



R.E.D. FACTS

Tebuthiuron

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 tebuthiuron.

Use Profile

Tebuthiuron is a relatively nonselective, soil activated herbicide that acts by inhibiting photosynthesis. It is used to control broadleaf and woody weeds, grasses and brush on feed crop sites (pasture and rangeland) and a variety of non-food crop sites including airports/landing fields, outdoor industrial areas, non-agricultural rights-of-way, fencerows, hedgerows, uncultivated areas/soils, and under paved roads and sidewalks in areas where no future landscaping is planned. Primary uses include rangeland and near railroads and other industrial facilities.

Single active ingredient formulations include granular, pelleted/tableted, wettable powder, water dispersible granules, and technical grade/solid products. Three multiple active ingredient formulations (granulars) also are registered. All formulations may be applied as broadcast, banded or spot treatments using ground equipment. The pelleted/tableted formulations also may be applied using aerial equipment.

Regulatory History

Tebuthiuron was first registered as a pesticide in the U.S. in 1974. EPA issued a Registration Standard for tebuthiuron in July 1987 (NTIS #PB87-231866), which identified the potential for groundwater contamination as well as hazards to endangered plant species from use of tebuthiuron on pasture and rangeland, and which required additional generic data.

In 1988, EPA issued a Ground Water Data Call-In which required a small scale retrospective ground water monitoring study. A 1991 Data Call-In required residue chemistry studies on residues in meat and milk. In 1992, the technical producer stopped supporting the only aquatic use site (ditchbanks).

Currently, 12 pesticide products are registered which contain the active ingredient tebuthiuron.

Human Health Assessment

Toxicity

In acute toxicity studies, tebuthiuron is moderately toxic by the oral route. It has been placed in Toxicity Category II for this effect in rats, rabbits and cats, and in Category III for mice and dogs. (Category I indicates the greatest degree of acute toxicity and IV the least.) Tebuthiuron is practically non-toxic by the dermal route (Toxicity Category IV), and only slightly toxic by the inhalation route (Toxicity Category III). The pesticide is not a dermal irritant, causes only slight irritation to the eyes (Toxicity Category IV), and is not a dermal sensitizer.

Tebuthiuron does not appear to cause any adverse developmental or reproductive effects. Based on an acceptable carcinogenicity study in rats and two supplemental carcinogenicity studies in mice, in which no compound-related carcinogenic effects were observed, tebuthiuron is classified as a Group D carcinogen (not classifiable as to human carcinogenicity). The available data indicate that tebuthiuron does not appear to be mutagenic.

Dietary Exposure

Tolerances or maximum residue limits are established for residues of tebuthiuron on grass hay and forage; in the meat of cattle, goats, horses and sheep; and in milk (see 40 CFR 180.390). A reduction in the grass hay and forage tolerance from 20 ppm to 10 ppm is recommended since residues do not typically exceed the lower value.

EPA's worst-case exposure estimates indicate that the overall U.S. population is exposed to 9% of the Reference Dose (RfD) or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. Non-nursing infants (up to 1 year old) are exposed to 32% of the RfD, and children age 1-6 are exposed to 21% of the RfD. The effect of

concern is depressed body weight gain, as observed in a rat reproduction study.

This worst-case estimate of tebuthiuron's chronic dietary risk assumes that residues are at tolerance level and that 100% of all commodities are treated. Actual exposure is less, and dietary risks are considered minimal.

Occupational and Residential Exposure

Pesticide handlers (mixers, loaders and applicators) may be exposed to tebuthiuron during normal mixing and loading operations, to mists during spray applications, and to dusts during application of solid formulations. This exposure is by inhalation and to the skin. However, tebuthiuron is of sufficiently low toxicity that exposure monitoring data are not required. The potential for post-application exposure is low due to the nature of the registered use sites. Again, since the pesticide is of relatively low toxicity, post-application/reentry data are not required.

Human Risk Assessment

Although tebuthiuron is moderately toxic by the oral route, it is only slightly toxic by inhalation and is practically non-toxic through the skin. It is not a skin irritant or sensitizer, and causes only slight irritation to the eyes. Tebuthiuron does not appear to cause developmental or reproductive effects, to be mutagenic or to cause cancer.

People may be exposed to residues of tebuthiuron in meat or milk. The dietary risk from this exposure, however, appears to be minimal. Occupational pesticide users (mixers, loaders and applicators) also may be exposed to tebuthiuron by inhalation and through the skin. The risks of this exposure again are considered minimal due to the pesticide's low toxicity.

Environmental Assessment

Environmental Fate

Tebuthiuron is persistent and mobile and can leach to ground water, as indicated by a small-scale retrospective ground water study. It is resistant to biological and chemical degradation, and its principle route of dissipation in the environment appears to be mobility. Transport to ground water through leaching and to surface water through run-off are likely as a result of tebuthiuron's persistence and low adsorption to soil. Tebuthiuron has been detected in ground water in Texas and California. The Agency is concerned about the potential for ground water contamination from registered uses of tebuthiuron.

Ecological Effects

Tebuthiuron is practically nontoxic on an acute basis to birds, fish and aquatic invertebrates, but is slightly toxic to mammals. Current registered uses of tebuthiuron should not pose a hazard to terrestrial or aquatic organisms. However, tebuthiuron may pose a significant risk to on- and off-site endangered terrestrial, semi-aquatic, and aquatic plant

species and may also have adverse effects on other off-site non-target plants.

Ecological Effects Risk Assessment

Application of tebuthiuron to rangeland (the most typical use pattern) exceeds the Agency's high level of concern for nontarget terrestrial and aquatic plants. Each application of tebuthiuron compounds this hazard due to the pesticide's extremely long half-life. By reducing the maximum application rates and limiting the frequency of applications to once every three years, EPA expects to reduce the risk to non-target plants.

All registered uses of tebuthiuron pose a significant risk to off-site endangered terrestrial, semi-aquatic and aquatic plant species. Further, all endangered species in certain use areas, such as rangelands and rights-of-way, are likely to be jeopardized as they may receive direct applications of tebuthiuron. EPA may require additional labeling and use modifications when implementing the Endangered Species Protection Program.

Additional Data Required

EPA is requiring additional generic confirmatory data for tebuthiuron including two product chemistry studies (Preliminary Analysis and Analytical Methods to Verify Certified Limits). The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula, and revised labeling for reregistration.

Product Labeling Changes Required

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

Worker Protection Standard (WPS) - The current registered uses of tebuthiuron do not include uses associated with the production of an agricultural plant on/in any farm, forest, nursery, or greenhouse. Thus, tebuthiuron, as currently registered, does not fall within the scope of the Worker Protection Standard for Agricultural Pesticides and the requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)," and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7," concerning the Agency's labeling regulations for worker protection statements (40 CFR 156, subpart K) are not applicable to tebuthiuron end-use products at this time.

Personal Protective Equipment (PPE) Requirements

Registrants must compare the following PPE requirements with those (if any) on their current labeling and retain the more protective. Labeling must bear the following minimum PPE requirement:

- "Applicators and other handlers must wear:
 - Long sleeved shirt and long pants
 - Shoes plus socks"

In addition, gloves are required if the product is in Toxicity Category I, II, or III for acute dermal toxicity or skin irritation potential. The glove statement must be one of the following:

- "Waterproof gloves" for dry formulations or for formulations where water is the only solvent;
- "Chemical-resistant gloves" for all other formulations.

See PR Notice 93-7 for additional guidance on glove selection.

Ground Water Label Advisory - Due to its persistence and mobility in the environment, tebuthiuron end-use products must bear the following Label Advisory:

"This chemical is known to leach through soil into ground water under certain conditions as a result of registered (rangeland and non-crop) uses. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination".

"A shallow water table is defined as depth to water table of 30 feet or less. Permeable soils include, but are not limited to sandy soils."

Additional use restrictions will be required for areas vulnerable to ground water contamination, once these areas are identified (within 4 months after issuance of this RED).

Use Rates and Number of Applications - The following maximum application rates and number and frequency of applications must be included in the Directions for Use section of the label, to reduce the potential for ground water contamination and the risks to non-target plants:

- Granular, Pelleted/Tableted, and Water Dispersable Granules (Dry Flowable) Formulations

For vegetation control by broadcast (aerial and ground equipment) and banded applications: The maximum label rate and frequency of application is 1-2 lbs ai/a once every three years for vulnerable areas (where soils are sandy and depth to water table is shallow) as identified in the specific soil series labeling supplement. For all other areas, may be applied one time in a 3 year period at rates up to 4 lb ai/A; however, no more than 6 lb ai/A may be applied in two consecutive treatments in any 6 year period.

Spot Treatments (hand-held equipment): May be applied at rates up to the equivalency of 6 lb ai/A when needed.

- Wettable Powder Formulation

For vegetation control by broadcast and banded applications (ground equipment): The maximum label rate and frequency of application is 1-2 lbs ai/a once every three years for vulnerable areas (where soils are sandy and depth to water table is shallow) as identified in the specific soil series labeling supplement. For all other areas, may be applied one time in a 3 year period at rates up to 4 lb ai/A; however,

no more than 6 lb ai/A may be applied in two consecutive treatments in any 6 year period.

For total vegetation control and maintenance of bare ground by broadcast and banded applications (ground equipment): may be applied one time per year at rates up to 4 lb ai/A; however, no more than 6 lb ai/A may be applied in any 3 year period.

Spot treatments (hand-held equipment): may be applied at rates up to the equivalency of 6 lb ai/A when needed.

Other Labeling Requirements (Environmental Hazard Statement)

Granular and Pelleted/Tableted Formulations

"In case of spills, collect, cover or incorporate granules/pellets spilled on the soil surfaces to prevent contamination to water. Do not apply 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".

Wettable Powder and Water Dispersable Granular (Dry Flowable) Formulation

"Do not apply 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".

Regulatory Conclusion

Based on reviews of the generic data for the active ingredient tebuthiuron, EPA has determined that tebuthiuron products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, products containing tebuthiuron for all registered uses are eligible for reregistration.

Products that contain tebuthiuron as the sole active ingredient will be reregistered once the required confirmatory generic data, product specific data, revised Confidential Statements of Formula and revised labeling are received and accepted by EPA. Products which also contain other active ingredients will be reregistered after the other active ingredients are determined to be eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for tebuthiuron 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.

Following the comment period, the tebuthiuron 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 tebuthiuron RED, or reregistration of individual products containing tebuthiuron, 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.