



R.E.D. FACTS

Streptomycin and Streptomycin Sulfate

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, 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 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 streptomycin and streptomycin sulfate, referred to as streptomycin.

Use Profile

Streptomycin is a human antibiotic drug which also is used as a pesticide, to control bacteria, fungi and algae. Streptomycin controls bacterial and fungal diseases of certain fruit, vegetables, seed, and ornamental crops, and controls algae in ornamental ponds and aquaria. The use of streptomycin to control fireblight on apples and pears accounts for 58% of its total use. Other significant uses are on nursery stock and in landscape maintenance (17% of use), and on tobacco (7% of use).

Regulatory History

Streptomycin has been used in the United States as a drug to treat bacterial infections in humans since the 1940s. It was first registered as a pesticide in 1955, for use in controlling bacterial and fungal diseases of certain agricultural and non-agricultural crops. EPA issued a Registration Standard for streptomycin in September 1988. Currently, sixteen end-use pesticide products containing streptomycin are registered.

Human Health Assessment

EPA has waived all generic toxicology data requirements for streptomycin because extensive information is available from studies conducted on animals in support of its use as a human drug.

Toxicity

Streptomycin is of low toxicity when taken orally, and has been placed in Toxicity Category IV (indicating the lowest level of acute toxicity) for this effect. A subchronic toxicity study showed that cats receiving intramuscular injections of streptomycin lost the righting reflex in three weeks, while those receiving oral doses did not. A chronic feeding study in rats indicated that streptomycin does not have the potential to cause cancer. An antibiotic resistance study using beagle dogs showed an increase in the resistance of coliform fecal bacteria to streptomycin. The same potential may exist for the development of chemical resistance in the respiratory flora.

Streptomycin is used as an antibiotic in humans to treat urinary tract infections, usually through intramuscular injections given for seven to 10 days. A variety of allergic reactions have been observed in sensitive patients treated, including redness of the skin, rashes, hives, drop in blood pressure, headache, nausea and vomiting.

Dietary Exposure

Tolerances or maximum residue limits of 0.25 parts per million (ppm) are established in 40 CFR 180.245 for residues of streptomycin in or on celery, peppers, tomatoes, potatoes and pome fruits (apples, pears, crabapples and quinces). EPA finds that these tolerances are acceptable. However, a tolerance also must be established for streptomycin in or on succulent and dried beans.

A state Special Local Need registration for foliar treatment of sugar beets grown for seed is considered a non-food use, so no tolerance is required. Other tolerances have been established by the Food and Drug Administration and the U.S. Department of Agriculture to regulate streptomycin residues resulting from its use as a veterinary medicine.

No international Codex or Canadian tolerances are established for streptomycin. Mexican tolerances are harmonized with the U.S. tolerances.

Occupational Exposures

EPA is not requiring occupational or residential exposure monitoring data for streptomycin since considerable information is available as a result of its use for many years as an antibiotic drug. However, since streptomycin has produced allergic reactions in some human patients, pesticide products containing streptomycin must bear label statements that restrict reentry into treated fields and require the use of certain protective clothing and equipment while handling and applying these products.

Human Risk Assessment

Streptomycin has been used as a beneficial human and animal drug for many years. Using its Dietary Risk Evaluation System, EPA finds that the dietary risk from pesticide products containing streptomycin appears minimal. Regarding the problem of drug resistance, EPA has no data indicating that streptomycin pesticide residues remaining in the food supply have a significant or even a measurable potential for increasing human resistance to that drug.

Workers may be exposed to streptomycin while applying products that contain this pesticide, or while working in fields where crops have been treated. If they are among those people who are sensitive to streptomycin, workers may have an allergic response. The potential also may exist for the development of chemical resistance in the respiratory flora. To lessen this risk, EPA is requiring through product labeling several exposure and risk reduction measures including the use of protective clothing during application, and the observation of a 12-hour reentry interval after application.

Environmental Assessment

Environmental Fate

Since there are no ecological or health effects concerns with the naturally-occurring antibiotic streptomycin, EPA has waived all environmental fate data requirements except for a hydrolysis study, which is being required as confirmatory data.

Ecological Effects

EPA has reviewed the available information for streptomycin and has determined that all ecological effects data requirements are satisfied except for an aquatic invertebrate toxicity study, which is being required as confirmatory data. Streptomycin is practically non-toxic to birds, freshwater invertebrates and honey bees, and is slightly toxic to cold water and warm water species of fish. Streptomycin is toxic to algae, so precautionary labeling for all non-aquatic uses is required.

Environmental Risk Assessment

Streptomycin products, when labeled and used as described in the RED, should not pose unreasonable risks or adverse effects on non-target species or the environment. They also should not pose a significant risk to threatened or endangered species.

Additional Data Required

Additional generic (active ingredient-specific) data required for confirmatory purposes include product chemistry data on technical grade streptomycin sulfate, a hydrolysis study and an aquatic invertebrate toxicity study.

Product-specific data, including a product chemistry study for each registration and acute toxicology studies, also are required for reregistration.

Product Labeling Changes Required

The labels of all streptomycin pesticide products must comply with EPA's current pesticide labeling requirements. Current label precautions still are applicable and required. The following new or revised label statements also are required:

- Products registered for commercial use on agricultural crops and ornamentals must include in the human hazards section the restricted entry statement, "Entry into treated fields is prohibited for 12 hours following application."
- Products registered for commercial use on agricultural crops and ornamentals must include in the human hazards section the protective clothing statement, "Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Do not breathe dust or spray mist. Wear a MSHA/NIOSH approved TC-21C dust/mist filtering respirator, long sleeved shirt, pants, shoes, and chemical-resistant gloves while handling or applying this product. Wash thoroughly after handling or applying."
- All products except those used as algicides in ornamental aquaria and ponds must include in the environmental hazards section the statement, "This product may be hazardous to aquatic plants. Do not apply directly to water, areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of wastes."

Regulatory Conclusion

- All currently registered pesticide products containing streptomycin or streptomycin sulfate as the active ingredient are not likely to cause unreasonable adverse effects in people or the environment, and are eligible for reregistration.

- These products will be reregistered once certain product-specific data, revised Confidential Statements of Formula and revised labeling are received and accepted by EPA. Although the reregistration of all products will proceed in the absence of the confirmatory data, the Agency does not anticipate any changes in its regulatory position based on these confirmatory data. If the product chemistry, hydrolysis and invertebrate toxicity data identify a risk that requires modification of the RED, EPA will publish its rationale in the Federal Register and notify affected registrants of its decision.

**For More
Information**

EPA is requesting public comments on the Reregistration Eligibility Document (RED) for streptomycin and streptomycin sulfate 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 703-305-5805.

In the future, the streptomycin and streptomycin sulfate 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 streptomycin and streptomycin sulfate 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 streptomycin and streptomycin sulfate products, please contact the Registration Division (7505C), OPP, US EPA, Washington, DC 20460, telephone 703-305-7382.

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.