, Hydrolysis.

Since ethylene thiourea (ETU) is a major degradate of nabam and one of toxicological concern, data on degradation and transport of ETU have been included in this assessment.

It is important to realize that all of the registered products containing nabam as an active ingredient also contain sodium dimethyldithiocarbamate (SDDC), another active ingredient regulated separately by the Agency. The present assessment is based on nabam alone.

b. Environmental Fate and Transport: Nabam and Ethylene Thiourea

Nabam and its primary degradates, except for ethylene thiourea (ETU), do not persist in the environment. They are susceptible to chemical and microbial degradation. ETU does biodegrade, but it is stable to chemical degradation (hydrolysis and photodegradation). ETU is persistent in abiotic environments, highly soluble in water and mobile, with low adsorption to soils, and thus may reach and persist in ground and surface waters. Because ETU is the most stable, toxic and mobile degradate of nabam, it is the degradate of environmental concern.

The degradation of nabam in aqueous media is driven by hydrolytic reactions. Hydrolytic and photolytic reactions further contribute to degrade some of the primary hydrolytic products, particularly ethylene bis-isocyanate (EBIS). In both the abiotic

hydrolysis and photolysis in water studies the amount of ETU present is the highest at pH 9, but at all pHs, the amount of ETU formed increases with time. However, in irradiated solutions, the amounts of ETU present at comparable sampling times are lower than in the abiotichydrolysis studies. Furthermore, the amounts of ethylene urea (EU) are much higher in irradiated solutions than in non-irradiated, abiotic solutions. There is evidence that EBIS, which is the first hydrolytic product of nabam, is likely to be the photolabile species and behaves as a precursor to ETU and EU via hydrolytic and/or photolytic reactions. Hydantoin is also a degradate of nabam, but it is a relatively minor degradation product.

Laboratory studies conducted with ETU as the test substance indicate that ETU is persistent to abiotic hydrolysis and direct photolysis, but that it does biodegrade. Data indicate that ETU may degrade rapidly in viable soils incubated under aerobic conditions; a laboratory half-life of less than 2 days has been reported. Under anaerobic conditions, ETU is more persistent, with reported half-lives of 149 days. The adsorption of ETU to soils is weak and seems to be controlled by the concentration of soil organic matter; K_{ads} values for ETU are less than or equal to 1.14 in all soils tested. Therefore, ETU has the potential to leach to and persist in ground water, particularly in areas of low organic matter, highly permeable soils and shallow ground water tables.

(1) Hydrolysis and Photodegradation of Nabam in Aqueous Media

The chemical transformations of parent nabam and its major degradation products in homogeneous aqueous media are complex and may involve labile intermediate products that are difficult to analyze. In addition, reaction products such as ethylene bis-isocyanate (EBIS) appears to undergo further hydrolysis and be prone to degrade by direct photolysis.

Parent nabam degrades very rapidly in abiotic aqueous media (estimated at less than 1 hour). The first major hydrolysis product is ethylene bisisocyanate sulfide (EBIS), but this degradate appears to undergo further degradation to ethylene thiourea (ETU). The amount of EBIS initially formed is higher at pH 9 than at pH 5. In general, the formation of ETU increases as a function of time, regardless of the pH of the medium, but the amount formed is higher at pH 9. Other hydrolytic products are hydantoin (present at pHs 5 and 7 but not at pH

9) and ethylene urea (EU). There was not a distinct pattern of formation and decline for any of the degradates. The maximum amount of ETU was near 88% of the recovered radioactivity after 504 hours (pHs 7 and 9), but the data suggest that ETU may be more stable at pH 9. No rate constants or half-lives were calculated for nabam because no degradation pattern could be established.

There is evidence that EBIS, the first major hydrolytic product of nabam, is a photolabile species. The electronic absorption spectra (260-430 nm) of EBIS in aqueous solutions at pHs 5, 7 and 9 show "tailing" of an absorption band above 290 nm, which indicates that EBIS would be prone to undergo direct photolysis reactions. In addition, EBIS is less persistent under irradiation than in the absence of irradiation. Less ETU and more EU are present in irradiated solutions than in non-irradiated solutions, suggesting that the relative increase in EU over ETU may be a result of a photoprocess (either from EBIS and/or from photo-oxidation of ETU). An estimate of the half-lives of EBIS in irradiated solutions was 19, 38 and 16 hours at pH 5, 7 and 9, respectively. These degradation kinetics data do not reflect the actual degradation of EBIS (as test substance), since EBIS was a reaction product of nabam that was degrading (hydrolytically and photolytically) as it was being formed (MRID #00165028, 40535201).

(2) Mobility of Nabam

Nabam and EBIS, its first major hydrolytic product, are not sufficiently persistent to estimate absorption constants in soils. Since ETU is a major degradate of nabam and one of toxicological concern, the mobility and other issues related to the environmental fate of ETU are addressed below.

(3) Ethylene Thiourea (ETU) - A Degradate of Concern

ETU is stable to abiotic hydrolysis at pH 5, 7 and 9 (MRID #40466103).

Irradiation of ETU solutions at pH 7 shows that ETU does not degrade significantly and thus, it is not expected to break down in the environment by direct photolysis. Photodegradation on Lawrenceville silty loam soil surfaces is not significant and any degradation occurring is the result of biodegradation or other oxidative processes, with half-lives of 2.5 days (dark) and 1.26 days (irradiated). Degradation products such as EU and 2-imidazoline were identified in this study,

where increasing amounts of non-extractable material were observed over time (MRID #40466101, 40466102).

There are no acceptable data on aerobic soil metabolism of ETU, but data such as that from photodegradation on soil surfaces indicate that ETU may degrade rapidly on viable soils under aerobic conditions. However, an anaerobic aquatic metabolism study conducted with maneb as the test substance indicates that the levels of ETU formed from the degradation of maneb (via EBIS) remain fairly constant, with an estimated half-life of 149 days (MRID #00163335).

Data from batch-equilibrium adsorption/desorption studies conducted with ETU as the test substance indicate that ETU does not bind strongly to soils. The Freundlich K_{ad} values ranged from 0.51 (clay loam) to 1.13 (silt loam). The organic carbon adsorption coefficients (K_{oc}) ranged from 34 (clay loam) to 145 (sand). However, there appears to be no strong correlation with percent soil organic matter, soil cation exchange capacity or soil pH (MRID #40222902).

c. Water Resources

(1) Ground Water

The current non-agricultural uses of nabam are not likely to impact ground water resources. All uses of nabam carry an NPDES permit requirement for discharge of treated effluents.

(2) Surface Water

Nabam is not applied directly to surface water, but industrial effluents with nabam residues require NPDES permits for discharge into water bodies.

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

The Agency requires only a limited set of ecotoxicology and environmental fate studies for microbiocides. While the hazard to aquatic organisms from nabam has been characterized, a quantitative risk assessment has not been conducted. The risks to aquatic environments are regulated under the NPDES permitting program of the Office of Water. The Agency currently requires that labels for all

nabam products require that discharges to aquatic environments comply with an NPDES permit.

For microbiocides with once-through cooling tower use patterns, the Agency uses a dilution factor model to calculate screening level EECs and develop risk quotients for a risk screen. Although nabam has a once-through cooling tower use pattern, the use is for shipboard systems and a screening-level EEC calculation is inappropriate because this calculation is designed to represent concentrations in rivers and streams, not complex marine environments. Methods for appropriately estimating the concentrations resulting from shipboard uses have not been developed. However, because of the large dilution factor, it is not expected that discharges into marine environments would result in concentrations of concern. Discharges into harbor waters may be more problematic because of the smaller, enclosed area of water and the potential for concentrations of many types of chemicals in these areas.

b. Water Resources Risk Implication for Human Health

The degradate ethylene thiourea (ETU), a probable human carcinogen, is regulated by the Agency's Office of Drinking Water. The longer-term Health Advisory for a 10 kg child is 0.1 mg/L and for a 70-kg adult, 0.4 mg/L.

c. Endangered Species

The Agency does not anticipate any exposure of concern to fish and wildlife, providing that all nabam products require that discharges to the environment comply with all disposal laws or a NPDES permit.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing nabam. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing nabam.

Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of nabam, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of nabam and to determine that nabam can be used as specified in this document without resulting in unreasonable adverse effects to humans and the environment, provided the changes specified in this document are implemented. The Agency therefore finds that all products containing nabam as the active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of nabam as specified in this document are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing nabam, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient nabam, the Agency has sufficient information on the health effects of nabam and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that nabam products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing nabam for all uses are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of nabam are eligible for reregistration. The Agency is prohibiting open pour applications of liquid formulations in water cooling systems (e.g. towers). Additionally, all solid/dry formulations of nabam must be placed in water soluble packaging.

C. Regulatory Position

The following is a summary of the regulatory positions and rationales for nabam. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Tolerance Reassessment

There are no existing tolerances for nabam regulated by EPA.

2. Reference Dose

The Agency has not set an RfD for nabam at this time.

3. Endangered Species Statement

The Agency does not anticipate any exposure of concern to fish and wildlife, providing that all nabam products require that discharges to the environment comply with all disposal laws or a NPDES permit.

4. Labeling Rationale

<u>Occupational and Residential Labeling Rationale/Risk Mitigation</u>

Personal Protective Equipment/Engineering Controls for Handlers

For each end-use product, PPE requirements for pesticide handlers are set during reregistration in one of two ways:

1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE must be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc.):

- In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most end-use products containing that active ingredient.
- These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of the end-use product.
- The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if chemical-resistant gloves are required, then long-sleeve shirts, long pants, socks, and shoes are assumed and are also included in the required minimum attire. If the requirement is for two layers of body protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.

Occupational-Use Products

EPA has determined that the establishment of active-ingredient-based minimum PPE requirements for occupational handlers is warranted for nabam. All the exposure studies were conducted with handlers wearing chemical-resistant gloves and there were not sufficient data to predict the probable exposure without chemical-resistant gloves; therefore, chemical-resistant gloves will be required on all nabam end-use product labeling. In addition, since the MOE was greater than 100 for metering-pump liquid applications in water cooling systems (e.g. towers), but less than 100 for open-pour liquid applications in water cooling systems, EPA will require liquid formulations in water cooling systems to be applied by mechanical loading delivery systems (such as metering pump, gravity fed, manual pump, pressurized, probe, etc.) and prohibit open-pour applications. The Agency is requiring dry formulations of nabam to be placed in water-soluble packaging.

Post-Application/Entry Restrictions

Occupational-Use Products

EPA has determined that no regulatory action must be taken to reduce post-application exposures to nabam, since post-application dermal and inhalation exposures are already likely to be minimal.

Homeowner-Use Products

There are no homeowner uses of nabam.

Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing nabam. The Agency is also requiring labeling statements to clarify the intent of the oil recovery drilling muds/packer fluids use either as an aquatic or terrestrial non-food use pattern. For the specific labeling statements, refer to Section V of this document.

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of nabam for the above eligible uses has been reviewed and determined to be substantially complete for all uses. The following data were previously required in the nabam Registration Standard and have data deficiencies which can be upgraded:

PRODUCT CHEMISTRY
Registrant: Vinings Industries
Product: TGAI isolated from EPA Reg. No. 9386-7, 9386-11, or 9386-23.

Guideline 61-2(b) - Discussion of Formation of Impurities
Guideline 63-13 - Stability

Registrant: Alco Chemical Division of National Starch and Chemical Co.
Product: TGAI isolated from EPA Reg. No. 31910-7

Guideline 63-13 - Stability

TOXICOLOGY

Guideline 81-3 - Acute Inhalation Toxicity - Rat

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. In addition, the MP labeling must bear the following statement under Directions for Use:

> "Only for formulation into an [fill blank with Insecticide, Herbicide or the applicable term which describes the type of pesticide use(s)] for the following use(s) [fill blank only with those uses that are being supported by MP registrant."]

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under

> "Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

(a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

(b) "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

Effluent Discharge Statement

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the

requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix D, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

Worker Protection Standard

No nabam end-use products are within the scope of the Worker Protection Standard for Agricultural Pesticides (40 CFR parts 170 and 156). However, personal protective equipment for non-WPS occupational use is required and is discussed below.

Effluent Discharge Labeling Statements

Refer to subsection A. above for labeling requirements for effluent discharge.

PPE/Engineering Control Requirements for Pesticide Handlers

For **sole-active-ingredient** end-use products that contain nabam, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain nabam, the handler personal protective equipment/engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

Products Intended Primarily for Occupational Use

Minimum (Baseline) PPE/Engineering Control Requirements

The minimum (baseline) PPE for all occupational uses of nabam end-use products is:

Minimum PPE:
"Applicators and other handlers must wear:

--long-sleeve shirt and long pants
--chemical-resistant gloves*,
--socks plus shoes

* For the glove statement, use the statement established for nabam through the instructions in Supplement Three of PR Notice 93-7.

Engineering Control Requirements

For liquid formulations:
In the "Directions For Use" portion of the label referring to these uses, registrants must insert the following language:

"This product must be loaded and transferred only using a metering-pump system or a closed loading/application system for the following uses: {list each of the following uses for which the end-use product is labeled: air washer water systems; commercial/industrial water cooling systems (includes shipboard seawater cooling systems); evaporative condenser water systems; pasteurizer/warmer/cannery cooling water systems; and heat exchanger water systems.}. Open pouring is prohibited."

For dry formulations:
All nabam end-use products formulated as a dry formulation must be placed in water-soluble packaging.

Determining PPE Requirements for End-Use Product Labels

The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient-based minimum (baseline) personal protective equipment specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Placement in Labeling

The personal protective equipment requirements must be placed on the end-use product labeling in the location specified in PR Notice 93-7, and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

Other Labeling Requirements

Registrants must specify on labeling the complete directions for use for each use pattern: site of application, type of application, timing of application, equipment used for application, and the rate of application (dosage).

Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing nabam that are intended primarily for occupational use.

Application Restrictions

"Do not apply this product in a way that will contact workers or other persons."

User Safety Requirements

1. Registrant: place the following statement on the end-use product label if coveralls are required for pesticide handlers:

"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."

2. Registrant: place the following statement on the end-use product label:

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

User Safety Recommendations

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

- "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

Skin Sensitizer Statement

"This product may cause skin sensitization reactions in some people."

3. Clarification of Oil Drilling Mud Use

The following statement must be added to the labels for terrestrial non-food oil/gas drilling muds and packer fluids:

"For use in terrestrial wells only."

And the following statement must be added to the precautionary labeling:

"Do not apply in marine and/or estuarine oil fields."

The following statement must be added to the labels for aquatic non-food industrial oil/gas drilling muds and packer fluids:

"For use in offshore wells only."

For use in both terrestrial and offshore oil/gas drilling muds and packer fluids, the following statement must be added:

> "This product may be used for terrestrial and offshore oil/gas drilling muds and packer fluids."

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell nabam products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A REPORT

Case 0641[Nabam] Chemical 014503[Nabam]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps Max. Dose [(AI unless noted otherwise)/A] /crop /year /crop /year cycle		Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES											
FOOD PROCESSING WATER SYSTEMS				Use Group: INDOOR FOOD							
Pesticides added to sugar mill processing water systems to control microorganisms are indirect food additives and therefore fall under FDA jurisdiction.											
Water treatment, Continuous feed (initial), Chemical pump, Not Applicable, Not applicable for this use	SC/L	W 1.494	W 2.988	*	NS	NS	NS	NS	NS	NS	A08, C12
	SC/L	W 1.4985	W 3.0015	*	NS	NS	NS	NS	NS	NS	A08, C12
	SC/L	W 1.4985	W 3.0015	*	NS	NS	NS	NS	NS	NS	C12, C18
	SC/L	W 1.5	W 3	*	NS	NS	NS	NS	NS	NS	A08, C12
Water treatment, Continuous feed (initial), Metering pump, Not Applicable, Not applicable for this use	SC/L	W 1.494	W 2.988	*	NS	NS	NS	NS	NS	NS	A08, C12
	SC/L	W 1.4985	W 3.0015	*	NS	NS	NS	NS	NS	NS	A08, C12
	SC/L	W 1.5	W 3	*	NS	NS	NS	NS	NS	NS	A08, C12
	SC/L	W 1.5	W 3	*	NS	NS	NS	NS	NS	NS	C18, C24
Water treatment, Continuous feed (initial), Not on label, Not Applicable, Not applicable for this use	SC/L	W 1.5	W 3	*	NS	NS	NS	NS	NS	NS	C18, C24
NON-FOOD/NON-FEED											
AIR WASHER WATER SYSTEMS				Use Group: AQUATIC NON-FOOD INDUSTRIAL							
Water treatment (recirculating system), Initial, Not on label, Not Applicable, Not applicable for this use	SC/L	W 18	W 30	*	NS	NS	NS	NS	NS	NS	A08, C12
	SC/L	W 18	W 18	*	NS	NS	NS	NS	NS	NS	A08, C18, C24
	SC/S	W 14	W 48	*	NS	NS	NS	NS	NS	NS	A08, C12

APPENDIX A REPORT

Case 0641[Nabam] Chemical 014503[Nabam]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps Max. Rate /crop /year /crop cycle	Max. Dose [(AI unless noted otherwise)/A] /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
AIR WASHER WATER SYSTEMS (con't)				Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)							
Water treatment (recirculating system), Not on label, Not on label, Not Applicable, Not applicable for this use	sC/L	No Calc	No Calc	* NS	NS	NS	NS	NS	NS		A08, C12
Water treatment (recirculating system), Subsequent/maintenance, Not on label, Not Applicable, Not applicable for this use	SC/L	W 2.9	W 5.9	* NS	NS	NS	NS	NS	NS		A08, C18, C24
	SC/L	W 3	W 6	* NS	NS	NS	NS	NS	NS		A08, C12
	SC/S	W 2.4	W 4.8	* NS	NS	NS	NS	NS	NS		A08, C12
COMMERCIAL/INDUSTRIAL WATER COOLING SYSTEMS				Use Group: AQUATIC NON-FOOD INDUSTRIAL							
Water treatment (once-through system), Not on label, Feed system (eductor), Not Applicable, Not applicable for this use	SC/L	U 1.5	U 1.5	* NS	NS	NS	NS	NS	NS		A08, A10(100), C23
Water treatment (once-through system), Not on label, Feed system (gravity), Not Applicable, Not applicable for this use	SC/L	U 1.5	U 1.5	* NS	NS	NS	NS	NS	NS		A08, A10(100), C23
Water treatment (recirculating system), Initial, Not on label, Not Applicable, Not applicable for this use	SC/L	W 16	W 16	* NS	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 17	W 17	* NS	NS	NS	NS	NS	NS		A08, C12
	SC/L	W 18	W 60	* NS	NS	NS	NS	NS	NS		A08, C12
	SC/L	W 18	W 18	* NS	NS	NS	NS	NS	NS		A08, C18, C24
	SC/S	W 14	W 48	* NS	NS	NS	NS	NS	NS		A08, C12
Water treatment (recirculating system), Subsequent/maintenance, Not on label, Not Applicable, Not applicable for this use	SC/L	W 2.7	W 5.3	* NS	NS	NS	NS	NS	NS		A08, C12, C18

APPENDIX A REPORT

Case 0641[Nabam] Chemical 014503[Nabam]

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USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED (con't)												
COMMERCIAL/INDUSTRIAL WATER COOLING SYSTEMS (con't)				Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)								
	SC/L	W 2.8	W 5.6	*	NS	NS	NS	NS	NS	NS		A08, C12
	SC/L	W 2.9	W 5.9	*	NS	NS	NS	NS	NS	NS		A08, C18, C24
	SC/L	W 3	W 6	*	NS	NS	NS	NS	NS	NS		A08, C12
	SC/S	W 2.4	W 4.8	*	NS	NS	NS	NS	NS	NS		A08, C12
EVAPORATIVE CONDENSER WATER SYSTEMS				Use Group: AQUATIC NON-FOOD INDUSTRIAL								
Water treatment (recirculating system), Initial, Not on label, Not Applicable, Not applicable for this use	SC/L	W 16	W 16	*	NS	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 17	W 17	*	NS	NS	NS	NS	NS	NS		A08, C12
	SC/L	W 18	W 60	*	NS	NS	NS	NS	NS	NS		A08, C12
	SC/L	W 18	W 18	*	NS	NS	NS	NS	NS	NS		A08, C18, C24
	SC/S	W 14	W 48	*	NS	NS	NS	NS	NS	NS		A08, C12
Water treatment (recirculating system), Subsequent/maintenance, Not on label, Not Applicable, Not applicable for this use	SC/L	W 2.7	W 5.3	*	NS	NS	NS	NS	NS	NS		A08, C12, C18
	SC/L	W 2.8	W 5.6	*	NS	NS	NS	NS	NS	NS		A08, C12
	SC/L	W 2.9	W 5.9	*	NS	NS	NS	NS	NS	NS		A08, C18, C24
	SC/L	W 3	W 6	*	NS	NS	NS	NS	NS	NS		A08, C12
	SC/S	W 2.4	W 4.8	*	NS	NS	NS	NS	NS	NS		A08, C12
FUELS/OIL STORAGE TANK BOTTOM WATER ADDITIVE				Use Group: INDOOR NON-FOOD								

APPENDIX A REPORT

Case 0641[Nabam] Chemical 014503[Nabam]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
FUELS/OIL STORAGE TANK BOTTOM WATER ADDITIVE (con't)			Use Group: INDOOR NON-FOOD (con't)								
Additive treatment, Initial, Not on label, Not Applicable, Not applicable for this use	SC/L	V 43	V 43	*	NS NS	NS NS	NS	NS			C12
Additive treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	V 43	V 43	*	NS NS	NS NS	NS	NS	CA		C12
Additive treatment, Subsequent/maintenance, Not on label, Not Applicable, Not applicable for this use	SC/L	No Calc	No Calc	*	NS NS	NS NS	NS	NS			C12
OIL RECOVERY DRILLING MUDS/PACKER FLUIDS			Use Group: AQUATIC NON-FOOD INDUSTRIAL								
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	V 12	V 66	*	NS NS	NS NS	NS	NS			C12
	SC/L	V 36	V 179	*	NS NS	NS NS	NS	NS			C12
	SC/L	V 37	V 150	*	NS NS	NS NS	NS	NS			C12
	SC/L	V 40	V 198	*	NS NS	NS NS	NS	NS			C12
	SC/L	V 40	V 199	*	NS NS	NS NS	NS	NS			C12, C18
	SC/L	V 210	V 210	*	NS NS	NS NS	NS	NS			C12, C18
	SC/S	No Calc	No Calc	*	NS NS	NS NS	NS	NS			C12
	SC/S	U 24	U 120	*	NS NS	NS NS	NS	NS			C12
	SC/S	W 13	W 64	*	NS NS	NS NS	NS	NS			C12
			Use Group: INDOOR NON-FOOD								

APPENDIX A REPORT

Case 0641[Nabam] Chemical 014503[Nabam]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
OIL RECOVERY DRILLING MUDS/PACKER FLUIDS (con't)				Use Group: INDOOR NON-FOOD (con't)									
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	V 12	V 66	*	NS	NS	NS	NS	NS	NS			C12
	SC/L	V 36	V 179	*	NS	NS	NS	NS	NS	NS			C12
	SC/L	V 37	V 150	*	NS	NS	NS	NS	NS	NS			C12
	SC/L	V 40	V 198	*	NS	NS	NS	NS	NS	NS			C12
	SC/L	V 40	V 199	*	NS	NS	NS	NS	NS	NS			C12, C18
	SC/L	V 210	V 210	*	NS	NS	NS	NS	NS	NS			C12, C18
	SC/S	No Calc	No Calc	*	NS	NS	NS	NS	NS	NS			C12
	SC/S	U 24	U 120	*	NS	NS	NS	NS	NS	NS			C12
	SC/S	W 13	W 64	*	NS	NS	NS	NS	NS	NS			C12
				Use Group: TERRESTRIAL NON-FOOD CROP									
Preservative treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/L	V 12	V 66	*	NS	NS	NS	NS	NS	NS			C12
	SC/L	V 36	V 179	*	NS	NS	NS	NS	NS	NS			C12
	SC/L	V 37	V 150	*	NS	NS	NS	NS	NS	NS			C12
	SC/L	V 40	V 198	*	NS	NS	NS	NS	NS	NS			C12
	SC/L	V 40	V 199	*	NS	NS	NS	NS	NS	NS			C12, C18
	SC/L	V 210	V 210	*	NS	NS	NS	NS	NS	NS			C12, C18
	SC/S	No Calc	No Calc	*	NS	NS	NS	NS	NS	NS			C12

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Case 0641[Nabam] Chemical 014503[Nabam]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
OIL RECOVERY DRILLING MUDS/PACKER FLUIDS (con't)			Use Group: TERRESTRIAL NON-FOOD CROP (con't)										
	SC/S	U 24	U 120	*	NS	NS	NS	NS	NS	NS			C12
	SC/S	W 13	W 64	*	NS	NS	NS	NS	NS	NS			C12
PASTEURIZER/WARMER/CANNERY COOLING WATER SYSTEMS			Use Group: INDOOR NON-FOOD										
Water treatment (recirculating system), Initial, Not on label, Not Applicable, Not applicable for this use	SC/S	W 14	W 48	*	NS	NS	NS	NS	NS	NS	CA		A08, C12
Water treatment (recirculating system), Subsequent/maintenance, Not on label, Not Applicable, Not applicable for this use	SC/S	W 2.4	W 4.8	*	NS	NS	NS	NS	NS	NS	CA		A08, C12
PULP/PAPER MILL WATER SYSTEMS			Use Group: AQUATIC NON-FOOD INDUSTRIAL										
Water treatment, Continuous feed (initial), Not on label, Not Applicable, Not applicable for this use	SC/L	W 34	W 114	*	NS	NS	NS	NS	NS	NS			A08, C12, C18
Water treatment, Continuous feed (subsequent), Not on label, Not Applicable, Not applicable for this use	SC/L	W 34	W 114	*	NS	NS	NS	NS	NS	NS			A08, C12, C18
Water treatment, Intermittent feed (initial), Not on label, Not Applicable, Not applicable for this use	SC/L	W 102	W 170	*	NS	NS	NS	NS	NS	NS			A08, A11(2), C12, C18
Water treatment, Intermittent feed (subsequent), Not on label, Not Applicable, Not applicable for this use	SC/L	W 102	W 170	*	NS	NS	NS	NS	NS	NS			A08, A11(2), C12, C18
Water treatment, Not on label, Chemical pump, Not Applicable, Not applicable for this use	SC/L	W 7.2	W 150	*	NS	NS	NS	NS	NS	NS			C12
	SC/L	W 7.4	W 150	*	NS	NS	NS	NS	NS	NS			C12

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Case 0641[Nabam] Chemical 014503[Nabam]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	@ Max. Rate	# Apps /crop cycle	# Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	Max. Dose [(AI unless noted otherwise)/A] /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION														
NON-FOOD/NON-FEED (con't)														
PULP/PAPER MILL WATER SYSTEMS (con't)			Use Group: AQUATIC NON-FOOD INDUSTRIAL (con't)											
	SC/L	W 7.5	W 150	*	NS	NS	NS	NS	NS	NS				C12
	SC/L	W 7.5	W 150	*	NS	NS	NS	NS	NS	NS				C18, C24
Water treatment, Not on label, Not on label, Not Applicable, Not applicable for this use	SC/S	W 8	W 150	*	NS	NS	NS	NS	NS	NS		CA		C12
SECONDARY OIL RECOVERY INJECTION WATER			Use Group: AQUATIC NON-FOOD INDUSTRIAL											
Water treatment, Intermittent (slug)(initial), Not on label, Not Applicable, Not applicable for this use	SC/L	W 145	W 145	*	NS	NS	NS	NS	NS	NS				C12, C18
Water treatment, Intermittent (slug)(subsequent), Not on label, Not Applicable, Not applicable for this use	SC/L	W 30	W 30	*	NS	NS	NS	NS	NS	NS				C12, C18
Water treatment, Not on label, Injection equipment, Not Applicable, Not applicable for this use	SC/L	W 4.9	W 73	*	NS	NS	NS	NS	NS	NS				C12
	SC/L	W 5.1	W 81	*	NS	NS	NS	NS	NS	NS				C12
	SC/L	W 5.2	W 76	*	NS	NS	NS	NS	NS	NS				C12
	SC/L	W 6.3	W 76	*	NS	NS	NS	NS	NS	NS				C12
	SC/S	W 3.4	W 76	*	NS	NS	NS	NS	NS	NS				C12
Water treatment, Shock/slug, Not on label, Not Applicable, Not applicable for this use	SC/L	W 145	W 145	*	NS	NS	NS	NS	NS	NS				C12, C18
SPECIALITY INDUSTRIAL PRODUCTS			Use Group: INDOOR NON-FOOD											
Preservative treatment, Not on label, Metering pump, Not Applicable, Not applicable for this use	SC/L	W 7.5	W 75	*	NS	NS	NS	NS	NS	NS		CA		C12

APPENDIX A REPORT

Case 0641[Nabam] Chemical 014503[Nabam]

LEGEND

Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate, Maximum Number of Applications at Maximum Rate, Maximum Dose per Crop Cycle or per Year, Minimum Interval Between Applications (Days), Restricted Entry Interval (Days), Allowed/Disallowed Geographical Areas, Use Limitations Codes.

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	: Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise)	: Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose	: Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate	: Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A]	: Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days)	: Minimum Interval between Applications (days)
Restr. Entry Interv (days)	: Restricted Entry Interval (days)
PRD Report Date	: LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

*	: Non-specific
C	: Coarse
M	: Medium
F	: Fine
O	: Others

FORMULATION CODES

SC/L	: SOLUBLE CONCENTRATE/LIQUID
SC/S	: SOLUBLE CONCENTRATE/SOLID

ABBREVIATIONS

AN	: As Needed
NA	: Not Applicable
NS	: Not Specified (on label)
UC	: Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE

DCNC	: Dosage Can Not be Calculated
No Calc	: No Calculation can be made
W	: PPM calculated by weight
V	: PPM Calculated by volume
U	: Unknown whether PPM is given by weight or by volume
cwt	: Hundred Weight
nnE-xx	: nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

APPENDIX A REPORT

Case 0641[Nabam] Chemical 014503[Nabam]

USE LIMITATIONS CODES
A08 : Preclean claim.
A10 : __ minute(s) contact time.
A11 : __ hour(s) contact time.
C12 : Do not apply in marine and/or estuarine, oil fields, or discharge effluent into lakes, streams, ponds or public water. (NPDES license restriction)
C18 : Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority (POTW).
C23 : NPDES license restriction.
C24 : Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water. (NPDES license restriction)
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES
CA : California

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case nabam covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to nabam in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Nabam

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
	Registrant: Vinings Industries **Product: EPA Reg. No. 9386-7, 9386-11 and 9386-23.**		
61-1	**Chemical Identity**	ALL	N/A
61-2A	**Start. Mat. & Mnfg. Process**	ALL	00155163
61-2B	**Formation of Impurities**	ALL	43183301, 43241301, **Upgradable**
62-1	**Preliminary Analysis**	ALL	43183301, 43183302
62-2	**Certification of limits**	ALL	N/A
62-3	**Analytical Method**	ALL	N/A
63-2	**Color**	ALL	00155163
63-3	**Physical State**	ALL	00155163
63-4	**Odor**	ALL	00155163
63-5	**Melting Point**	ALL	42163002
63-6	**Boiling Point**	ALL	00155163
63-7	**Density**	ALL	N/A
63-8	**Solubility**	ALL	00155163
63-9	**Vapor Pressure**	ALL	N/A
63-10	**Dissociation Constant**	ALL	42163002
63-11	**Octanol/Water Partition**	ALL	00155163

Data Supporting Guideline Requirements for the Reregistration of Nabam

REQUIREMENT		USE PATTERN	CITATION(S)
63-12	**pH**	ALL	00155163
63-13	**Stability**	ALL	**Upgradable**
63-14	**Oxidizing/Reducing Action**	ALL	N/A
63-15	**Flammability**	ALL	N/A
63-16	**Explodability**	ALL	N/A
63-17	**Storage stability**	ALL	N/A
63-18	**Viscosity**	ALL	N/A
63-19	**Miscibility**	ALL	N/A
63-20	**Corrosion characteristics**	ALL	N/A

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Nabam

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
	Registrant: Alco Chemical Division of National Starch and Chemical Co Product: EPA Reg. No. 31910-7		
61-1	**Chemical Identity**	ALL	**Upgradable**
61-2A	**Start. Mat. & Mnfg. Process**	ALL	Database[1]
61-2B	**Formation of Impurities**	ALL	Database[1]
62-1	**Preliminary Analysis**	ALL	42163003, 43212401
62-2	**Certification of limits**	ALL	**Upgradable**
62-3	**Analytical Method**	ALL	**Upgradable**
63-2	**Color**	ALL	Database[1]
63-3	**Physical State**	ALL	Database[1]
63-4	**Odor**	ALL	Database[1]
63-5	**Melting Point**	ALL	42163002
63-6	**Boiling Point**	ALL	Database[1]
63-7	**Density**	ALL	N/A
63-8	**Solubility**	ALL	Database[1]
63-9	**Vapor Pressure**	ALL	N/A
63-10	**Dissociation Constant**	ALL	42163002
63-11	**Octanol/Water Partition**	ALL	Database[1]

Data Supporting Guideline Requirements for the Reregistration of Nabam

REQUIREMENT		USE PATTERN	CITATION(S)
63-12	**pH**	ALL	Database[1]
63-13	**Stability**	ALL	**Upgradable**
63-14	**Oxidizing/Reducing Action**	ALL	**Upgradable**
63-15	**Flammability**	ALL	N/A
63-16	**Explodability**	ALL	N/A
63-17	**Storage stability**	ALL	**Upgradable**
63-18	**Viscosity**	ALL	Database[1]
63-19	**Miscibility**	ALL	N/A
63-20	**Corrosion characteristics**	ALL	Database[1]
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	CFLM	00159771
71-1B	**Acute Avian Oral - Quail/Duck TEP**		Not Required
71-2A	**Avian Dietary - Quail**	CFLM	00022923
71-2B	**Avian Dietary - Duck**	C[2]	00022923
71-3	**Wild Mammal Toxicity**		Not Required
71-4A	**Avian Reproduction - Quail**		Not Required
71-4B	**Avian Reproduction - Duck**		Not Required
71-5A	**Simulated Field Study**		Not Required
71-5B	**Actual Field Study**		Not Required
72-1A	**Fish Toxicity Bluegill**	C[2]	00157611

Data Supporting Guideline Requirements for the Reregistration of Nabam

REQUIREMENT		USE PATTERN	CITATION(S)
72-1B	**Fish Toxicity Bluegill - TEP**	[CF]^3	00157611, 00104057
72-1C	**Fish Toxicity Rainbow Trout**	CFLM	00157611
72-1D	**Fish Toxicity Rainbow Trout-TEP**	[CF]^3	00157611, 00104057
72-2A	**Invertebrate Toxicity**	CFLM	00157611
72-2B	**Invertebrate Toxicity - TEP**	$[CF]_3$	00157611
72-3A	**Estuarine/Marine Toxicity - Fish**	F^4	40961601
72-3B	**Estuarine/Marine Toxicity - Mollusk**	F^4	40966801
72-3C	**Estuarine/Marine Toxicity - Shrimp**	F^4	00107905, 40966701
72-3D	**Estuarine/Marine Toxicity Fish-TEP**	F^3	40961601, 00107906
72-3E	**Estuarine/Marine Toxicity Mollusk - TEP**	F^3	40966801, 00097064
72-3F	**Estuarine/Marine Toxicity Shrimp - TEP**	F^3	00097064, 40966701, 00107905
72-4A	**Early Life Stage Fish**		Not Requried
72-4B	**Life Cycle Invertebrate**		Not Required
72-5	**Life Cycle Fish**		Not Requried
72-6	**Aquatic Organism Accumulation**		Not Required
72-7A	**Simulated Field - Aquatic Organisms**		Not Required
72-7B	**Actual Field - Aquatic Organisms**		Not Required

Data Supporting Guideline Requirements for the Reregistration of Nabam

REQUIREMENT		USE PATTERN	CITATION(S)
122-1A	**Seed Germination/Seedling Emergence**		Not Required
122-1B	**Vegetative Vigor**		Not Required
122-2	**Aquatic Plant Growth**		Not Required
123-1A	**Seed Germination/Seedling Emergence**		Not Required
123-1B	**Vegetative Vigor**		Not Required
123-2	**Aquatic Plant Growth**		Not Required
124-1	**Terrestrial Field**		Not Required
124-2	**Aquatic Field**		Not Required
141-1	**Honey Bee Acute Contact**	C[2]	00036935
141-2	**Honey Bee Residue on Foliage**		Not Required
141-5	**Field Test for Pollinators**		Not Required
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	CFLM	00121050, 00097093
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	CFLM	00159774
81-3	**Acute Inhalation Toxicity - Rat**	CFLM	00159770, **Upgradable**
81-4	**Primary Eye Irritation - Rabbit**	CFLM	00159775
81-5	**Primary Dermal Irritation - Rabbit**	CFLM	00159776, 40024201
81-6	**Dermal Sensitization - Guinea Pig**	CFLM	00121050

Data Supporting Guideline Requirements for the Reregistration of Nabam

REQUIREMENT		USE PATTERN	CITATION(S)
81-7	**Acute Delayed Neurotoxicity - Hen**		Not Required
82-1A	**90-Day Feeding - Rodent**	CFLM	42791601, 42378801, 42751601
82-1B	**90-Day Feeding - Non-rodent**		Waived
82-2	**21-Day Dermal - Rabbit/Rat**	CFLM	42791602
82-3	**90-Day Dermal - Rodent**	CFLM	Reserved
82-4	**90-Day Inhalation - Rat**	CFLM	Reserved
82-5A	**90-Day Neurotoxicity - Hen**		N/A
82-5B	**90-Day Neurotoxicity - Mammal**	CFLM	42751601
83-1A	**Chronic Feeding Toxicity - Rodent**	CFLM	Waived
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	CFLM	Waived
83-2A	**Oncogenicity - Rat**	CFLM	Waived
83-2B	**Oncogenicity - Mouse**	CFLM	Waived
83-3A	**Developmental Toxicity - Rat**	CFLM	41935001, 40733101, Wavied
83-3B	**Developmental Toxicity - Rabbit**	CFLM	40873301, 42437701
83-4	**2-Generation Reproduction - Rat**	CFLM	Waived
84-2A	**Gene Mutation (Ames Test)**	CFLM	00153559, 00152701, 00152702,
84-2B	**Structural Chromosomal Aberration**	CFLM	00152700, 00152699, 00160516, 00151954, 41089901, 41177201,
84-4	**Other Genotoxic Effects**	CFLM	00151955, 00151954, 41174601, 00160517, 42303601, 41221201

Data Supporting Guideline Requirements for the Reregistration of Nabam

REQUIREMENT		USE PATTERN	CITATION(S)
85-1	**General Metabolism**	CFLM	00160125, 00161804
85-2	**Dermal Penetration**	CFLM	40317901, 00156613
86-1	**Domestic Animal Safety**		Not Required
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	**Foliar Residue Dissipation**	C	**Waived**
132-1B	**Soil Residue Dissipation**	C	**Waived**
133-3	**Dermal Passive Dosimetry Exposure**		**Not Required**
133-4	**Inhalation Passive Dosimetry Exposure**		**Not Required**
231	**Estimation of Dermal Exposure at Outdoor Sites**		**Not Required**
232	**Estimation of Inhalation Exposure at Outdoor Sites**		**Not Required**
233	**Estimation of Dermal Exposure at Indoor Sites**		**Not Required**
234	**Estimation of Inhalation Exposure at Indoor Sites**		**Not Required**
ENVIRONMENTAL FATE			
160-5	**Chemical Identity**		Not Required
161-1	**Hydrolysis**	CF	00165028, 40466103, 40535201
161-2	**Photodegradation - Water**	CF	00165028, 40535201
161-3	**Photodegradation - Soil**	C	40466101

Data Supporting Guideline Requirements for the Reregistration of Nabam

REQUIREMENT		USE PATTERN	CITATION(S)
161-4	**Photodegradation - Air**		Not Required
162-1	**Aerobic Soil Metabolism**	C	Waived
162-2	**Anaerobic Soil Metabolism**	C	Waived
162-3	**Anaerobic Aquatic Metabolism**	CF	Waived
162-4	**Aerobic Aquatic Metabolism**	CF	Waived
163-1	**Leaching/Adsorption/Desorption**	CF	Waived
163-2	**Volatility - Lab**		Not Required
163-3	**Volatility - Field**		Not Required
164-1	**Terrestrial Field Dissipation**	C	Waived
164-2	**Aquatic Field Dissipation**		Not Required
164-3	**Forest Field Dissipation**		Not Required
164-5	**Long Term Soil Dissipation**		Not Required
165-1	**Confined Rotational Crop**	C	Waived
165-2	**Field Rotational Crop**		Not Required
165-3	**Accumulation - Irrigated Crop**		Not Required
165-4	**Bioaccumulation in Fish**	CF	Waived
165-5	**Bioaccumulation - Aquatic NonTarget**		Not Required
166-1	**Ground Water - Small Prospective**		Not Required
166-2	**Ground Water - Small Retrospective**		Not Required

Data Supporting Guideline Requirements for the Reregistration of Nabam

REQUIREMENT		USE PATTERN	CITATION(S)
166-3	**Ground Water - Irrigated Retrospective**		Not Required
201-1	**Droplet Size Spectrum**		Not Required
202-1	**Drift Field Evaluation**		Not Required
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	L	00088825, 00088826, 00088833, 00097231, 00088921, Waived
171-4B	**Nature of Residue - Livestock**	L	00088831, 00088834, 00088835, Waived
171-4C	**Residue Analytical Method - Plants**	L	00088826, 00097051, 00041704, 40065801, 00088891, 00088826, 00159693, 40118601, 40065803, 40065802, Waived
171-4D	**Residue Analytical Method - Animal**	L	Waived
171-4E	**Storage Stability**	L	Waived
171-4F	**Magnitude of Residues - Potable H2O**		Not Required
171-4G	**Magnitude of Residues in Fish**		Not Required
171-4H	**Magnitude of Residues - Irrigated Crop**		Not Required
171-4I	**Magnitude of Residues - Food Handling**		Not Required
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	L	Waived
171-4K	**Crop Field Trials**		Waived

Data Supporting Guideline Requirements for the Reregistration of Nabam

REQUIREMENT		USE PATTERN	CITATION(S)
171-4L	**Processed Food**	L	Waived
171-5	**Reduction of Residues**		Not Required
171-6	**Proposed Tolerance**		Not Required
171-7	**Support for Tolerance**		Not Required
171-13	**Analtyical Reference Standard**		Not Required

[1] The product chemistry "database" includes data reviewed in the Reregistration Standard in addition to the following studies which were reviewed in the Reregistration Standard addendum #2 dated 12/3/86 or were submitted in response to the Reregistration Standard and the Guidance Document: 1986-1988; MRIDs 00158666, 00159387, 00161339, 00162198 through 00162204, 00162208 through 00162210, 00162237, 00162311 through 00162319, 00162400, 00162401, 40441601, and 40957301.

[2] Not required to support the oil recovery drilling muds/packer fluids use pattern.

[3] Presently not required to support any existing use.

[4] Required to support the following uses: oil recovery drilling muds/packer fluids and pulp and paper mill water systems.

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

   c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

BIBLIOGRAPHY

MRID	CITATION
00001503	Waggoner, P.E. (1956) Chemical treatment of potato seed in Connecticut 1955. Plant Disease Reporter 40(5):411-413. (Also In unpublished submission received Jan 15, 1957 under 400-11; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:003230-E)
00001545	Borders, H.I., (1953?) Downy Mildew (Peronospora parasitica): Cabbage Crop Test. (Unpublished study received Feb 2, 1954 under 279-835; prepared by Georgia Agricultural Experiment Station, submitted by FMC Corp., Philadelphia, Pa.; CDL: 002272-B)
00003679	FMC Corporation (1964) 1964 New York State Insecticide and Fungicide Recommendations. (p. V15 only; unpublished study received Jul 9, 1965 under 279-1182; CDL:008883-C)
00004985	Wells, H.D.; Gay, ?; Littrell, ? (1969?) Efficacy Data of Demonsan on Crops. (Unpublished study including letter dated May 23, 1969 from H.D. Wells to Bob Miller, received Jul 23, 1969 under 352-344; prepared by U.S. Agricultural Research Service, Crops Research Div., Georgia Coastal Plain Experiment Station, submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL: 003046-M)
00011559	Richardson, L.T. (19??) The persistence of Thiram in soil and its relationship to the microbiological balance and damping-off control. Canadian Journal of Botany 32(?):335-346. (Also In unpublished submission received Sep 26, 1972 under 1023-15; submitted by Upjohn Co., Kalamazoo, Mich.; CDL:024388-B)
00011566	Couch, H.B.; Cole, H., Jr. (1956) Five compounds tested for control of Merion bluegrass rust. Plant Disease Reporter 40(2):103-105. (Also In unpublished submission received Mar 6, 1958 under 1023-10; submitted by Upjohn Co., Kalamazoo, Mich.; CDL: 024377-B)
00011568	Couch, H.B. (1955) 1955 Merion Bluegrass Rust Fungicide Trials. (Unpublished study including letter dated Nov 2, 1955 from H.B. Couch to William J. Klomparens, received Mar 6, 1958 under 102310; prepared by Pennsylvania State Univ., Dept. of Botany and Plant Pathology, submitted by Upjohn Co., Kalamazoo, Mich.; CDL: 024377-E)
00011574	Swartwout, H.G. (1951) 1951--Strawberry Leaf Spot and Leaf Scorch Control. (Unpublished study including letter dated Mar 25, 1952 from H.G. Swartwout to Jared H. Ford, received Oct 15, 1953 under 1023-9; prepared by Univ. of Missouri, Dept. of Horticulture, submitted by Upjohn Co., Kalamazoo, Mich.; CDL:005440-H)

BIBLIOGRAPHY

MRID	CITATION
00012840	Weiss, F.A. (1959) Summary of Tests of Acti-Dione and Acti-Dione RZ for Control of Azalea Petal Blight (Ovulinia azaleae). (Unpublished study including letter dated May 22, 1959 from C.N. Hastie, Jr. to George Swank, received Aug 20, 1959 under 102310; prepared by Magnolia Gardens and Nurseries, submitted by Upjohn Co., Kalamazoo, Mich.; CDL:024382-G)
00013810	Andison, H. (1961) Control of blister mite on holly. Insecticide Newsletter 10(7):261-262. (Also In unpublished submission received Mar 1, 1962 under 201-EX-16; submitted by Shell Chemical Co., Washington, D.C.; CDL:122685-M)
00013926	Talmadge, J. (1962) Bidrin Insecticide Field Scale Test Data. (Unpublished study received Jan 28, 1966 under 201-142; submitted by Shell Chemical Co., Washington, D.C.; CDL:000833-AK)
00019691	Betz Entec, Incorporated (19??) Betz Entec 346: Efficacy Data. (Unpublished study received Apr 23, 1975 under 34571-7; CDL: 240034-A)
00022926	McClure, T.T. (1951) Experiences with cherry sprays in 1951. Phytopathology 42(?):14. (Abstract; also In unpublished submission received Dec 2, 1976 under 1023-50; submitted by Upjohn Co., Kalamazoo, Mich.; CDL:095620-K)
00024918	McLeod, H.A.; McCully, K.A. (1969) Head space gas procedure for screening food samples for Dithiocarbamate pesticide residues. Journal of the Association of Official Analytical Chemists 52(6):1226-1230. (Also In unpublished submission received Oct 18, 1979 under 400-112; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:241184-B)
00025590	Sterner, P.W. (1971) Use of XD-7287L (Slimicide) in Paper Mills: DP-313. (Unpublished study received Jun 11, 1974 under 464-426; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:241465-J)
00025816	Davis, H.C.; Hidu, H. (19??) Effects of pesticides on embryonic development of Clams and Oysters and on survival and growth of the Larvae. Fishery Bulletin 67(2):393-400,403. (Also In unpublished submission received Jan 2, 1980 under 2217-485; submitted by PBI-Gordon Corp., Kansas City, Kans.; CDL:241581-W)

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MRID	CITATION
00030082	Chase, C. (1979) API Bacteriostatic Testing on an Antimicrobial Agent for Vinings Chemical Company: Project No. 069-07-199. (Unpublished study including published data, received Mar 20, 1980 under 9386-7; prepared by Weintritt Testing Laboratories in cooperation with American Petroleum Institute, submitted by Vining Chemical Co., Atlanta, Ga.; CDL:242250-A)
00031110	Miller, P.M. (1956) Control of black root rot of strawberries with nematocide-fungicide combinations. Plant Disease Reporter 40(1):45-47. (Also In unpublished submission received Feb 6, 1961 under 464-186; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:003459-AB)
00031558	Mogul Corporation (1978) Laboratory Study: Pilot Plant Study: Field Trials. (Unpublished study received Mar 25, 1980 under 8591-EX2; CDL:242184-B)
00034382	Heuberger, J.W.; Wilson, J.D.; Partyka, R.E.; et al. (1953) Efficacy Study Using Potatoes, Tomatoes and Celery. (Unpublished study received Feb 11, 1954 under 279-837; prepared in cooperation with Univ. of Delaware, Agricultural Experiment Station, Dept. of Botony and others, submitted by FMC Corp., Philadelphia, Pa.; CDL:002274-A)
00041704	Clarke, D.G.; Baum, H.; Stanley, E.L.; et al. (1951) Determination of dithiocarbamates. Analytical Chemistry 23(12):1842-1846. (Also In unpublished submission received Apr 3, 1972 under 2F1258; submitted by Rohm & Haas Co., Philadelphia, Pa., CDL: 095544-F)
00041801	Krister, C.J.; Wilson, C.E., Jr. (1952) Residues of Dithiocarbamate fungicides--on food crops. Agricultural Chemicals 7(9): 45-48. (Also In unpublished submission received Jun 15, 1955 under PP0021; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:090020-F)
00044028	Nash Chemical Company (1953?) Kaybam Data. (Unpublished study received Nov 17, 1964 under unknown admin. no.; submitted by ?; CDL:104252-A)
00047527	Aqua-Treat Chemicals, Incorporated (19??) Water Cooling Tower Application. Houston, Tex.: Aqua-Treat. (Also In unpublished submission received on unknown date under unknown admin. no.; CDL:227869-A)
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-96).

This Notice is divided into six sections and six Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Compensation Forms, and Confidential Statement of Formula

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment 2). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not

submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other

registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, as appropriate.

III-D REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

    a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;

    b. fulfill the commitment to develop and submit the data as required by this Notice; or

c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and

use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment 2 and Attachment 3 for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Compensation Forms and the Confidential Statement of Formula Form

NABAM DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing nabam.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of nabam. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this nabam Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for nabam are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on nabam are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible nabam products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Jean Holmes at (703) 308-8008.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Jean Holmes
Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **nabam**

INSTRUCTIONS FOR COMPLETING THE **DATA CALL-IN RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

Item 7a. For each **manufacturing use product** (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**."

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**." If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

INSTRUCTIONS FOR COMPLETING THE **REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9. **Enter <u>only one</u> of the following response codes <u>for each data requirement</u> to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and

only if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed **"Certification of Offer to Cost Share in the Development Data" form**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or

Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you

have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

EPA'S BATCHING OF NABAM PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient Nabam, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decidewhether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the

choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

One product in this group of chemicals, 31910-7, has only one active ingredient, Nabam. This product was used to provide the data used in the Acute Toxicity section of the Science Assessment: III(B)(1)(a). As can also be seen from this section, the acute toxicity data is incomplete, missing a valid inhalation toxicity study. To complete re-registration of this product the missing data is required.

The remainder of products in the category have two actives, Nabam and sodium dimethyldithiocarbamate, or Dibam, in about equal amounts.

The table below shows five products which were batched together.

BATCH NO.	EPA REG. NO.	% of Nabam	% of Dibam	Formulation
Type 1	9386-7	15.0	16.0	Liquid
	9386-11	15.0	15.0	Liquid
	31910-2	15.0	15.0	Liquid
	31910-12	18.0	18.0	Liquid
	56473-3	15.0	15.0	Liquid

The table below shows products which were not batched because of significant differences in active concentrations and inert ingredients.

EPA REG. NO.	% of Nabam	% of Dibam	Formulation Type
9386-23	4.5	4.5	Liquid
31910-11	4.5	4.5	Liquid
31910-16	12.5	12.5	Liquid
31910-18	12.5	12.5	Liquid
31910-20	40	40	Liquid

In the table above, the product with the greatest percentage of Nabam and Dibam is 31910-20. Because EPA does not wish for excess duplicative tests to be performed, the following testing scheme is suggested:

> Do complete acute toxicity testing on 31910-20. At this point it may be possible to bridge to Batch 1 and/or 9386-23. If bridging is not possible, a complete test battery on one product from Batch 1 will be necessary, and with this, it may be possibe to bridge this to 9386-23.

At this point acute oral toxicity tests will need to be performed on 31910-11 and 31910-18 with the possibility of bridging to 31910-16.

ATTENTION CRM::: PLEASE NOTE:::
REMOVE THIS PAGE AND INSERT THE LIST OF REGISTRANTS RECEIVING THIS DCI

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation
16. Typed Name of Approving Official				17. Total Weight	100%			

18. Signature of Approving Official	19. Title	20. Phone No. *(Include Area Code)*	21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

EPA	United States Environmental Protection Agency Washington, DC 20460 **CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA**	Form Approved OMB No. 2070-0106 2070-0057 Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
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CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

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Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistratiion under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
Name and Title (Please Type or Print)	

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-96)

The following is a list of available documents for nabam that my further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Jean Holmes at (703)-308-8008.

1. PR Notice 86-5.

2. PR Notice 91-2 (pertains to the Label Ingredient Statement).

3. A full copy of this RED document.

4. A copy of the fact sheet for nabam.

The following documents are part of the Administrative Record for nabam and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1.Health and Environmental Effects Science Chapters.

2.Detailed Label Usage Information System (LUIS) Report.

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.

2. EPA Acceptance Criteria