United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-97-011 January 1998

EPA **R.E.D. FACTS**

Terbacil

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 before November 1, 1984, 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. To implement provisions of the Food Quality Protection Act of 1996, EPA considers the special sensitivity of infants and children to pesticides, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with common mechanisms of toxicity. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that meet the safety standard of the FQPA and can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0039, Terbacil.

Use Profile

Terbacil is a selective herbicide used to control broadleaf weeds on terrestrial food/feed crops (e.g., apples, mint/peppermint/spearmint, sugarcane, and ornamentals), forestry [e.g., cottonwood (forest/shelterbelt)], terrestrial food (e.g., asparagus, blackberry, boysenberry, dewberry, loganberry, peach, raspberry, youngberry and strawberry), and terrestrial feed (e.g., alfalfa, sainfoin (hay and fodder), and forage).

Formulations include a wettable powder and products are applied by aircraft or ground equipment including boom sprayers.

Use practice limitations include prohibition of applications through any type of irrigation system. They also prohibit grazing treated crops or allowing hay, seeds or seed screening from treated crops to be used for food

or feed. Grazing or feeding forage or hay from treated areas to livestock is prohibited.

Regulatory History

Terbacil was first registered for use as a herbicide in the U.S. in 1966. EPA issued a Registration Standard for terbacil in May 1982. In August 1989 a Registration Standard (Second Round Review) was issue for terbacil. This document reviewed data submitted in response to the 1982 Registration Standard, updated the Agency's assessment of the terbacil data base, and included a tolerance reassessment. The Second Round Review required additional data in the area of toxicology, environmental fate, ecological effects, and residue chemistry. On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The FQPA amendments went into effect immediately and were considered during this reregistration decision. Currently, there are 5 active terbacil products registered.

Human Health Assessment

Toxicity

In studies using laboratory animals, terbacil is slightly toxic by the oral and dermal routes and has been placed in Toxicity Category IV (the lowest of four categories) for these effects. For the inhalation route, the Toxicity Category is III. Terbacil *per se* is mildly irritating to the eyes (Toxicity Category III).

In a chronic feeding study using beagle dogs, terbacil caused increased thyroid to body weight ratios, slight increase in liver weights, and elevated alkaline phosphatase levels.

Terbacil has been evaluated for potential carcinogenic activity in mice and rats. Terbacil did not induce any increase in tumor incidence in the treated animals. Terbacil is classified in Group E (no evidence of carcinogenicity in animals studies) with respect to its cancer potential.

Terbacil demonstrates some evidence of causing developmental toxicity effects in rats and rabbits. These effects are likely due to maternal toxicity from exposure to bromacil rather than from specific developmental toxicity of terbacil. Therefore, the Agency does not consider terbacil a developmental toxicant.

Dietary Exposure

People may be exposed to residues of terbacil through the diet. Generally, acute dietary margins of exposure greater than 100 tend to cause no dietary concern. Because the endpoint of concern was a developmental effect, the only sub-population of concern is females of child bearing age (i.e., females, 13+years old). Presently registered commodities result in an MOE for females (13+ years) of 3125, which demonstrates that there is no

cause for concern regarding acute dietary exposure from terbacil for both existing and proposed uses.

In assessing chronic dietary risk from food, EPA estimates that terbacil residues in food account for 12.2% of the RfD, based on existing tolerances and assuming 100% of the crop treated. Incorporating the results of the Agency's reregistration review (i.e., recommendationns to revoke tolerances for citrus fruits and pears, and to raise tolerances on caneberries, blueberries, peaches, apples, and sugarcane), 4.5% of the RfD is utilized.

No Codex Maximum Residue Limits (MRLs) have been established for terbacil for any agricultural commodity. Therefore, no compatibility questions exist with respect to U.S. tolerances.

Occupational Exposure

An occupational exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. The Toxicity Endpoint Selection Committee found that neither dermal nor inhalation toxicity criteria were triggered for terbacil. Therefore, no assessments are needed for occupational exposure/risk at this time.

Human Risk Assessment

EPA conducted additional risk analyses using available data in response to the new FQPA requirements. Based on current data requirements, terbacil has a complete database for developmental and reproductive toxicity. Because the developmental NOELs were the same as those for maternal toxicity, and the NOEL for systemic (parental) toxicity was higher than the NOEL for reproductive toxicity, these data do not suggest increased pre- or post-natal sensitivity of children and infants to terbacil exposure. Therefore, EPA concludes that the available toxicology data do not support an uncertainty factor of 1000 as specified in FQPA and that the present uncertainty factor of 100 is adequate to ensure the protection of infants and children from exposure to terbacil. EPA estimates that terbacil residues in the diet of infants and children account for 12.8% of the RfD and residues in drinking water account for 81% of the RfD. Therefore, the Agency concludes that aggregate risks for infants and children resulting from terbacil uses are not of concern.

In assessing aggregate risk dietary, exposure from food and drinking water were considered. Aggregate acute dietary risk for females of child-bearing age was calculated and the MOE=1563. Acute dietary risk from food alone was calculated for females of child-bearing age and the MOE=4166 (based on tolerance levels reassessed in this RED and 100% crop treated). In assessing aggregate chronic dietary risk, exposures from food and drinking water were considered. The aggregate exposures account for 27.6% of the RfD. Aggregate exposure/risk values are all below the

level of Agency concern. This includes the acute exposure of females of child-bearing age.

In evaluating the potential for cumulative effects, EPA compared terbacil with other structurally similar substituted uracil compounds, such as bromacil and lentacil, and then with other compounds producing similar effects. A comparison of the available toxicological database for terbacil and bromacil revealed no clear common mode of toxicity for the chemicals. The toxicology database for lentacil was not considered because there are currently no registered uses of lentacil. Based on the available data, the Agency has determined that there is no clear common mode of toxicity between terbacil and bromacil.

Environmental Assessment

Ecological Effects Risk Assessment

Minimal adverse acute effects are expected for avian, mammalian, and aquatic species from labeled uses of terbacil. Chronic effects for avian and aquatic species cannot be evaluated at this time because of insufficient data. However, chronic risk quotients (RQs) for mammals indicate that adverse effects are possible from labeled uses of terbacil. There is some uncertainty in assessing adverse chronic mammalian effects because the NOEL is greater than the maximum concentration tested in rat reproduction study design. Therefore, the highest concentration is a default toxicity endpoint which is a conservative estimate of risk. Since terbacil is a persistent and mobile herbicide, non-target terrestrial plants are expected to be adversely affected from runoff and spray drift. Minimal adverse effects, however, are expected for non-target aquatic plants. Because terbacil is used exclusively on minor crops, terbacil exposure is expected to be very localized and dependent on site specific conditions. The localized nature of terbacil use areas is expected to limit human and ecological exposure.

Risk Mitigation

To lessen the risks posed by terbacil, EPA is requiring the following risk mitigation measures.

- Maximum label application rates should be reduced to be representative of typical application rates.
- The Agency recommends a surface water label advisory on terbacil because it has characteristics (persistent and very mobile) of pesticides found in surface waters. Surface water modeling for a Louisiana sugarcane scenario indicates terbacil may accumulate at concentrations greater than 1 mg/L. Since terbacil is used on vulnerable soils for surface water contamination such as the Louisiana production area, a surface water label advisory is recommended. The label advisory should state: "Terbacil has properties that may result in surface water contamination via dissolved runoff and runoff erosion. Practices should be followed to minimize the potential for dissolved runoff and runoff and/or runoff erosion."

- Terbacil is more mobile and persistent than a number of herbicides which have been found to contaminate ground water. EPA has recommended a ground water label advisory since 1989, and continues to recommend this. The following label language is appropriate:

"This chemical has properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination."

Additional Data Required

EPA is requiring the following additional generic studies for terbacil to confirm its regulatory assessments and conclusions:

- Avian Reproduction Quail [71-4(a)]
- Avian Reproduction Duck [71-4(b)]
- Early Life-Stage Fish [72-4(a)]
- Life-Cycle Aquatic Invertebrate [72-4(b)]
- Aerobic Aquatic Metabolism [162-4]

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 terbacil end-use products must comply with EPA's current pesticide product labeling requirements and with the following. For a comprehensive list of labeling requirements, please see the terbacil RED document.

PPE/Engineering Control Requirements for Pesticide Handlers

For sole-active-ingredient end-use products that contain terbacil, the product labeling must be revised to adopt the handler personal protective equipment requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For multiple-active-ingredient end-use products that contain terbacil, the handler personal protective equipment requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

Minimum PPE/Engineering Control Requirements

EPA is not establishing active ingredient-specific PPE or engineering control requirements for terbacil end-use products.

Actual end-use product PPE requirements

Any necessary PPE for each terbacil occupational end-use product will be established on the basis of the end-use product's acute toxicity category.

Placement in labeling

The personal protective equipment must be placed on the end-use product labeling in the location specified in PR Notice 93-7 and the format

and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

Entry Restrictions

For sole-active-ingredient end-use products that contain terbacil the product labeling must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on the current labeling must be removed.

For multiple-active-ingredient end-use products that contain terbacil the entry restrictions set forth in this section must be compared to the entry restrictions on the current labeling and the more protective must be retained. A specific time-period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

Restricted-entry interval

A 12-hour restricted-entry interval (REI) is required for uses within the scope of the WPS on all terbacil end-use products.

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Regulatory Conclusion

The use of currently registered products containing terbacil 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.

Terbacil 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 terbacil 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 Information and Records Integrity Branch, Information Resources and Services (7502C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet are available on the Internet. See http://www.epa.gov/REDs.

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 45242-2419, telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the terbacil 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 terbacil RED, or reregistration of individual products containing terbacil, 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 6:30 am to 4:30 pm Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week.