United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-012 April 1995

R.E.D. FACTS

Aliphatic Alcohols

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 4003, aliphatic alcohols, which contains the active ingredients ethanol and isopropanol.

Use Profile

Aliphatic alcohols are registered for uses which include hard surface treatment disinfectants, sanitizers, a sterilant, virucides, fungicides, and mildewcides. Ethanol also is registered for use as a plant growth regulator (a ripener), and is used with quaternary ammonium compounds in swimming pool water systems. Isopropanol also is used in combination with other pesticide active ingredients to kill fleas, ticks, and other household insects. Both ethanol and isopropanol are well known substances and have a wide range of human uses. For example, ethanol is contained in some beverages, and isopropanol is the major ingredient in rubbing alcohol.

Aliphatic alcohols are applied as surface wipes, sprays, mop-on, sponge-on, wipe-on or pour-on treatments, by immersion, and through closed systems (for commercial/industrial water cooling systems).

Use practice limitations for ethanol include cautions not to use the product on polished wood furniture or rayon fabrics, and not to get the product on foods, drinks, feeds, or surfaces they may contact. Isopropanol is not recommended for use on aluminum, should not be used on polished wood furniture or rayon fabrics, and should not be sprayed on lacquered or

shellacked surfaces. Used solution should not be poured back into the bottle.

Regulatory History

Aliphatic alcohols were first registered as indoor disinfectants in the U.S. as early as 1948. Currently, 73 ethanol and 67 isopropanol pesticide products are registered. Ethanol and isopropanol are considered inert ingredients in some pesticide formulations; a determination is made on a case-by-case basis.

Historically, aliphatic alcohols have been regulated both as pesticides under EPA's jurisdiction and as devices under the Food and Drug Administration (FDA)'s purview. This regulatory burden has been reduced by a 1993/94 Memorandum of Understanding (MOU) which divides liquid chemical germicides into two categories: sterilants (which FDA will regulate) and general purpose disinfectants (which EPA will regulate). Both Agencies will continue to have jurisdiction over all liquid chemical germicides until rulemaking has been completed, but product performance and efficacy data need only be reviewed by the Agency with primary jurisdiction.

The case aliphatic alcohols contains three other active ingredients--methanol, propyl alcohol, and tert-butyl alcohol--which are not being supported for reregistration.

Human Health Assessment

Toxicity

In studies using laboratory animals, aliphatic alcohols have been shown to be of low acute toxicity. Ethanol has been placed in Toxicity Category IV (indicating the lowest degree of acute toxicity) for all effects tested including acute oral and inhalation toxicity, and primary eye and skin irritation. Isopropanol also has been placed in Toxicity Category IV for all effects except acute oral toxicity, for which it is placed in Toxicity Category III. In an acute neurotoxicity study using rats, isopropanol vapors caused decreased motor activity and effects on nervous system functions at the higher dose levels.

In a subchronic toxicity study using rats, ethanol caused decreased body weights and fatty degeneration in the livers of treated animals. In a study using human volunteers, ethanol-saturated patches caused skin irritation at 19-21 days of exposure. An inhalation study using rats, guinea pigs, rabbits, monkeys, and dogs resulted in no signs of toxicity.

In a subchronic inhalation study using rats and mice, isopropanol caused some clinical signs including ataxia, narcosis, hypoactivity, and lack of startle response, as well as kidney lesions. In a subchronic inhalation study using rats, no treatment-related changes were noted but motor activity was increased at the highest dose level.

In a chronic toxicity study using rats, ethanol caused decreased mean body weights, decreased activity, and impaired maze learning ability. In a

chronic dermal toxicity study, no treatment-related effects were noted. Two similar studies with isopropanol caused similar results.

EPA's review of the scientific literature indicates that carcinogenic effects are not expected from the uses of ethanol. In a carcinogenicity study using rats, isopropanol caused an increased incidence of granular kidneys, thickened stomachs, and kidney lesions. A second study using mice also caused increased incidence of stomach and kidney lesions, which were determined not to be of biological significance.

Ethanol is generally recognized as a human developmental neurotoxicant, causing Fetal Alcohol Syndrome in the offspring of mothers who chronically consume high amounts of ethyl alcohol. However, the risk in an industrial environment appears to be minimal.

Developmental toxicity studies using rats and rabbits show that isopropanol causes reduced fetal body weights, decreased maternal body weights, and increases in liver or kidney weights.

Ethanol was negative for mutagenicity effects in six out of seven studies, while isopropanol was negative in all three studies available.

Dietary Exposure

Dietary exposure is not expected to result from the approved uses of ethanol and isopropanol, including the plant regulator (ripener) use.

Occupational and Residential Exposure

Use of aliphatic alcohols may result in high dermal and inhalation exposure of mixers, loaders and applicators, especially when power sprays are used. However, the risk from exposure to these active ingredients is considered to be incidental, considering the frequent intentional human exposures to these substances.

Human Risk Assessment

Aliphatic alcohols are of low acute toxicity. No dietary exposure is expected from their use as pesticides. EPA does not expect developmental or reproductive effects to occur from the potential dermal and inhalation exposures that may result from the registered pesticidal uses of ethanol and isopropanol.

Environmental Assessment

Environmental Fate

Aliphatic alcohols are organic chemical compounds. They are flammable liquids and are highly soluble in water and many organic solvents. Highly volatile liquids, they are stable in water under typical use conditions. EPA does not anticipate significant exposure to the environment from their uses.

Ecological Effects

Ethanol and isopropanol are practically non-toxic to mammals, fish, and aquatic invertebrates.

Ecological Effects Risk Assessment

Aliphatic alcohols are practically non-toxic to all species tested. They are used primarily indoors. Both are highly volatile. Exposure to terrestrial organisms would be extremely minimal.

Additional Data Required

EPA is requiring product-specific data including product chemistry, acute toxicity, and efficacy studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All aliphatic alcohol end-use products must comply with EPA's current pesticide product labeling requirements. In addition, the following statement must be added to the label of each product, except sterilant products, that is registered for treatment of any medical device or medical equipment surface:

> "This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection."

Regulatory Conclusion

The use of currently registered products containing aliphatic alcohols (ethanol and isopropanol) in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Aliphatic alcohol 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 aliphatic alcohols 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 aliphatic alcohols 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 aliphatic alcohols RED, or reregistration of individual products containing aliphatic alcohols, 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.