United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-96-016 August 1996

EPA R.E.D. FACTS

Cryolite

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 before November 1, 1984, 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 develops any mitigation measures or regulatory controls needed to effectively reduce 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 explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0087, cryolite.

Use Profile

Cryolite is an insecticide used on many fruits, vegetables and ornamental crops to protect against leaf eating pests. Currently, the predominant uses are on grapes, potatoes and citrus. Cryolite is formulated as dusts, wettable powders and water dispersable granulars and can be applied by ground or air equipment. Multiple applications at high rates are typical. The highest single application rate is 30 lbs/acre on citrus and ornamentals; the highest seasonal rate from multiple applications is 154 lbs/acre on lettuce. Cryolite is a naturally occurring mineral that is also synthetically produced.

Regulatory History

Cryolite was first registered as a pesticide in the U.S. in 1957. EPA issued a 1983 Guidance Document and a superseding 1988 Registration Standard requiring environmental, toxicological and residue data needed to determine cryolites reregistration eligibility. A 1990 Data Call-In required additional product-specific data.

Currently, four cryolite products are registered.

Human Health Assessment

Toxicity

In studies using laboratory animals, cryolite generally has been shown to be slightly to practically non-toxic on an acute basis. The acute dermal LD50 in rats is 2.1 g/kg, placing cryolite in Toxicity Category III (the second lowest of four categories) for this effect. Cryolite is considered a moderate irritant based on eye irritation studies and classified in Toxicity Category IV for acute oral exposure, acute inhalation and skin irritation. Cryolite is classified as a non-sensitizer based on dermal sensitization tests conducted with Guinea pigs.

Cryolite has been classified as a Group "D" chemical, "not classifiable as to human carcinogenicity". It has been the subject of a comprehensive review by the National Research Council (National Academy of Sciences Subcommittee of Health Effects of Ingested Fluoride) who concluded that "...the available data are insufficient to demonstrate a carcinogenic effect of fluoride in animals." and that "..the weight-of-evidence from more than 50 epidemiological studies does not support the hypothesis of an association between fluoride exposure and increased cancer risk in humans." The Agency is in agreement with the conclusion reached by the National Academy of Sciences.

Dietary Exposure

People may be exposed to residues of cryolite through the diet. Tolerances or maximum residue limits have been established for the fluorine compounds cryolite and synthetic cryolite in or on raw agricultural commodities. These include a regional registration tolerance for kiwi-fruit and a time-limited tolerance to expire May 6, 1996, on potatoes. EPA has reassessed the cryolite tolerances and found that some are acceptable, others must be revoked because the registrants have chosen not to support the uses; and based on new data, tolerances will be proposed/established for cabbage, citrus, collards, eggplant, lettuce (head and leaf), peaches, potatoes and tomatoes. Food additive tolerance increases must be proposed for raisins and tomato paste, and data must be submitted to determine appropriate food additive tolerance levels for prunes. The Agency has completed its review of the data needed to establish a permanent tolerance for potatoes. The Agency will propose in the Federal Register permanent tolerances for potatoes at 2 ppm and potato waste at 22 ppm.

EPA has assessed the dietary risk posed by cryolite. A qualitative dietary risk assessment was performed to include the daily intake of fluoride from other sources, i.e. fluorinated public water sources. The Agency concluded that levels of fluoride in/on food from the agricultural use of cryolite plus fluoride levels in U.S. drinking water supplies results in a high-end daily dietary intake of fluoride of approximately 0.085 mg/kg/day. This is less than the Agency's determined Maximum

Concentration Limit Goal (MCLG) of 4.0 mg/L [0.114 mg/kg/day], a level which provides no known or anticipated adverse health effects. The MCLG has been reviewed and is supported by the Surgeon General.

Environmental Assessment

Acute risk is not expected to birds, mammals, aquatic organisms or beneficial insects from exposure to cryolite. Chronic ecological risk also is not expected because, in the presence of sufficient water, cryolite is quickly converted to near natural background levels of simple inorganic compounds containing its constituent elements (sodium, aluminum, fluorine). Once cryolite dissolves and penetrates to shallow depths in soil or is transported to natural waters, any minor chemical imbalances caused by its insecticidal application are offset by the mineral buffering capacity of the environment and/or self-correcting agricultural practices (such as calcium applications and pH adjustments to the soil). Ground or surface water effects should be negligible.

Additional Data Required

EPA is requiring the following additional generic studies for cryolite to confirm its regulatory assessments and conclusions: Magnitude of the residue in field grown cranberries and plums. Before determining the eligibility of cryolite for use on strawberries EPA is requiring a generic study on the magnitude of the residue in field grown strawberries. 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

All cryolite end-use products must comply with EPA's current pesticide product labeling requirements. Some of the required labeling are: Worker Protection restrictions that include 12 hour restricted entry intervals and the minimal early entry personal protective equipment requirements; user safety recommendations; environmental hazards statement prohibiting application or contamination of water or intertidal areas; spray drift precautions. For a comprehensive list of labeling requirements, please see the cryolite RED document.

Regulatory Conclusion

EPA has determined that the following uses of cryolite have been supported and are eligible for reregistration: broccoli, Brussels sprouts, cabbage, cauliflower, citrus fruits, collards, cranberries, cucumbers, eggplant, grapes, kohlrabi, lettuce (leaf and head), melons, peaches, peppers, plums (fresh prunes), pumpkins, squash (winter and summer), tomatoes, kiwi, potatoes, ornamental herbaceous plants, ornamental nonflowering plants, ornamental woody shrubs and vines and shade trees. The use on strawberries is being supported but there are no residue data at this time upon which to base an eligibility decision. The Agency will evaluate the eligibility of this use after the data are submitted and reviewed.

The use of eligible cryolite products in accordance with labeling specified in this RED will not pose unreasonable adverse effects to humans or the environment. These products will be reregistered once the required product specific data, CSFs, and revised labeling are received and accepted by EPA. Products which contain active ingredients in addition to cryolite will be reregistered when all of their other active ingredients also are eligible for reregistration.

There are several currently registered uses for cryolite that are not being supported and their tolerances are being proposed for revocation: apples, apricots, beans, beets (roots and tops), blackberries, boysenberries, carrots, corn, dewberries, kale, loganberries, mustard greens, nectarines, okra, peanuts, pears, peas, quinces, radishes (roots and tops), turnips (roots and tops) and youngberries.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for cryolite 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 cryolite 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 cryolite RED, or reregistration of individual products containing cryolite, 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 9:30 am and 7:30 pm Eastern Standard Time, Monday through Friday.