

US EPA ARCHIVE DOCUMENT



R.E.D. FACTS

Sodium Fluoroacetate

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 3073, sodium fluoroacetate, also known as compound 1080.

Use Profile

Sodium fluoroacetate is an acute toxicant predacide which is used against coyotes which prey on sheep and goats. Registered end-use products are injected into the rubber reservoirs of the Livestock Protection collars, also referred to as the "toxic collar", which are strapped to the throats of sheep or goats. Coyotes attempting to kill collared livestock are likely to puncture the collars and to be fatally poisoned by sodium fluoroacetate as a result of the attack. When predation is anticipated, up to 20 collars may be used in fenced pastures up to 100 acres in size; up to 50 collars may be used in pastures of 101 to 640 acres; and up to 100 collars may be used in pastures of 641 to 10,000 acres.

Sodium fluoroacetate is a restricted use pesticide which may be used only by trained, certified applicators and which is only registered for use in livestock protection collars. Sodium fluoroacetate will retain the restricted

use classification imposed by the Agency in 1978 due to its high acute toxicity and the need for highly specialized applicator training. The Agency also has reviewed concerns about the exposure of threatened and endangered animal species with the United States Fish and Wildlife Service (USFWS). The March 1993 USFWS final biological opinion on the effects of sodium fluoroacetate on threatened and endangered species addressed the livestock protection collar and included jeopardy determinations to the gray wolf and grizzly bear. Specific areas were identified where the collar could not be used and such restrictions have been incorporated on the livestock protection collar labels. No additional use restrictions to further protect threatened and endangered species are being imposed at this time.

Regulatory History

Development and use of sodium fluoroacetate as a predicide and rodenticide in the U.S. began in the 1940s prior to the 1947 enactment of the Federal Insecticide, Fungicide, and Rodenticide Act by which requirements for federal registration of pesticide products were instituted. In 1964 and again in 1971, the use of poisons to control predatory mammals were reviewed by selected committees. In 1972 EPA cancelled all registered predator control uses of sodium fluoroacetate, sodium cyanide, and strychnine.

In 1977, the U.S. Department of the Interior (USDI) applied for an Experimental Use Permit (EUP) to investigate the potential risks and benefits associated with the use of sodium fluoroacetate in "toxic collars" which would be placed on the necks of sheep and goats. The toxic collar containing sodium fluoroacetate solution would be positioned around the animals' throat regions where they would be likely to be ruptured by the teeth of coyotes that attempted to kill the livestock with species-typical throat bites.

In 1981, EPA was petitioned by the USDI and livestock interests to revisit the 1972 predicide cancellation decision with respect to sodium fluoroacetate. EPA held informal hearings in 1981 and formal administrative hearings in 1982 resulting in a final decision to permit EPA to consider applications for registration of sodium fluoroacetate in toxic collars and single-dose baits.

In 1985, EPA granted a registration to USDI for a toxic collar product which was transferred in 1986 to the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA).

The rodenticide uses of sodium fluoroacetate were cancelled due to lack of supporting data. In 1989, all "special local needs" registrations

issued under § 24(c) of FIFRA were cancelled, and all pending applications for Federal registration were denied by August 1990.

Human Health Assessment

Toxicity

Sodium fluoroacetate is a sodium salt of fluoroacetic acid which is a tan colored alkaline powder with a pH of 10.3. It melts at 197-203°C with decomposition. It is soluble in water, but practically insoluble in all non-polar solvents. Sodium fluoroacetate is stable in sunlight, at a temperature of 54°C, and in tin coated metal containers.

The toxicological data base on sodium fluoroacetate is adequate and will support reregistration eligibility. Sodium fluoroacetate has been placed in Toxicity Category I, which indicates the highest degree of acute toxicity, for acute oral toxicity; Toxicity Category II, moderately toxic, for acute dermal toxicity; Toxicity Category III, slightly toxic, for primary eye irritant; and Toxicity Category IV, practically non-toxic, for dermal irritation. The requirements for acute inhalation toxicity and dermal sensitization studies were waived due to the severe acute toxicity of the compound.

Sodium fluoroacetate caused dose-related findings in histopathology and decreased size and weight of testes and epididymides in males in a subchronic dietary study in rats. In a subchronic study of sodium fluoroacetate in drinking water of rats, no effects were seen in the kidney or liver, but testicular atrophy and nonreversible tubular degeneration were found at the mid-and high-doses. Testicular atrophy with reversible tubular degeneration was found at the low dose. The metabolism of sodium fluoroacetate is understood in the mammalian body. It can be absorbed through the gastrointestinal tract, respiratory tract, or open wounds, but only slowly through intact skin.

Human Risk Assessment

Because of the specific nature of this registered use, EPA's primary concern is for the potential risk of acute toxicity. Under the current limited use pattern, no sodium fluoroacetate exposure to the general population is expected. Risk of acute toxicity to applicators is mitigated by the pesticide's use restrictions and its classification as a restricted use pesticide.

Environmental Assessment

Environmental Fate

The Agency has reviewed published literature which suggests that leaching and metabolism are the major routes of dissipation. However, undegraded fluoroacetate is considered mobile and consequently has a high potential to move downward in the soil and reach ground water. While sodium fluoroacetate has the potential to reach groundwater, the Agency's Pesticides in Ground Water Database reports no detections for the period 1971 to 1991.

Ecological Effects

The Agency has adequate data to assess the hazard of sodium fluoroacetate to nontarget organisms. Sodium fluoroacetate is very highly toxic to the mallard duck, chukar, ring-necked pheasant, widgeon, golden eagle, black vulture and the black-billed magpie on an acute oral basis. Substantial chronic exposure to birds is not expected with the use of the sodium fluoroacetate livestock protection collar. Because the livestock protection collar is specifically designed to kill a wild mammal (coyote), wild mammal toxicity testing was required for sodium fluoroacetate. Sodium fluoroacetate can be classified as very highly toxic to coyotes, cotton rat, deer mouse, raccoon, opossum and skunk on an acute oral basis. It is slightly toxic to rainbow trout and practically non-toxic to bluegill sunfish. Sodium fluoroacetate is practically non-toxic to *Daphnia magna*, a freshwater invertebrate. The terrestrial non-food use of sodium fluoroacetate will not result in substantial exposure to marine and estuarine organisms, therefore, these data were not required.

Certain nontarget species of birds and mammals, including threatened and endangered species, may be exposed to sodium fluoroacetate used in livestock protection collars. Based on a variety of studies that have been reviewed by the Agency, the principal source of risk is exposure of scavengers feeding on the head and neck area of dead livestock bearing sodium fluoroacetate livestock protection collars. Factors that reduce the risk associated with use of these collars include rapid decomposition of carcasses, selective feeding of scavengers from wounds on the carcass rather than contaminated skin surface of the head or neck, and the emetic property of the chemical. The concerns for risk to wildlife can be addressed by hazard statements, special use restrictions, and endangered species protection statements that are required to be placed on the product label.

Additional Data Required

The generic database supporting the reregistration of sodium fluoroacetate for use in livestock protection collars has been determined to

be substantially complete. No new generic data are being required at this time.

The Agency also 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

The labels of all registered pesticide products containing sodium fluoroacetate must comply with EPA's current pesticide labeling requirements as specified in 40 CFR § 156.10 and other applicable notices. The statements must also appear on the labels of sodium fluoroacetate end use products consistent with the USDA/APHIS product's 18 use restrictions. (See "Use Restrictions" in the RED document for the 18 use restrictions). In addition, the states may add use restrictions consistent with EPA's regulatory position and legal decisions regarding predacidal uses of sodium fluoroacetate, but no requirements may be dropped or mitigated. Any changes to the use restrictions must be requested through the amendment process and must be accepted in advance by E.P.A.

Regulatory Conclusion

The use of registered products containing sodium fluoroacetate will not pose unreasonable risks or adverse effects to humans or the environment, provided that these products are used in accordance with the restrictions on product labeling. Therefore, the current use of these products is eligible for reregistration. Sodium fluoroacetate products will be reregistered once the required product-specific data, 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 Fluoroacetate 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 Fluoroacetate 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 Fluoroacetate RED, or reregistration of individual products containing Sodium Fluoroacetate, 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.