



R.E.D. FACTS

Sulfuryl Fluoride

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 Document, or RED. This fact sheet summarizes the information in the RED for sulfuryl fluoride.

Use Profile

Sulfuryl fluoride is an insecticide used to fumigate closed structures and their contents such as domestic dwellings, garages, barns, storage buildings, commercial warehouses, ships in port, and railroad cars. It controls numerous insect pests including termites, powder post beetles, old house borers, bedbugs, carpet beetles, clothes moths and cockroaches, as well as rats and mice. The end-use product is marketed as a liquid gas in pressurized steel containers.

Regulatory History

Sulfuryl fluoride was first registered in December 1959. In June 1985, EPA issued a registration standard entitled "Guidance for the Reregistration of Pesticide Products Containing Sulfuryl Fluoride as an Active Ingredient" (NTIS PB87-124392), requiring additional product chemistry and occupational and residential exposure studies. Data Call-In Notices issued in July 1990 and November 1992 required additional toxicity data.

Currently, no manufacturing use products and only one end-use product containing the active ingredient sulfuryl fluoride are registered. The single registered product, Vikane, contains 99% sulfuryl fluoride and 1% inert impurities. Vikane is classified as a restricted use pesticide due to its inhalation toxicity.

Human Health Assessment

Toxicity

In acute oral toxicity studies using rats and guinea pigs, sulfuryl fluoride has been shown to be moderately toxic; it has been placed in Toxicity Category II for these effects (Category I indicates the highest and Category IV the lowest level of acute toxicity). Sulfuryl fluoride has been placed in Toxicity Categories III and IV for acute inhalation and Category IV for acute dermal vapor toxicity. A two-day neurotoxicity study using rats showed no effects at the highest dose levels.

Four subchronic toxicity studies using rats, rabbits and dogs showed similar results including fluorosis of the teeth, decreased body weights, and effects to the lung, nervous system and brain. In developmental toxicity studies using rats and rabbits, at the highest dose levels or in range-finding studies, some maternal toxicity (reduced body weight gain) and developmental toxicity (reduced fetal body weights) were observed. A reproductive toxicity study using rats showed parental effects to the lungs and brain, and reduced pup weights. Sulfuryl fluoride was negative in three mutagenicity studies.

Several humans poisonings and two deaths have been attributed to sulfuryl fluoride exposure. All resulted from reentering treated homes before they had adequately aerated, inconsistent with label directions.

Dietary Exposure

Sulfuryl fluoride is not registered for any food- or feed-related uses. No tolerances or exemptions from the requirement of a tolerance have been established, and no dietary exposure is anticipated.

Occupational and Residential Exposure

Sulfuryl fluoride is dispensed as a pressurized gas from a steel cylinder through a hose into the interior of an enclosed, sealed structure. People must be evacuated from the structure before it is treated; chlorpicrin, which produces a strong odor and eye irritation, is used as a warning agent and is released within the structure 5 to 10 minutes before sulfuryl fluoride is applied to ensure that the site is vacated. After treatment, the structure remains closed for a period of time (refer to the product label for specific times regarding target pest and environmental conditions) after which the applicator reenters and begins to aerate the area. People not wearing a respirator may not reenter the treated structure

until air levels of sulfuryl fluoride have declined to 5 part per million (ppm) or less. Because sulfuryl fluoride is a Restricted Use Pesticide, it may only be applied by or under the direct supervision of a trained, certified applicator.

Applicators may be exposed to sulfuryl fluoride while applying the pesticide. However, sulfuryl fluoride is introduced as a gas into the target area through a hose, thus, negligible exposure to the applicator is expected until the time of reentry into the treated structure to monitor air levels.

Applicators and residents may be exposed to sulfuryl fluoride through inhalation upon reentry and/or reoccupation of treated structures. Exposure to workers is acute and intermittent, while exposure to residents is acute and lasting. Current product labeling requires applicators to wear protective clothing including respirators when reentering treated structures and prohibits other people from reoccupying treated structures until air levels of sulfuryl fluoride have declined to 5 ppm.

Human Risk Assessment

Sulfuryl fluoride poses no human dietary risks since no food- or feed-related uses are registered and dietary exposure is not anticipated.

EPA is concerned with neurotoxicity associated with inhalation exposure to sulfuryl fluoride. Residents and workers reentering treated structures may be at risk for acute neurotoxic effects from this exposure, which currently is limited to 5 ppm. The Agency has concern that the 5 ppm reentry level may not be appropriate based on the calculated Margins Of Exposure (MOEs) which suggest 2 ppm for adults. In order to provide a further safety measure for children, the current data and the limit of detection of the monitoring devices suggest a reentry level of 1 ppm. However, certain post treatment decline data are not available which might enable the Agency to refine the reentry level. The sulfuryl fluoride registrant has been given the option in the RED document to submit exposure data and any other data that can be used to refine the decline rate of sulfuryl fluoride. These data are due by August 1, 1994. By October 1, 1994, the Agency will make a decision on the reentry level but until these data are evaluated the 5 ppm reentry level will remain in place. If these new data are not useful or not received by August 1, 1994, the reentry level will be established at 1 ppm and revised labeling will be implemented on an accelerated basis.

In addition, a fact sheet must be provided in advance to an adult occupant of each structure to be fumigated, describing why and how buildings are fumigated, the potential risks and safety precautions, as well as who to contact for more information.

Because of uncertainty about neurotoxic effects due to long term exposure to sulfuryl fluoride, workers will be required to wear a NIOSH-approved, self-contained breathing apparatus (SCBA) upon reentry,

regardless of air levels of sulfuryl fluoride. EPA is requiring a 90-day inhalation neurotoxicity study in rats to more fully assess human subchronic and chronic effects. Assessment of risks to workers during their working life span, and the need to continue wearing the SCBA upon reentry at all air levels of sulfuryl fluoride, will be addressed after this study is received and evaluated.

Environmental Assessment

Environmental Fate

Since sulfuryl fluoride is registered for highly specialized uses, and due to its chemical properties, EPA is not requiring the usual supporting environmental fate data for reregistration. After fumigation and aeration of treated structures, there is little likelihood that nontarget organisms would be exposed to residues of sulfuryl fluoride, or that the pesticide would leach to ground water. Residues of the parent chemical are not expected to remain in the environment for any significant length of time.

Ecological Effects Risk Assessment

Based on its limited use sites and chemical properties, significant environmental exposure is not expected to result from use of sulfuryl fluoride. Therefore, wildlife toxicity data were not required for reregistration, and an ecological risk assessment was not conducted.

Additional Data Required

The generic data base for sulfuryl fluoride is substantially complete. However, EPA is requiring a new 90-day neurotoxicity study in rats, as confirmatory data. Method validation data for indoor air monitoring devices are also required.

EPA is not requiring product-specific data, but is requiring a revised Confidential Statement of Formula and revised labeling for reregistration of the pesticide product containing sulfuryl fluoride.

Product Labeling Changes Required

The end-use product must comply with EPA's current pesticide product labeling requirements. In addition:

- The label must provide specific directions for the use of chlorpicrin as a warning agent to be present in the structure during fumigation at a level $\leq 0.25\%$. Instructions must be provided that the chlorpicrin must be used by persons certified to apply sulfuryl fluoride and that applicators must observe the precautionary statements and safety recommendations appearing on the label of this product.

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- The label must require that a pesticide fact sheet be provided to an adult occupant of the structure to be fumigated prior to the initiation of the fumigation contract. This fact sheet, which is labeling, must contain as a minimum of information the following:

- a) Why buildings are fumigated.
- b) How buildings are fumigated.
- c) Potential health risks from overexposure.
- d) Safety precautions and homeowner preparation.
- e) A contact point for additional information.

- Add the following under the Environmental Hazards Statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide is a violation of Federal Law. If these wastes cannot be disposed of by use according to the label instructions, consult your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative of the nearest EPA Regional Office for guidance."

- Due to concern for neurotoxic effects from long term exposure to sulfuryl fluoride upon reentry to treated structures, the Agency requires the following:

Applicators must wear a NIOSH approved self-contained breathing apparatus (SCBA) when reentering a treated structure regardless of air levels of sulfuryl fluoride.

Regulatory Conclusion

Use of the currently registered pesticide product containing sulfuryl fluoride as labeled and specified in the RED document will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of this product are eligible for reregistration.

The sulfuryl fluoride product will be reregistered once the confirmatory generic data, revised Confidential Statement of Formula and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Document (RED) for sulfuryl fluoride 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 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.

Following the comment period, the sulfuryl fluoride RED document 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 sulfuryl fluoride RED document, EPA's pesticide reregistration program, or reregistration of individual products containing sulfuryl fluoride, 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 6:00 pm Central Time, Monday through Friday.