



R.E.D. FACTS

Fosetyl-Al (Aliette)

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 from pesticide producers and reviews a complete set of studies 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 fosetyl-Al.

Fosetyl-Al

Fosetyl-Al, which is sold under the trade name Aliette, is a systemic fungicide used to control damping-off and rot of plant roots, stems and fruit. It is applied as a plant dip treatment and a drench for transplants, by incorporating it into the soil prior to planting, and by applying it to foliage. Fosetyl-Al is registered for use on the following food crops and ornamentals, and all of these uses are eligible for reregistration:

Almonds (non-bearing)	Ginseng
Asparagus	Ornamental plants, lawn and turf
Avocados (non-bearing)	Caneberries
Pome fruits (non-bearing)	Citrus (bearing and non-bearing)
Pineapples	Stone fruits (non-bearing)

Only two pesticide products containing fosetyl-Al are registered, a technical grade product and an end use product.

Regulatory History

Fosetyl-Al was first registered by EPA in 1983. EPA issued a Registration Standard for fosetyl-Al in February 1988, after circulating a December 1986 draft for public comment.

Health Effects

All of EPA's toxicology data requirements for fosetyl-Al have been satisfied. These toxicity studies indicate the following effects.

Acute and Subchronic Health Effects

Fosetyl-Al is a severe eye irritant, but it does not irritate the skin or pose a notable inhalation hazard.

Chronic Health Effects

Some laboratory animal feeding studies indicate that fosetyl-Al has a slight degenerative effect on the testes of dogs and shows evidence of cancer effects (urinary bladder tumors) in male rats, when these test animals are fed high doses of the pesticide. Considering these and other available oncogenicity studies, EPA has classified fosetyl-Al as a category C oncogen--that is, a possible human carcinogen with limited evidence of carcinogenicity in animals. Fosetyl-Al is not a mutagen and it does not pose developmental or reproductive effects of concern.

Routes Of Exposure

Through the Diet

People may be exposed to small amounts of fosetyl-Al through the food supply. However, the amount of fosetyl-Al in the U.S. consumer's diet is far below the level at which adverse health effects could occur. The dietary risk from fosetyl-Al is very low.

Tolerances, or legal residue limits, have been established for residues of fosetyl-Al in or on food or feed crops, as follows. (Also see 40 CFR 180.415.) There are no international Codex tolerances established for fosetyl-Al.

Asparagus	0.1 ppm (California only)
Caneberries	0.1 ppm
Citrus	0.5 ppm
Ginseng root, fresh	0.1 ppm (Wisconsin only)
Pineapple	0.1 ppm
Pineapple fodder	0.1 ppm
Pineapple forage	0.1 ppm

EPA has reassessed these existing tolerances and finds that they are set at appropriate levels. They provide an adequate margin of safety to protect the public health. No new tolerances are required to cover existing uses of the pesticide.

Studies available indicate that residues of fosetyl-Al decrease rapidly in food. Most residues in crops are expected to decline to lower-than-observable levels between the last field application of the pesticide and harvest time.

During Application

People can be exposed to fosetyl-Al while applying the pesticide to field crops, lawns and turf, or ornamentals. The pesticide poses a low degree of oral, dermal and inhalation toxicity. However, fosetyl-Al is a severe eye irritant. To protect applicators, therefore, labels of products containing fosetyl-Al as the active ingredient must warn the user to wear goggles or a face shield.

Environmental Hazards

All of EPA's environmental fate and ecological effects data requirements for fosetyl-Al have been satisfied. The studies show the following.

Environmental Fate

The potential for ground water and/or surface water contamination by fosetyl-Al is expected to be very low in most cases. Fosetyl-Al degrades rapidly in soil to non-toxic components. However, the pesticide is quite persistent on vegetation. When it is applied to plant foliage, it probably can be washed off by heavy rainfall. Since it is soluble in water, susceptible to leaching, and stable to decomposition by water, fosetyl-Al may possibly leach to ground water in cases where unexpected heavy rainfall closely follows foliar application of the pesticide.

Ecological Effects

The ecological effects data base for fosetyl-Al is complete. Studies available to the Agency show that fosetyl-al does not pose a risk to birds or fish. Two newly submitted studies also show that fosetyl-Al is practically non-toxic to honey bees, and does not adversely effect aquatic plants.

Risks to Non-Target Species

Fosetyl-Al poses no risk to non-endangered species. However, pesticides that are similar to fosetyl-Al and have similar use patterns have been found to pose a hazard to endangered species. It is possible that use of fosetyl-Al on apples and pears may pose undue risks to endangered freshwater mussels as residues of the pesticide run off into adjacent ponds. EPA has therefore initiated a consultation with the Office of Endangered Species of the Fish and Wildlife Service (FWS) regarding the use of this pesticide on pome fruits. No labeling changes are being required at this time, but they may be required in the future as a result of the ongoing EPA/FWS consultation.

Additional Data Required

EPA has sufficient data to support reregistration of the two currently registered products containing fosetyl-Al; no further generic or product-specific data are required.

Product Labeling Changes Required

The end-use fosetyl-Al product label must include an additional water contamination warning, and a reentry and protective clothing statement. End-use products with citrus use on the label must also bear a grazing restriction. Please see the Reregistration Eligibility Document for a detailed list of labeling requirements.

Regulatory Conclusion

- * EPA has some data indicating that fosetyl-Al is a possible human cancer agent. However, the cancer evidence was observed only in certain studies, and then only in test animals fed the highest dose levels of the pesticide, far in excess of the amount to which people may be exposed.
- * Fosetyl-Al's eye irritation risk to applicators can be managed by product labeling that requires protective clothing, especially goggles or a face shield.
- * An endangered species concern has been identified but no conclusion has been reached. This concern may result in additional label requirements later.

In summary, EPA has sufficient data on fosetyl-Al to conduct a reasonable risk assessment and to determine that the pesticide can be used without causing unreasonable adverse effects in people or the environment. Therefore, the two registered products containing fosetyl-Al are eligible for reregistration. These products will be reregistered once revised labeling is submitted to and accepted by EPA.

For More Information

EPA will accept and consider public comments on the Reregistration Eligibility Document for fosetyl-Al for several months. To obtain a copy, or to submit written comments, please contact the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, U.S. EPA, Washington, D.C. 20460. Call 703-557-4436, or fax to 703-557-1884.

To obtain a copy of the Registration Standard for fosetyl-Al, please contact the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA. 22161. Call 703-487-4650, and request document #PB84206564.

For more information about fosetyl-Al or EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (7508W), Office of Pesticide Programs, U.S. EPA, Washington, D.C. 20460. Call 703-308-8000, or fax your request to 703-308-8005.

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.