US ERA ARCHIVE DOCUMENT



SEPA R.E.D. FACTS

N6-Benzyladenine

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 for reregistration Case 2040, N6-Benzyladenine.

Use Profile

N6-Benzyladenine is a plant growth regulator used on certain fruit and white pine trees, calla lily tubers, and spinach grown for seed. It enhances the size and shape of fruit, lateral bud break and lateral shoot growth, leading to improved branching in fruit trees and fuller white pine trees. It causes an increase in the number of calla lily flowers while decreasing time lag between first and second flowering. It also causes uniform bolting and increased seed production in spinach. N6-Benzyladenine is formulated as a soluble concentrate/liquid, and is applied using spray, brush-on and sponge-on techniques.

Regulatory **History**

N6-Benzyladenine was first registered as a pesticide in the U.S. in 1979. In January 1990, EPA classified it as a biochemical pesticide because it resembles natural plant growth regulators and uses a non-toxic mode of action. Currently, three products are registered and there are two Special Local Need registrations.

Human Health Assessment

Toxicity

In acute toxicity studies, N6-Benzyladenine is slightly toxic by the oral route and produces moderate eye irritation; it has been placed in Toxicity Category III (the second-to-lowest of four categories) for these effects. It is of relatively low acute dermal and inhalation toxicity, and is only a slight irritant to the skin; it has been placed in Toxicity Category IV for these effects. N6-Benzyladenine does not appear to be a skin sensitizer or mutagenic.

In a subchronic toxicity study using rats, N6-Benzyladenine caused decreased food consumption, decreased body weight gain, increased blood urea nitrogen, and minimal changes in kidney tissue. It shows some evidence of causing developmental toxicity and maternal toxicity.

Dietary Exposure

Although N6-Benzyladenine has two food crop-related uses (on fruit-bearing apple trees and spinach grown for seed), it is exempt from the requirement of a tolerance because it is a biochemical pesticide used at a rate of less than 20 grams of active ingredient per acre. Therefore, the Agency will revoke the existing tolerance and establish an exemption from the requirement of a tolerance for the currently registered uses of this pesticidal compounds on apples and spinach.

Because the use rate is low and application precedes harvest by approximately four months, the potential for dietary exposure is considered to be negligible.

Occupational and Residential Exposure

Pesticide workers (mixers, loaders and applicators) may be exposed to N6-Benzyladenine during application. Dermal exposure is expected to be moderate to high for workers who open, pour, mix and load the pesticide, and to applicators using hand sprayers and air blast equipment.

To reduce worker exposure, EPA is requiring use of the personal protective equipment (PPE) and Restricted Entry Interval set forth in the Agency's Worker Protection Standard (WPS). Because formulated products that contain N6-Benzyladenine are in Toxicity Category II, use of the following PPE is required: long-sleeved shirt and pants, socks, chemical-resistant footwear, chemical-resistant gloves, respiratory protection devices, and protective eyewear. Although the PPE requirement is based on the acute toxicity of the end-use product, it will mitigate exposure substantially and thus will serve to protect pesticide handlers from potential developmental toxicity effects. Further, the Restricted Entry Interval of 12 hours set forth in the WPS will be required, reducing the risks of post-application exposure to N6-Benzyladenine.

Human Risk Assessment

N6-Benzyladenine is of moderate to relatively low acute toxicity, but has been demonstrated to cause developmental toxicity and maternal toxicity in laboratory animals. The potential for dietary exposure is negligible. Applicator exposure and risk of developmental and maternal toxicity will be reduced through use of personal protective equipment (PPE) and the Restricted Entry Interval (REI) set forth in the Worker Protection Standard (WPS).

Environmental Assessment

Environmental Fate

Environmental fate studies were not required for N6-Benzyladenine because it is a biochemical pesticide. Soil metabolism studies indicate that it has a half-life of 7 to 9 weeks.

Ecological Effects

N6-Benzyladenine does not cause adverse effects to nontarget avian or aquatic species. It is practically nontoxic to birds, and slightly toxic to fish and freshwater invertebrates.

Ecological Effects Risk Assessment

Use of N6-Benzyladenine is not expected to pose a significant risk to terrestrial or aquatic organisms. Further, no risk to endangered species is anticipated.

Additional Data Required

EPA is requiring several generic studies as confirmatory information, including additional data for analysis of samples, a dermal sensitization study, and a mutagenicity study.

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, as well as revised Confidential Statements of Formula (CSF) and revised labeling for reregistration.

Product Labeling Changes Required

All N6-Benzyladenine end-use products must comply with EPA's current regulations and labeling requirements, and the following:

Worker Protection Standard (WPS) - All N6-Benzyladenine products within the scope of the Worker Protection Standard (WPS) for Agricultural Pesticides (see PR Notice 93-7) must, within the timeframes listed in PR Notices 93-7 and 93-11, revise their labeling to be consistent with the WPS, as directed in those notices and the requirements of the RED.

Restricted Entry Interval (REI) - The 12 hour REI set forth in the WPS is required. Labels must bear this Reentry Restriction:

- Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

Personal Protective Equipment (PPE) Requirements - Pesticide handlers must wear:

- --coverall over short sleeved shirt and short pants;
- --chemical-resistant gloves;
- --chemical-resistant footwear plus socks;
- --chemical-resistant headgear for overhead exposure;
- --respiratory protection devices;
- --protective eyewear
- --chemical-resistant apron when cleaning equipment, mixing, or loading.

Regulatory Conclusion

The use of currently registered pesticide products containing N6-Benzyladenine in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

These products will be reregistered once the required confirmatory generic data, product specific data, Confidential Statements of Formula and revised labeling are received and accepted by EPA.

Products which contain active ingredients in addition to N6-Benzyladenine will be reregistered when all of their other active ingredients also are eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for N6-Benzyladenine during a 60-day time period, as announced in a Notice of Availability published in the <u>Federal Register</u>. 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.

Following the comment period, the N6-Benzyladenine RED document 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 N6-Benzyladenine RED, or reregistration of individual products containing N6-Benzyladenine, 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, from 8:00 am to 6:00 pm Central Time, Monday

through Friday.