

US EPA ARCHIVE DOCUMENT



R.E.D. FACTS

Pesticide Reregistration

Terbuthylazine

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 appropriate 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 2645, terbuthylazine.

Use Profile

Terbuthylazine is an algicide, microbicide and microbiostat used to control slime-forming algae, fungi, and bacteria. It is registered for use in commercial and industrial water cooling systems, and in residential and commercial ornamental ponds, fountains and aquaria. Terbuthylazine is formulated as a soluble concentrate/liquid, and is applied as a continuous feed or intermittent slug treatment, using either open pouring or closed system methods.

Use practice limitations currently require users to preclean systems before applying the pesticide, and prohibit: discharge of effluent containing the pesticide into sewage systems without notifying the sewage treatment plant authority; discharging effluent containing the pesticide into lakes, streams, ponds, estuaries, oceans, or public waters; use where treated water will come into contact with lawns, trees, shrubs, or other desirable plants since injury may result; and using water from treated systems for irrigation or spraying of agricultural crops, lawns, or ornamental plants, or for watering cattle, goats, hogs, horses, poultry or sheep, or for human consumption.

Regulatory History

Initially, in 1975, terbutylazine was registered as a herbicide in the U.S., and several tolerances for residues in food and feed were established. However, since no end-use products were registered for these uses, the tolerances were revoked in 1992. Meanwhile, in 1986, algicide and microbicide/microbistat end-use products were registered. EPA has issued four Data Call-In notices for terbutylazine. Five products currently are registered.

Human Health Assessment

Toxicity

Terbutylazine generally is of relatively low acute toxicity. It has been placed in Toxicity Category III, the second-to-lowest of four categories, for acute oral, dermal, and inhalation effects. Terbutylazine is mildly to moderately irritating to the eyes, and slightly irritating to the skin, and has also been placed in Toxicity Category III for these effects. It is not a skin sensitizer.

In a subchronic toxicity study using rats, terbutylazine caused decreased body weight gain as well as decreased thymic, kidney and liver weights. A study using rabbits resulted in decreased body weight gain and food consumption, and mortality in one female. In another rabbit study, all the animals developed difficulty in breathing, piloerection, sedation, curved body posture, dermal irritation, and decreased body weight gain and food consumption.

In chronic toxicity and carcinogenicity studies using mice and rats, decreases in body weight gain and food consumption were observed. Two studies using mice and rats caused no increase in tumors. However, a third study using rats caused an increased incidence of testicular tumors in males and mammary gland carcinomas in females, but only at a dose at which excessive systemic toxicity also was observed. Based on this study, EPA's Carcinogenicity Peer Review Committee has classified terbutylazine as a Group D carcinogen--one for which there is inadequate evidence to determine carcinogenicity in humans.

Terbutylazine caused no signs of developmental toxicity in a study using rabbits. However, in a study using rats, maternal toxicity was observed as reduced body weight gain and food intake, and developmental toxicity was observed in the litter as a lack of bone formation in one toe. Reproductive toxicity data is not available, but will be required if food uses are proposed in the future. Available studies indicate that terbutylazine is not mutagenic.

Dietary Exposure

Dietary exposure to terbutylazine is not expected since no products with food uses currently are registered.

Occupational and Residential Exposure

Workers may be exposed to terbutylazine during applications in commercial/industrial settings. In addition, workers may be exposed to this pesticide after application, while cleaning or maintaining water cooling towers, and other people (including children) may be exposed while wading or swimming in treated ornamental ponds or fountains. Because of the use patterns and dilution factors involved, however, EPA believes that post-application exposure to terbutylazine in both commercial and residential settings is minimal.

Since terbutylazine is associated with developmental toxicity effects, EPA assessed the risks to workers who apply this pesticide using the open pouring method compared to the metering pump method. The Agency found that the risk to commercial applicators who routinely use the open pouring method is unacceptable. Margins of Exposure (MOEs) for these workers are very low for both typical and high use rates, both short- and intermediate-term. However, MOEs for workers using closed pump systems are well above 100, the margin generally considered acceptable. MOEs for workers using both open pouring and metering pump methods in residential settings also are acceptably high.

EPA therefore is prohibiting commercial applications of terbutylazine using the open pouring method, and is requiring use of closed systems along with certain personal protective equipment (PPE), to reduce exposure and risk to acceptable levels for all commercial uses.

Human Risk Assessment

Terbutylazine is of relatively low acute toxicity, and is classified as a Group D carcinogen because there is inadequate evidence to determine its carcinogenicity in humans. However, it is associated with developmental toxicity in a study using rats.

Terbutylazine has no food-related uses at present so dietary exposure is not of concern. However, workers are exposed while applying this pesticide in commercial/industrial and residential settings, using open pouring and closed system methods. EPA has found that the risk to commercial/industrial workers using open pouring methods is unacceptable. The Agency is prohibiting open pouring methods for commercial/industrial uses of terbutylazine, and requiring use of closed systems with PPE in commercial/industrial settings.

Environmental Assessment

Environmental Fate

Terbutylazine is stable to hydrolysis, and to aqueous photolysis. It degrades very slowly under aerobic aquatic conditions, and will persist under most aquatic conditions.

Ecological Effects

Terbuthylazine is practically nontoxic to birds on an acute and subacute dietary basis. However, it is moderately toxic to both cold and warm water fish, slightly toxic to aquatic invertebrates, and highly toxic to estuarine/marine invertebrates from acute exposures. Terbuthylazine is expected to be phytotoxic to aquatic plants because it belongs to the triazine family (which includes many herbicides), is released to waterways, and dissipates slowly in the environment.

Ecological Effects Risk Assessment

No significant risks to birds or mammals are expected from use of terbuthylazine. Although terbuthylazine is moderately toxic to fish and slightly toxic to freshwater invertebrates, these species are not expected to be at risk under typical use and exposure scenarios. In high exposure situations, however, levels of concern for high risk, restricted use, and endangered species are met or exceeded. Because its use patterns are not associated with estuarine or marine environments, significant risk to estuarine/marine invertebrates is not expected. Phytotoxicity to aquatic plants is anticipated, and EPA has required relevant studies as confirmatory data.

Risk Mitigation

EPA is requiring the following risk mitigation measures for terbuthylazine, as discussed earlier:

- To reduce risks to commercial/industrial applicators, EPA will prohibit open pouring methods and require that only closed system methods of application, with specified PPE, be used for commercial application of terbuthylazine.
- To adequately mitigate potential risks to fish, freshwater invertebrates, and aquatic plants from release of effluent to waterways:
 - EPA will coordinate regulatory oversight of terbuthylazine under FIFRA, the federal pesticide law administered by the Agency's Office of Pesticide Programs, and the National Pollutant Discharge Elimination System (NPDES) administered by the Office of Water in conjunction with the states.
 - EPA will require compliance with the Endangered Species Protection Program when it goes into effect.

Additional Data Required

The generic database supporting terbuthylazine is substantially complete. Confirmatory data measuring the toxicity of this pesticide to aquatic plants were recently required of registrants, and must be submitted to EPA by January 1996. 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 terbutylazine end-use products must comply with EPA's current pesticide product labeling requirements, and with the following:

Effluent Discharge Labeling Statements

All end-use products that may be contained in an effluent discharged to the waters of the U.S. or municipal sewer systems must bear the effluent discharge labeling statements described in PR Notice 93-10.

Other Labeling Requirements

Except where indicated otherwise, the following statements must appear on all end-use products containing terbutylazine that are intended primarily for industrial use:

Application Restrictions:

For products intended for industrial use:

"Open pouring of this product is prohibited."

"Mixing, loading, and application must be with a closed system (one that prevents the chemical from contacting handlers or other persons) and during handling of the chemical personal protective equipment must be worn. Personal protective equipment includes a long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves. A chemical-resistant apron must be immediately available during loading and application and must be worn in case of a leak, spill, or other exposure to the concentrate."

For products intended for homeowner use:

"Persons that mix, load, or apply this product must wear a long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves."

User Safety Requirements:

"Follow manufacturer's instructions for cleaning/maintaining Personal Protective Equipment. If no such instructions for washables exist, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry."

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 personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

**Regulatory
Conclusion**

Currently registered pesticide products containing the active ingredient terbutylazine, labeled and used as specified in the RED document, will not pose unreasonable risks or adverse effects to humans or the environment.

Therefore, all uses of these products are eligible for reregistration. Terbutylazine 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 terbutylazine 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 terbutylazine 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 terbutylazine RED, or reregistration of individual products containing terbutylazine, 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.