



R.E.D. FACTS

Butralin

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 2075, Butralin.

Use Profile

Butralin is a dinitroaniline herbicide used as a plant growth regulator on flue-cured and air-cured tobacco. The one end use product formulation is a ready-to-use solution. Tobacco use is considered to be a non food use.

Regulatory History

Butralin was first registered as a pesticide in the U.S. in 1976. As part of the re-registration process the Agency issued a Data Call-In (DCI) for data needed to support the continued registration of butralin products.

The DCI required additional data to support the turf grass uses registered at that time. In addition, there were tolerances for food uses that were no longer on the label. The food uses were not supported and the Agency is in the process of revoking the tolerances.

Human Health Assessment

Toxicity

In studies using laboratory animals, butralin generally has been shown to be of low acute toxicity. It has been placed in Toxicity Category III for effects via the oral route of exposure and eye irritation, and Toxicity Category IV for the dermal and inhalation routes. The carcinogenicity classification for butralin has been not determined.

Dietary Exposure

People are not likely to be exposed to residues of butralin either through their diet or drinking water since there are no food or feed uses and groundwater contamination from butralin is unlikely.

Occupational Exposure

Workers can be exposed to this pesticide during mixing/loading and application to tobacco fields as well as from post application exposure.

EPA is generally not concerned with occupational risk if MOEs (margins of exposures) are greater than 100. For butralin, the calculation for intermediate term dermal risk show that MOEs are less than 100 for:

- 1). mixing/loading liquids for groundboom;
- 2). mixing/loading/applicators spraying with a backpack sprayer;
- 3). mixing/loading/applicators spraying with a low volume pressure hand wand; and,
- 4). by jug application.

All of the above use scenarios have acceptable MOEs with the use of chemical resistant gloves.

Other Considerations

Because butralin has no food uses the specific determinations outlined in FQPA are not required. There are no residential uses and exposure from drinking water is not expected.

The Agency has not made a determination whether butralin and any other pesticide have a common mechanism of toxicity that would require a cumulative risk assessment. For the purposes of this RED, EPA has considered only the risks from butralin. If required, cumulative risks will be assessed when methodologies for determining common mechanism of toxicity and for performing cumulative risk assessments are finalized.

Environmental Assessment**Environmental Fate**

For the currently registered use of butralin, the Agency typically requires an abbreviated set of environmental fate data on hydrolysis, metabolism, and mobility.

Based on existing data, butralin is likely to be moderately persistent to persistent and relatively immobile in terrestrial environments. Butralin is stable to abiotic hydrolysis and photodegradation on soil. It does not exhibit fate and transport characteristics similar to chemicals that are known to leach to groundwater.

Ecological Effects/Risk

Calculated acute avian risks do not exceed the Level of Concern (LOC). The acute LOC has been exceeded for small mammals such as the meadow vole and least shrew, but the Agency is not recommending a restricted use classification since the actual exposure is expected to be reduced because of the directed spray application method to the tobacco plant. The acute LOC to freshwater fish has not been exceeded although they have been for freshwater invertebrates. The acute LOC for estuarine and marine fish and shrimp have been slightly exceeded. The Agency concludes that the overall acute impact on freshwater and terrestrial non-target organisms from the use of butralin on tobacco will be minimal. The Agency is requiring Tier 2 testing for terrestrial and aquatic plants. The Agency cannot determine the impact of butralin to non-target plants but it can be assumed that the plant growth regulator will adversely affect non-target plants if they are exposed.

Risk Mitigation

The Agency is requiring the use of chemical resistant gloves and a 12 hour re-entry interval. The Agency is also establishing the minimum Worker Protection Standard (WPS) Personal Protective Equipment (PPE) of coveralls, chemical-resistant gloves, shoes and socks for early re-entry.

Additional Data Required

EPA is requiring product-specific data including product chemistry and acute toxicity studies, and revised labeling for reregistration. Some additional ecological effects and environmental fate data are being required for confirmatory purposes.

Product Labeling Changes Required

All butralin end-use products must comply with EPA's current pesticide product labeling requirements and the chemical resistant glove requirement, the 12 hour restricted entry interval, the early entry PPE

requirements and the user safety recommendations below. The following labeling changes are required.

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 protective clothing and equipment immediately after handling this product. Wash the outside of gloves before removing. Keep and wash protective clothing and equipment separately from other laundry."

Regulatory Conclusion

The use of currently registered products containing butralin in accordance with changes specified in this document will not pose unreasonable risks of adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Butralin products will be reregistered once the required product-specific data, any required confirmatory generic data, product specific data, CSFs, 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 butralin 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 Division (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/oppsrrd1/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, phone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the butralin RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, phone 703-605-6000.

For more information about EPA's pesticide reregistration program, the butralin RED, or reregistration of individual products containing butralin, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, phone 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.