United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-026 January 1996

R.E.D. FACTS

Sodium Omadine

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 years ago 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 imposes any regulatory controls that are needed to effectively manage 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 announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 209, sodium omadine.

Use Profile

Sodium omadine is a broad spectrum antimicrobial compound used as a preservative in certain manufacturing materials and as additive in process fluids which may otherwise be subject to deterioration through bacterial and/or fungal growth. Sodium omadine may be used as a biocide in: aqueous metalworking, cutting, cooling and lubricating fluids; latex emulsions used in adhesives, caulks, patching compounds, sealants, pastes and grouts; latex emulsions; aqueous fiber lubricants and inks; laundry rinse additives and detergents; carpet cleaners and analytical and diagnostic reagents. This RED did not address the use of sodium omadine as an in can preservative of water based chemical or mineral add mixtures used in concrete preparation, registered by the Agency on March 23, 1995. Currently there are 5 registered products that contain from 3.6 to 40 percent sodium omadine. All of these end-use products are formulated as liquid soluble concentrates. There are no registered food uses.

Regulatory History

Sodium omadine was first registered in the United States in 1968 for use as a biocide. The Registration Standard on sodium omadine (NTIS # PB86-173929) was issued in July 1985, and required submission of product chemistry, toxicology, ecotoxicity and environmental fate data. The 1987 Antimicrobial Data Call-In (DCI) required the submission of a variety of subchronic and chronic toxicology and occupational exposure studies.

Human Health Assessment

Toxicity

Sodium omadine caused slight erythema and edema in a dermal irritation study using rabbits. Sodium omadine was found to be moderately toxic by the dermal route (Toxicity Category II), slightly toxic by the oral and inhalation routes (Toxicity Category III) and did not cause skin sensitization in animals studies.

In a 90-day rat dermal toxicity study, there was no evidence of dose-related dermal irritation. Dose related clinical signs seen in females included emaciation, hunched posture, stiff hindlimbs, incoordination and tremors. In a subchronic oral toxicity/neurotoxicity study, high dose rats exhibited treatment related neurotoxic signs.

In a chronic toxicity study, clinical signs of toxicity noted in monkeys administered sodium omadine by gavage included prostration, decreased activity, emesis, thinness, weakness and cold extremities. Slight hematologic changes were observed and were considered of minor toxicologic importance.

In a rat oral carcinogenicity study, an increase in neoplasms was not observed at any site. In a mouse dermal carcinogenicity study, application of sodium omadine did not induce any benign or malignant neoplasms. Although this study was found to be inadequate because the chemical was not tested at a sufficiently high dose level, the Agency concluded that a new study will not be required as long as the use patterns do not dramatically change and the potential for human exposure remains low. Sodium omadine has been classified as a Group D carcinogen based on the insufficient weight of evidence regarding its cancer-causing potential.

In a developmental toxicity study in rabbits, there was no evidence of maternal or fetal toxicity at any dose. In a two-generation reproduction study, rats showed parental (skeletal muscle atrophy and decreased body weight) and reproductive effects (slightly decreased number of pups per litter, delayed development, decreased pup body weight and weight gain). Sodium omadine was negative in three mutagenicity studies. Metabolism studies indicated that it was rapidly absorbed, metabolized, and excreted at all dosing levels tested.

Dietary Exposure

No dietary exposure is expected from the pesticide uses of sodium omadine since no food or feed uses are registered.

Occupational and Residential Exposure

Based on current use patterns, handlers may be exposed to sodium omadine through dermal or inhalation routes from pouring and pumping of sodium omadine in metal working fluids.

EPA has conducted exposure and risk assessments for workers exposed to sodium omadine during pouring and pumping operations and finds that margins of exposure (MOEs) for workers are greater than 100. Thus, minimal risks are posed to workers during the pouring and pumping of liquids that contain sodium omadine. The Agency has not evaluated occupational risk to machinists because these worker's exposure is regulated by the Occupational Safety Administration (OSHA). Available information indicates that the amount of active ingredient (0.005 to 0.5%) present in the oil used by machinists would most likely be even lower than the amount to which handlers would be exposed. Therefore, exposure to sodium omadine treated fluids would represent a lesser hazard to the machinist than to handlers involved in pumping and pouring operations.

Sodium omadine is not registered for homeowner uses; therefore, risk characterization of residential exposure is not required. The Agency, however, believes that the amount of sodium omadine in products that may enter the home or occupational setting such as laundry rinse additives, detergents, carpet cleaners, emulsions and jet printer inks would be very low due to dilution. For this reason, health risks to consumers from exposure to products containing sodium omadine are also expected to be very low.

Human Risk Assessment

Because sodium omadine is slightly to moderately acutely toxic, the Agency is establishing active-ingredient-based minimum (baseline) personal protective equipment (PPE) and engineering control requirements (chemical resistant gloves) for end-use products that are intended primarily for occupational use. All end-use product labels must also require, at a minimum, that applicators and other mixer/loader handlers a wear long-sleeve shirt, long pants and socks plus shoes. If the required eye irritation study indicates that the end-use product is classified as toxicity category I or II for eye irritation potential, protective eyewear is also required.

Environmental Assessment

Environmental Fate

Under normal environmental conditions, the hydrolytic half-life of sodium omadine will likely be 23 days or longer. Photolysis is probably a more important route of dissipation than hydrolysis. Photolytic half-lives of 40-126 minutes have been reported with irradiation by natural sunlight.

Ecological Effects

An acute oral toxicity study shows that sodium omadine is moderately toxic to bobwhite quail. On a subacute dietary basis, sodium omadine has been characterized as slightly toxic to mallard ducks and bobwhite quails. Sodium omadine was found to be very highly toxic to rainbow trout, bluegill sunfish and freshwater invertebrates.

Ecological Effects Risk Assessment

While the hazard to aquatic organisms from exposure to sodium omadine has been characterized, a quantitative risk assessment has not been conducted. The Office of Pesticide Programs has established a policy that risks to aquatic environments from use of biocides such as sodium omadine are best characterized and regulated under the NPDES permitting program of EPA's Office of Water. All sodium omadine products are required to state on their labels that discharges to aquatic environments must comply with an NPDES permit.

Additional Data Required

All generic data requirements have been satisfied for sodium omadine. The Agency is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All sodium omadine end-use products must comply with EPA's current pesticide product labeling requirements, and with the additional requirements summarized below. Please see the RED document for the complete text of these labeling requirements.

Effluent Discharge and Aquatic Hazard Labeling Statements:

"This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public 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."

"This pesticide is a chelating agent and should not be used with other chelating agents or with chlorine."

Worker Protection Labeling Statements

●Minimum (Baseline) PPE/Engineering Control Requirements

For **sole-active-ingredient** end-use products that contain sodium omadine, revise the product labeling to adopt these handler PPE/engineering control requirements and remove any conflicting PPE requirements.

For **multiple-active-ingredient** end-use products, compare these handler PPE/engineering control requirements to those on current labeling and retain the more protective. To determine which requirements are considered more protective, see PR Notice 93-7.

The minimum (baseline) PPE for occupational uses of sodium omadine end-use products is chemical-resistant gloves. (For the glove statement, use the statement established for sodium omadine through the instructions in Supplement Three of PR Notice 93-7). Please note: All end-use product labels must also require, at a minimum, that applicators and other mixer/loader handlers wear a long-sleeve shirt, long pants, and socks plus shoes. If the end-use product is classified as toxicity category I or II for eye irritation potential, protective eyewear is also required.

●Other Labeling Requirements for Occupational Use Products

Application Restrictions

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

User Safety Requirements

"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."

Application Method Timing and Equipment

All labeling must contain instructions stating when (i.e., as needed, during manufacture, etc.) and how (i.e., pour from container, applied through a closed delivery system, etc.) the preservative is added.

Regulatory Conclusion

The use of currently registered products containing sodium omadine in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of sodium omadine registered prior to March 23, 1995, are eligible for reregistration. (Uses registered on or after that date not included in this RED).

Sodium omadine 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 sodium omadine 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 sodium omadine 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 sodium omadine RED, or reregistration of individual products containing sodium omadine, 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 8:00 am and 8:00 pm Eastern Standard Time, Monday through Friday.