



R.E.D. FACTS

Nabam

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0641, Nabam.

Use Profile

Nabam is a fungicide/bactericide/algicide used in aquatic nonfood industrial, indoor nonfood, terrestrial nonfood and indoor food use sites. Nabam is currently registered for the control of algae, slime-forming bacteria and slime-forming fungi in the following: 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, fuels/oil storage tank bottom water additive, pasteurizer/warmer/cannery cooling water systems, specialty industrial products (flue gas desulfurization thickeners), and food processing water systems (cane and beet sugar mill processing water - regulated by the Food and Drug Administration (FDA)).

Regulatory History

Nabam was first registered in the United States 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 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.

EPA initiated the first Special Review in 1977 and concluded it in 1982, issuing 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 this 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. EPA does not require data for this food use since it falls under the purview of FDA (see 36 FR 24234 dated 12/22/71).

In the Registration Standard for nabam issued in April 1987 (NTIS #PB88-192745), EPA reported its evaluation of all scientific studies submitted to the Agency as a result of several Data Call-In (DCI) Notices issued between 1983 and 1985. The 1987 Registration Standard also required further data to evaluate the associated environmental and human risks. The nabam RED document reflects a reassessment of all data that were submitted in response to the DCI's and the Registration Standard.

Human Health Toxicity Assessment

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), based on studies which show that it induced an increased incidence of thyroid tumors in rats and liver tumors in mice. An 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.

Dietary Exposure

Dietary exposure to residues of nabam from EPA-regulated uses is not expected.

Occupational and Residential Exposure

The toxicological endpoint 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 are acceptable (greater than 100) for all uses except two. 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 the nabam RED.

Human Risk Assessment

Human risk from dietary exposure was not assessed because nabam has no registered food uses under EPA purview.

Risks to handlers (mixers/loaders/applicators) of nabam and its contaminant ETU are acceptable except for open-pour liquid applications in water cooling systems and open-pour solid applications to drilling muds and packer fluids. To minimize the risks to handlers from these scenarios, EPA is requiring liquid formulations in water cooling systems (e.g. towers) to be applied by mechanical loading delivery systems (such as metering pump, gravity fed, manual pump, pressurized, probe, etc.) and is prohibiting open-pour applications. The Agency is also requiring that dry formulations of nabam be placed in water-soluble packaging. Additionally, since 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, EPA is requiring use of baseline PPE (chemical-resistant gloves) for all nabam end-use product labeling.

Environmental Assessment

Environmental Fate

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 are regulated under the NPDES permitting program of the Agency's Office of Water. Labels for all nabam pesticide products must require that discharges to aquatic environments comply with an NPDES permit.

Ecological Effects

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.

Ecological Effects Risk Assessment

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.

Risk Mitigation

To lessen the risks of nabam to handlers, EPA is requiring the following risk mitigation measures.

- All liquid formulations in water cooling systems (e.g. towers) must be applied by mechanical loading delivery systems (such as metering pump, gravity fed, manual pump, pressurized, probe, etc.).
- Open-pour applications are prohibited.
- Dry formulations of nabam must be marketed in water-soluble packaging.
- Use of baseline PPE (chemical-resistant gloves) is required for all nabam end-use products.

Additional Data Required

EPA is not requiring any additional generic studies for nabam however, several previously required studies still have data deficiencies. These studies are upgradable with the submission of acceptable data. See Appendix B of the Nabam RED for specific data deficiencies.

For the reregistration of nabam products, the Agency is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling.

Product Labeling Changes Required

All nabam end-use products must comply with EPA's current pesticide product labeling requirements, and with the following labeling requirements. For the complete text of labeling changes required, please see the nabam RED document.

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.

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 that the following statements be located on labels of 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 exist 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."

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."

Regulatory Conclusion

The use of currently registered products containing nabam in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Nabam products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for nabam during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet 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*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the nabam RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the nabam RED, or reregistration of individual products containing nabam, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 9:30 am and 7:30 pm Eastern Standard Time, Monday through Friday.