



R.E.D. FACTS

Butylate

Pesticide Reregistration

All pesticides sold or used 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 butylate.

Use Profile

Butylate is a selective herbicide registered solely for use on corn crops including field corn, sweet corn and popcorn, to control grassy and broadleaf weeds and nutsedge. Formulations include emulsifiable concentrates, a granular and an encapsulated form. Butylate is applied with ground equipment and is incorporated into the soil immediately after application.

Regulatory History

Butylate was first registered as a pesticide in the U.S. in 1967. EPA issued a Data Call-In (DCI) Notice in 1981, and a Registration Standard in September 1983 (NTIS PB85-147304), which required additional product chemistry, toxicology, ecological effects and environmental fate data. The Agency issued a second DCI in October 1990, requiring submission of product chemistry, ecotoxicity, toxicology, environmental fate, residue chemistry and exposure information.

Currently, there are 14 active registered products which contain the active ingredient butylate. Between 6 and 15 million pounds of butylate are applied annually, treating 2 to 7% of the field corn grown in the U.S. Butylate is most commonly used in combination with the herbicides atrazine and/or cyanazine. Butylate and atrazine products are classified as Restricted Use Pesticides due to ground water concerns.

Human Health Assessment

Toxicity

Based on results of acute toxicity studies, butylate has been placed in Toxicity Category I for primary eye irritation. (Category I indicates the greatest and Category IV the lowest degree of acute toxicity.) It has been placed in Category III for acute oral and dermal toxicity, dermal irritation, and acute inhalation toxicity. EPA is requiring acute and subchronic neurotoxicity studies for butylate because it is chemically related to several pesticides which have shown neurotoxicity in long-term animal studies.

A chronic toxicity study using rats showed decreased body weight gain and liver effects in high-dose males. A study with Beagle dogs showed decreased body weight, increased platelet count, increased thyroid weight and liver effects at high doses.

Butylate does not appear to be carcinogenic in the mouse. In a study using rats, a significant increase in benign lesions was found in the livers of males at the highest dose tested. The Agency has classified butylate as a "Group E" carcinogen (evidence of non-carcinogenicity for humans).

In developmental toxicity studies, no teratogenicity was found in rats. Although maternal toxicity was observed at the highest dose level, no developmental effects were noted at any dose in rabbits. A reproductive toxicity study using rats showed kidney effects and changes in blood, organ weights and liver cells at the highest dose level.

Butylate is not mutagenic. Metabolism studies show that it is rapidly and completely metabolized and excreted, does not bioaccumulate, and does not produce metabolites of toxicological concern.

Dietary Exposure

People may be exposed to butylate residues when consuming treated corn. Tolerances or maximum residue limits of 0.1 ppm have been established for butylate in or on corn grain (including popcorn), fresh corn (including sweet corn), and corn forage and fodder (please see 40 CFR 180.232). The Agency has reassessed these tolerances and found that no changes are needed.

Residues of butylate do not concentrate in processed food or feed. Therefore, no food or feed additive tolerances have been required. Since it is metabolized rapidly, finite residues of butylate are not expected in meat, milk, poultry or eggs. There are no residues of concern to be regulated in rotational crops.

Plant metabolism studies indicate that no residues of intact butylate are found in corn at harvest. Storage stability studies show that residues of butylate in corn grain stored frozen remain stable for up to one year, but decline by about 50% within 2 to 3 years.

EPA conducted a chronic dietary exposure assessment for butylate using a Reference Dose (RfD) of 0.05 mg/kg body weight/day, using tolerance-level residues, and assuming 100% of the crop was treated. A "worst case" Theoretical Maximum Residue Concentration (TMRC) was estimated for the overall U.S. population and 22 subgroups. The TMRC for the general population was found to represent 0.1% of the RfD, and the TMRC for the most highly exposed subgroups (non-nursing infants and children 1 to 6 years old) represents 0.3% of the RfD for each subgroup.

Occupational and Residential Exposure

There is potential for dermal and inhalation exposure among workers involved in mixer/loader/applicator and soil incorporation activities. However, butylate is of low toxicity so worker exposure studies are not needed. Further, since butylate is incorporated into soil well before plants are mature, post-application exposure is unlikely and reentry data are not needed.

Human Risk Assessment

EPA has concluded that the human health risks from current, low-level exposure to butylate are minimal due to its low acute toxicity and because it is not believed to cause cancer in humans.

Environmental Assessment

Environmental Fate

The available data indicate that butylate is highly volatile and degrades moderately rapidly under aerobic conditions. Once in the atmosphere, butylate may be transported in fogs, mists and rainwater. Runoff to surface water may follow rainfall.

Based on these properties, EPA has additional questions regarding runoff into surface water (do concentrations of butylate exceed the Levels of Concern for fish?), persistence (would butylate residues remain at high levels long enough to present a chronic risk to terrestrial animals ?), volatility (what is the amount and nature of residues in air from volatilization of butylate as a result of normal agricultural use?), and ground water (is degradation sufficiently rapid to preclude leaching to ground water?). The Agency is requiring field dissipation studies with volatilization measurements and aged leaching data to confirm its assessment of butylate's environmental fate.

Ecological Effects

Technical butylate is practically nontoxic to birds, highly toxic to freshwater fish, slightly toxic to freshwater invertebrates and relatively nontoxic to honey bees. Available data indicate a potential for chronic risk to birds and mammals, but butylate residues are not expected to persist long enough to allow chronic exposure. Runoff, spray drift and volatility from sprinkler application can be expected to reach plants in adjacent fields. Thus, butylate may pose a hazard to endangered or threatened species.

Ecological Effects Risk Assessment

Based on available use and exposure information, EPA calculated risk quotients to assess the acute and chronic risks of butylate granular and spray formulations to small mammals, birds and aquatic organisms. When the risk quotient is greater than the LOC, the species exposed may be at risk.

Regarding acute exposure, LOC triggers were exceeded for small mammals and birds. However, based on mitigating factors including butylate's use patterns, its low acute toxicity to birds, and the feeding habits and preferences of small mammals, the Agency has concluded that minimal acute risks actually exist for nonendangered species.

LOC chronic risk triggers also were exceeded for small mammals and birds, but only immediately after application of butylate granules. The Agency concludes that actual chronic risks are unlikely based on environmental fate data and mitigating factors including butylate's volatility, its use patterns (it is soil incorporated or watered in immediately after application), and the feeding habits of small mammals and birds, who could not likely consume enough granules per day required to reach the LEL over an extended period.

Neither acute nor chronic risks to aquatic organisms appear likely. Acute risks to nontarget insects also are unlikely. However, since butylate is a herbicide, risks to nontarget plants are likely.

Endangered Species

Potential acute risks exist for nontarget endangered mammals, freshwater vertebrates and amphibians. There also is a possibility of chronic risks to endangered mammals and birds, as well as risks for endangered plants, which may impact endangered insects. EPA is working with the U.S. Fish and Wildlife Service to develop a program to avoid jeopardizing the continued existence of identified species by the use of pesticides. When this program goes into effect, endangered species labeling will be required.

Additional Data Required

The generic data base for butylate is substantially complete. However, for confirmatory purposes, EPA is requiring additional generic studies including product chemistry, storage stability, aged leaching, terrestrial field dissipation with volatilization measurements, seed germination/seedling emergence, vegetative vigor, aquatic plant growth, droplet size, spray drift and acute and subchronic neurotoxicity.

EPA also is requiring product-specific data, including product chemistry and acute toxicity studies, as well as revised Confidential Statements of Formula and revised labeling for reregistration of pesticide products containing butylate.

Product Labeling Changes Required

All end-use butylate products must comply with EPA's current pesticide product labeling requirements. In addition:

Ⓟ Effluent Discharge Statement

All end-use or manufacturing-use products that may be contained in an effluent discharged to the waters of the U.S. or municipal sewer systems must bear the following effluent discharge labeling statement, modified to include a fish toxicity statement:

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA.

Ⓟ Worker Protection Standard (WPS) Requirements

Any product whose labeling permits use in the production of an agricultural plant on any agricultural establishment (farm, forest, nursery or greenhouse) must, within the deadlines specified, comply with the labeling 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."

Unless specifically directed in the RED document, all statements required by these two PR Notices must appear on product labeling exactly as instructed in the PR Notices.

Labels must be revised to comply with the WPS requirements --

- After April 21, 1994, for products distributed or sold by the primary registrant or any supplementally registered distributors, and
- After October 23, 1995, for products distributed or sold by any person.

Ⓟ Restricted Use Pesticides

The 2 registered butylate and atrazine combination products, classified as Restricted Use Pesticides due to ground water concerns, must retain current label precautions regarding toxicity and protection of ground and surface water.

Ⓟ Personal Protective Equipment (PPE)

The following PPE labeling is required for all end-use products:

Applicators and other handlers must wear:

- *Long-sleeved shirt and long pants*
- *Chemical-resistant or waterproof gloves*

- *Shoes plus socks*

Registrants must compare these PPE requirements with those on current labeling (if any), and retain the more protective. For guidance, please see Supplement Three of PR Notice 93-7.

þ Entry Restrictions

A 12-hour restricted entry interval (REI) is required for all uses on all butylate end-use product labels. This REI should be inserted into the standard REI statement required by PR Notice 93-7.

The PPE for early entry should be that required for applicators (see above), except:

- No apron or respirator (if on the label) is required, and
- "Coveralls" must be specified instead of "long-sleeved shirt and pants."

This information should be inserted into the standard early entry PPE statement required by PR Notice 93-7.

þ Sole Active Ingredient Products - Registrants must adopt these entry restrictions, and remove any conflicting entry restrictions from their labels.

þ Multiple Active Ingredient Products - Registrants must compare these entry restrictions with those on current labeling, and retain the more protective.

þ Protection of Aquatic Organisms

The Environmental Hazard Section of the label must include the following statements:

þ For Granular End-Use Products:

This pesticide is toxic to fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate.

þ For Non-Granular End-Use Products:

This pesticide is toxic to fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate.

**Regulatory
Conclusion**

The use of currently registered pesticide products containing butylate as labeled and 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.

Products containing butylate as the sole active ingredient may be reregistered once the generic and product-specific data, revised Confidential Statements of Formula and revised labeling are received and accepted by EPA.

Products also containing other active ingredients may be reregistered only when 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 butylate 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 butylate 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 butylate RED, or reregistration of individual products containing butylate, 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.