United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-005 January 1995

R.E.D. FACTS

Fosamine ammonium

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 2355, fosamine ammonium.

Use Profile

Fosamine ammonium is an herbicide/plant growth regulator used to control brush and herbaceous plants on noncropland. It is applied to nonagricultural rights-of-way (e.g. highways, railroads, and utilities), industrial sites, and fencerows.

Fosamine ammonium is formulated in end use products as a water soluble liquid. It is applied once per year from Spring to early Fall, by aircraft, backpack and handwands. After application, the brush control effects of the pesticide are achieved by inhibiting bud growth the following year.

Use practice limitations prohibit fosamine ammonium from being used on croplands or in irrigation systems. It may not be applied directly to water, or areas where surface water is present, including intertidal areas. Soils treated with this herbicide cannot be converted to food/feed croplands within one year of treatment.

Fosamine ammonium is not registered for use in California and Arizona.

Regulatory

Fosamine ammonium was first registered as a pesticide in the U.S. in

History

1975. It was registered for non-cropland (non-food use) areas such as railroads, pipelines, utility and highway rights-of way, reforestation areas, drainage ditch banks, storage areas, industrial plants, and other similar sites. However, this product was voluntarily cancelled on June 22, 1994.

A second product was registered in 1980 with the same uses as the original product except for reforestation uses. This product currently is marketed under two trade names. The registrant requested to voluntarily cancel direct applications to water, ditch banks, and to other sites which are adjacent to and surrounding domestic water supply reservoirs, supply streams, lakes and ponds. The Agency is processing this request, which involves publishing a Notice of Intent to delete these uses in the Federal Register. Because there are no other current registrants and there are outstanding environmental data requirements to support continued registration of these uses, the Agency expects that these sites will be deleted from the label by early 1995.

Human Health Assessment

Toxicity

Fosamine ammonium is classified as Toxicity Category II for acute dermal studies in mammalian species. This classification represents the second most severe level of acute toxicity for studies using laboratory animals (Toxicity Category I is the highest). Fosamine ammonium is very mildly toxic for acute oral and acute inhalation (Toxicity Category IV), and is not a dermal sensitizer.

In one subchronic oral study, the laboratory animals given the highest dose of fosamine ammonium exhibited some statistically significant effects, including effects to the kidneys, bladder and decreases in body weight. There were no subchronic neurotoxic effects of fosamine ammonium at any dose level.

Fosamine ammonium displayed some mutagenic potential in one in vitro test for chromosome aberrations, while four other tests were negative for mutagenic potential.

Dietary Exposure

Since there are no registered food uses for fosamine ammonium, no dietary exposure is expected.

Occupational and Residential Exposure

Based on current use patterns, workers may be exposed to fosamine ammonium during and after application of the pesticide. Worker exposure estimates are based on the assumption that workers wear long pants, long sleeved shirt, shoes, and no gloves, except for workers using backpacks (who are assumed to wear chemical resistant gloves). The primary route of exposure to fosamine ammonium is expected to be dermal. Another potential route of exposure is through inhalation. However, based on the exposure assumptions, the potential for inhalation exposure is negligible.

Human Risk Assessment

Since no food uses are registered, fosamine ammonium poses no human dietary risks. Regarding acute toxicity, fosamine ammonium falls in Toxicity Category II for acute dermal exposure. However, the mild skin effects observed with this chemical do not trigger any significant toxicological concerns. The herbicide/plant growth regulator is of low toxicity by the oral and inhalation routes. Based on the mixed results of studies suggesting mutagenetic potential, the Agency is requiring additional testing with germ cells as a confirmatory study.

Based on the current use pattern of fosamine ammonium, the estimated exposure to workers, which is likely to reflect a worse-case scenario, does not pose a serious threat to workers. However, there are no known significant acute or chronic toxicological endpoints that warrant the establishment of risk mitigation measures or minimum personal protective equipment (PPE) requirements to protect handlers of the pesticide. Clothing as described in the exposure assessment will provide adequate protection to handlers. In addition, EPA is requiring application restrictions and user safety recommendations on end-use product labeling.

Environmental Assessment

Environmental Fate

Fosamine ammonium is not very persistent under aerobic or anaerobic conditions and degrades rapidly in most soils. Dissipation of fosamine ammonium is dependent on rapid, microbial mediated degradation. Thus, in field studies fosamine ammonium was found to be highly soluble in water and is mobile in various soils. However, in the sterile conditions of the laboratory, fosamine ammonium is stable to hydrolysis. Although fosamine ammonium is a mobile compound, there is little evidence that leaching is a major route of dissipation. Data on the residues of fosamine ammonium indicate they are also relatively mobile.

Fosamine ammonium may be found in surface waters with low microbiological activities or long hydrological residence times.

Exposure of fosamine ammonium to non-target aquatic plants can result from spray drift from treated areas, surface runoff, or wind blown soil particles. However, no acute risk quotients exceed the level of concern, so no acute effects to aquatic plants are expected from the normal use of fosamine ammonium.

The risk to terrestrial non-target plants cannot be determined until Tier I and Tier II data requirements have been fulfilled. Results of the most sensitive terrestrial plant species tested are needed in order to conduct an acute risk assessment.

Any movement of fosamine ammonium from the treatment site via spray drift, surface runoff, or wind blown soil particles can adversely affect non-target and endangered/threatened plants. Direct application of rights-of-way are a special concern, because large numbers of endangered plants grow in rights-of-way areas. Thus applications of fosamine ammonium at

the registered rates may pose a significant risk to endangered plant species inhabiting treated rights-of-way.

EPA has been working with the U.S. Fish and Wildlife Service and other federal and state agencies to develop a program to avoid jeopardizing endangered species. The Endangered Species Program is expected to be final soon. Further limitations on the use of fosamine ammonium may be imposed at that time.

Further droplet size spectrum and field drift studies are due to the Agency at the end of June 1995 as part of the spray drift data requirements to be submitted by the Spray Drift Task Force. If the new data suggest substantially different drift potential, the Agency will reassess its impact on the associated environmental risks at that time.

Ecological Effects

Exposure to non-target aquatic organisms can result from spray drift and runoff from treated areas. However, acute effects to freshwater fish and aquatic invertebrates are not expected from the normal use of fosamine ammonium. Fosamine ammonium is practically nontoxic to coldwater and warmwater fish, and does not appear to bioaccumulate in fish. However, a nine percent fish mortality was observed in the accumulation in fish study. Fosamine ammonium is practically nontoxic to freshwater invertebrates and to estuarine species.

Fosamine ammonium is practically nontoxic to honey bees, which are used to assess the effects on non-target insects.

Fosamine ammonium is practically nontoxic to avian species on an acute oral and a subacute dietary basis. Mixed results were found in the avian reproductive studies. In one mallard duck study, there was some indication of chronic reproductive effects. However, in another avian reproductive study, using the bob white quail as the test organism, there were no reproductive effects at any dose level.

Fosamine ammonium is practically nontoxic to small mammalian species. Acute oral and subacute dietary risks to non-endangered and endangered non-target mammals are not expected to result from current label uses.

Ecological Effects Risk Assessment

Based on the data, fosamine ammonium dissipation is predominantly dependent on rapid microbial-mediated degradation. It is also mobile in mineral soils. However, fosamine ammonium should not pose a threat to groundwater or surface waters because it rapidly degrades in aerobic and anaerobic environments. There are no Maximum Concentration Levels

(MCLs) or drinking water health advisories for fosamine ammonium or its degradates.

The health and environmental data on fosamine ammonium indicate a low level of toxicity of this pesticide. However, the inconclusive results in the avian reproductive studies have led the Agency to require a new mallard duck reproduction study on a confirmatory basis. In addition, risk mitigation measures are required to reduce the potential for avian reproductive effects.

Additional Data Required

EPA is requiring the following additional generic data for fosamine ammonium to confirm its regulatory assessments and conclusions: Certification of limits (62-2), Avian reproduction, mallards (71-4b), In-vivo cytogenetics (84-2a), Droplet size spectrum and field drift data (201-1, 202-1), Method validation for worker exposure (231, 232), Terrestrial plant (122-1, 123-1), and Aerobic aquatic (164-2, 162-4) if aquatic sites are not deleted.

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 fosamine ammonium end-use products must comply with EPA's current pesticide product labeling requirements, and with the following:

a) Within the Environmental Hazards section of the Precautionary Statement of the label:

> "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate."

b) To reduce environmental loading and potential exposure to non-target species, the product label must include language to limit use as outlined below:

> i) the end-use product can be applied only once annually during the period after spring growth has hardened to the development of fall coloration in deciduous species, and
>
> ii) the maximum application rate for low shrubs/brush is 16 lb a.i./A, and for tall dense woody species with very heavy foliage can be 24 lb a.i./A.

c) The end-use product labels cannot include directions for applications to aquatic sites. The current, sole registrant has submitted an application for amended registration to delete these uses from its product registration. Future submissions of appropriate data to support registration for these uses will be considered by the Agency.

d) The Agency is requiring the following labelling statements to be located on all end-use products containing fosamine ammonium:

> Application Restrictions:

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during applications."

Entry Restrictions

The Agency is establishing the following entry restrictions for the occupational uses of fosamine ammonium end-use products:

For liquid applications:

"Do not enter or allow others to enter the treated area until sprays have dried."

Other Labelling Requirements:

User Safety Recommendations:

"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

"Users should remove clothing immediately after handling this product. If gloves are worn, wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

These statements must be included on the labels, as they are appropriate, after product-specific PPE requirements are set by the Agency. Although it is not required under the current labeling, it is assumed that the workers wear long pants, long sleeved shirts, shoes, and socks.

Regulatory Conclusion

The use of currently registered products containing fosamine ammonium in accordance with approved labeling, except use in aquatic sites, will not pose unreasonable risks or adverse effects to humans or the environment. The registrant has voluntarily requested cancellation of the aquatic uses. The Agency is not including the aquatic uses in its eligibility decision, because of the inadequate environmental data and the impending deletion of those uses from all current registrations. Therefore, all uses of fosamine ammonium products, other than application to aquatic sites, are considered eligible for reregistration.

Fosamine ammonium 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 fosamine ammonium 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 fosamine ammonium 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 fosamine ammonium RED, or reregistration of individual products containing fosamine ammonium, 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 6:00 pm Central Time, Monday through Friday.