United States Environmental Protection Agency | Pesticides And Toxic Substances (7508W) | 738-F-91-107 September 1991

R.E.D. FACTS

Silicon Dioxide and Silica Gel

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 silicon dioxide and silica gel.

Use Profile

Silicon dioxide and silica gel are insecticides and acaracides, used in controlling insects, mites and ticks in a variety of indoor and outdoor sites. Silicon dioxide dust is applied with a hand-held or power duster to stored grain, other food, feed and ornamentals; in food handling areas; and on pets and their living/sleeping quarters. Silica gel dust or pressurized liquid is applied by hand-held power duster, aerosol can or injection into cracks and crevices. Silica gel is used to control target pests in stored grain crops, food handling areas, hospitals, sewage systems, and on animals/pets and their living quarters.

Silicon dioxide is diatomaceous earth, a naturally-occurring material composed of the shells of minute, single-celled algae. Silica gel is an amorphous form of silicon dioxide. Both employ a physical mode of action to control insects. They are abrasive and act as desiccants, removing the oily, protective film that covers insects' bodies, causing them to dry out and die.

Regulatory History

Silicon dioxide and silica gel were first registered as pesticides in 1960 and 1956, respectively. Currently, 18 registered pesticide products contain silicon dioxide and 55 contain silica gel, usually in combination with other active ingredients. Because of their low toxicity when ingested, silicon dioxide and silica gel have been exempted from tolerance, or legal residue limit, requirements (please see Dietary Exposure, below).

Human Health Assessment

Toxicity

Available studies demonstrate that silicon dioxide and silica gel have moderate to low acute toxicity. These pesticides have been placed in Toxicity Category III for acute oral and dermal effects (Toxicity Category I indicating the highest degree of toxicity, and IV the lowest). Similarly, an inhalation study and eye and dermal irritation studies suggest moderate to low toxicity.

With regard to subchronic and chronic effects, crystalline silicon dioxide has long been associated with silicosis, a progressive lung disease which may result in lung cancer in humans. However, amorphous silicon dioxide (used in pesticide formulations) has not been associated with silicosis. The International Agency for Research on Cancer (IARC) conducted an in-depth evaluation of the potential carcinogenicity of silicon dioxide. They found that there is inadequate evidence to link amorphous silica with cancer effects in humans or test animals.

Dietary Exposure

People may be exposed to silicon dioxide and silica gel through their diets, since these pesticides may be applied to certain crops and used in and around food handling and preparation areas. However, due to their negligible toxicity, silicon dioxide and/or silica gel have been exempted from the requirement of a tolerance, or legal residue limit, when applied to growing crops and raw agricultural commodities after harvest (40 CFR 180.1001 (c) and (d)); to animals (40 CFR 180.1001 (e)); to growing crops, raw agricultural commodities after harvest, and animals (40 CFR 180.1017); and in food and feed processing and storage areas (40 CFR 185.1700 and 186.1700). Both silicon dioxide and silica gel are Generally Recognized as Safe, or GRAS, as food additives (21 CFR 182.90 and 182.1711).

Applicator Exposure

People may inhale particles of silicon dioxide and silica gel when applying these dust, aerosol, or crack-and-crevice injection formulations. Current product labels for dust formulations require the use of a dust mask for prolonged periods of use. EPA believes that applicators' dermal exposure to these products also may be significant. However, since applications and exposures normally occur only several times a year (or

less), the Agency is not requiring additional protective clothing or other changes in use, at this time.

Human Risk Assessment

EPA concludes that the human health risk from exposure to silicon dioxide and silica gel is low and not unreasonable. These pesticides are of moderate to low acute toxicity. Dietary exposure is believed to be insignificant from a toxicological standpoint. Applicator exposure may be significant for each application, however, these products generally are used infrequently.

Environmental Assessment

All environmental fate and ecological effects data requirements for silicon dioxide and silica gel have been waived, as explained below.

Environmental Fate

Silicon dioxide consists of diatomaceous earth, a naturally-occurring material. Its primary component, silica, is found in common minerals like quartz, sand and agate. Silica gel is simply an amorphous form of silicon dioxide. These materials are ubiquitous, and unlikely to react chemically with any other substances in the environment.

Ecological Effects

Silicon dioxide and silica gel are naturally-occurring, ubiquitous, and chemically unreactive in the environment. There is no evidence to suggest that the use of these materials as pesticides, in accordance with approved labeling, presents a hazard to nontarget organisms or the environment.

Additional Data Required

While the generic data base for silicon dioxide and silica gel is complete, product-specific product chemistry data are required for reregistration, as specified in the Data Call-In Notice issued in conjunction with the RED.

Product Labeling Changes Required

The labels of end-use products containing silicon dioxide and silica gel must comply with EPA's current pesticide labeling requirements. Any product label that allows both manufacturing and end use must be amended to specify one use or the other.

In addition, product labels must specify the active ingredient concentration as a percentage if solid, or in pounds per gallon if liquid. The application rate, maximum number of applications, and the pre-harvest interval also must be included. All sites where application is permitted must be listed.

Regulatory Conclusion

- Registered pesticide products containing silicon dioxide and silica gel can be used without causing unreasonable adverse

effects in people or the environment. Therefore, they are eligible for reregistration.

- End-use products containing silicon dioxide or silica gel as the sole active ingredient will be reregistered once product-specific data and amended labeling are received and accepted by EPA.
- End-use products containing silicon dioxide or silica gel in combination with other active ingredients will be reregistered once product-specific data and amended labeling are received and accepted by EPA, and when the other active ingredients in these products also are eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Document for silicon dioxide and silica gel 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 silicon dioxide and silica gel, 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 silicon dioxide and silica gel 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.