



R.E.D. FACTS

Sodium Hydroxide

Pesticide Reregistration

All pesticides sold or used 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 undue hazards to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Document, or RED. This fact sheet summarizes the information in the RED for sodium hydroxide.

Use Profile

Sodium hydroxide is registered for use as a herbicide to control tree roots in sewer systems; as a fungicide and algicide for use on water-well casings; and as a disinfectant in various indoor settings. Also known as caustic soda, this corrosive substance also has many non-pesticidal uses, particularly in the rayon, film and chemical industries.

Regulatory History

Sodium hydroxide first was registered as a pesticide in 1951. Currently, seven products are registered which contain sodium hydroxide, most in combination with other pesticide active ingredients. The Food and Drug Administration (FDA) considers sodium hydroxide generally recognized as safe (GRAS) for use in food.

Under a memorandum of understanding issued in 1971, FDA evaluates the dietary risks of sanitizers used on food contact surfaces while EPA assesses the product chemistry, efficacy and applicator risks. Since sodium hydroxide is included under this agreement, EPA has deferred to FDA's assessment of dietary risks in preparing this RED.

Human Health Assessment**Toxicity**

Sodium hydroxide is a widely used chemical whose toxicity has been well known for some time. It is corrosive and irritating to the skin, eyes and mucous membranes, and has been placed in Toxicity Category I (indicating the highest degree of toxicity) for acute eye and skin irritation effects.

A subchronic inhalation study showed bronchial and lung effects in rats. Chronic carcinogenicity studies using mice and rats showed no cancer effects. The chemical is not mutagenic. Human poisoning cases indicate that less than 10 grams taken orally is fatal.

Dietary Exposure

Sodium hydroxide is not used directly on food or feed, but is used on food contact surfaces and well-head casings. These uses have been evaluated by FDA under the memorandum of understanding described earlier, and have been found not to pose unacceptable dietary risks.

Occupational and Residential Exposure

Based on approved product formulation types and application methods, mixers, loaders and applicators in commercial and institutional settings may be exposed to sodium hydroxide. However, as long as label directions and precautions are followed, exposure of eyes and skin should be minimal.

Human Risk Assessment

Sodium hydroxide is corrosive and irritating to the skin, eyes and mucous membranes but does not appear to cause chronic health effects. Dietary exposure to the chemical is minimal and has been cleared by FDA. The potential for significant eye and skin exposure to mixers, loaders and applicators in commercial and institutional settings exists. However, if products are used in accordance with label precautions for eye and skin protection, worker exposure should be minimal. Therefore, the most significant human health risks posed by use of sodium hydroxide are adequately mitigated by product labeling.

Environmental Assessment**Environmental Fate**

Sufficient information is available in the public literature on the fate of sodium hydroxide in the environment. No further environmental fate data are required for reregistration.

Ecological Effects

One outdoor use of sodium hydroxide, to treat sewage systems, also is regulated by State agencies through the National Pollution Discharge Elimination System (NPDES) permit program; therefore, EPA did not conduct a risk assessment for this use. Current product labeling warns that sewer treatment effluent containing sodium hydroxide may not be discharged into lakes, streams, ponds, estuaries, oceans, or public waters

without an NPDES permit. The water well casings use of sodium hydroxide is believed to result in only minimal exposure of birds, mammals and other terrestrial organisms. Current product labeling helps protect wildlife from undue exposure to sodium hydroxide.

Additional Data Required

EPA has waived all generic data requirements for sodium hydroxide except basic product identity and chemistry information. Generic data on the composition, manufacturing process and impurities of each technical source used in registered pesticide products is required for reregistration.

Product-specific data, including product chemistry and efficacy studies, also are required for reregistration.

Product Labeling Changes Required

The labels of all registered sodium hydroxide products must comply with EPA's current pesticide labeling requirements.

- In addition, manufacturing- and end-use products registered to control roots in sanitary sewer lines (except products intended solely for residential use, which are exempt) must bear the following statement:

"This pesticide is toxic to wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage plant authority. For guidance contact your State Water Board or Regional office of the U.S. Environmental Protection Agency."

- For end-use products for use on well-head casings the Agency requires label statements concerning wildlife toxicity and prohibition against contamination of water by disposal of equipment, wash water, or rinsate.

- The Agency is requiring the following label statement on all end-use products to mitigate the potential for irreversible eye tissue damage: "When using this product, wear eye goggles or safety glasses."

Regulatory Conclusion

- None of the registered pesticide products containing the active ingredient sodium hydroxide are likely to cause unreasonable adverse effects in people or the environment, and all are eligible for reregistration. These products will be reregistered once the required generic data, product-specific data and revised labeling are received and accepted by EPA.

- Registered products containing sodium hydroxide as well as other active ingredients will be reregistered once the other active ingredients also are determined to be eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Document (RED) for sodium hydroxide 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 or to submit written comments, please contact the

Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

In the future, the sodium hydroxide RED 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 sodium hydroxide or about EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000. For information about reregistration of individual sodium hydroxide products, please contact the Registration Division (7505C), OPP, US EPA, Washington, DC 20460, telephone 703-305-7830.

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, 24 hours a day, seven days a week, or fax your inquiry to 806-743-3094.