



R.E.D. FACTS

Sodium Diacetate

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, showing 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 diacetate.

Use Profile

Sodium diacetate is a fungicide and bactericide registered to control molds and bacteria, and thus prevent spoilage, in stored grains. The pesticide is applied to hay as a dust or soluble concentrate (liquid spray) during the baling process. It is applied to silage as an "aid" in fermentation, to preserve the quality of field corn, alfalfa, sorghum, oats and grasses, stored in silos.

Sodium diacetate is composed of acetic acid and sodium acetate. It dissociates to acetate, sodium and hydrogen ions, normal components of plants and animals, and of human foods. Acetates are formed in living organisms during the metabolism of food. Acetates and acetic acid have long been used in both human and animal foods, without significant adverse effects.

Regulatory History

Sodium diacetate was first registered in 1968, for use as a food preservative. Later products were registered to preserve the quality of livestock feed crops. Currently, two such end-use pesticide products are registered, each containing sodium diacetate as its sole active ingredient. Based on the chemical's Generally Recognized as Safe or GRAS status, the post-harvest feed uses of sodium diacetate have been exempt from tolerance, or legal residue limit, requirements since 1981.

Human Health Assessment**Toxicity**

Based on acute toxicity studies, EPA places sodium diacetate in Toxicity Category IV (the least toxic of four categories) for oral and dermal toxicity and for primary dermal irritation. However, sodium diacetate is an eye irritant, and has been placed in Toxicity Category II for this effect.

In some subchronic feeding studies, the highest dose test animals experienced reduction in body weight gain, loss of appetite and reduction in food consumption. Others had raised white blood cell counts.

No maternal, fetal or teratogenic effects, and no signs of tumors, were seen in chronic animal feeding studies. Mutagenicity tests also have shown negative results.

Dietary Exposure

People could be exposed to very low level residues of sodium diacetate by eating meat, milk, poultry or eggs from animals fed hay or silage treated with the pesticide. However, since acetic acid is completely utilized in metabolism, the residues of sodium diacetate in meat, milk or poultry are considered to be negligible. Sodium diacetate is exempt from the requirement of a tolerance, or legal residue limit, when used post-harvest on certain hays and grains, as listed in 40 CFR 180.1058. It is considered Generally Recognized as Safe, or GRAS, for use in food (please see 21 CFR 184.1754). Thus, EPA believes that any dietary exposure to sodium diacetate is inconsequential.

Applicator Exposure

Workers mixing and loading the dust formulation of sodium diacetate, or the soluble powder for liquid application, may experience significant exposure via the dermal and (for the dust formulation) the inhalation routes. If mixing and loading is performed using a closed system, the potential for exposure is minimized. Without a closed system, protective clothing is needed to protect the eyes from irritation. Product labels must be amended accordingly, as specified in the RED.

Human Risk Assessment

EPA concludes that the general public's dietary exposure to sodium diacetate resulting from proper use of the pesticide to protect livestock feed is inconsequential. However, workers mixing and loading the pesticide may suffer eye irritation effects unless appropriate protective clothing (such as goggles or a face shield) is worn. Therefore, EPA is requiring the use of such protective equipment.

Environmental Assessment

EPA does not foresee the potential for significant environmental risks associated with the registered uses of sodium diacetate. All environmental fate and ecological effects data requirements are waived, as explained below.

Environmental Fate

Post-harvest applications of sodium diacetate to hay and silage are made primarily within farm facilities, so limited environmental exposure results. There is sufficient knowledge about sodium diacetate to make the assessment that the compound's impact on the environment will be negligible. EPA therefore is not requiring any environmental fate studies.

Ecological Effects

The limited outdoor use of sodium diacetate is likely to have a minimal impact on wildlife. Since this pesticide is of low toxicity, and is normally present and functioning in the metabolic pathways of animals, its use in treating hay and forage crops does not warrant the development of ecological effects studies for reregistration.

Additional Data Required

While the generic data base for sodium diacetate is complete, product-specific acute toxicity and product chemistry data are required for reregistration.

Product Labeling Changes Required

The labels of the two end-use products containing sodium diacetate must comply with EPA's current pesticide labeling requirements. In addition, since these products cause eye irritation, their labels must be amended to include the following statement: "Causes eye irritation. Do not get in eyes. Wear goggles or a face shield during use."

Regulatory Conclusion

- Registered pesticide products containing sodium diacetate can be used without causing unreasonable adverse effects in people or the environment. Therefore, they are eligible for reregistration.
- The two end-use products containing sodium diacetate as the sole active ingredient will be reregistered once product-specific data and amended labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Document for sodium diacetate 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 703-557-2805.

In the future, the 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 diacetate 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

diacetate products, please contact the Registration Division (7505C), OPP, US EPA, Washington, DC 20460, telephone 703-557-5447.

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.