

US EPA ARCHIVE DOCUMENT



R.E.D. FACTS

Pesticide Reregistration

Bromacil

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.

Under the Food Quality Protection Act of 1996, EPA must consider the increased susceptibility of infants and children to pesticide residues in food, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with a common mechanism of toxicity in establishing or reassessing tolerances.

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 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 0041, bromacil and salts, which includes bromacil *per se* and the lithium salt of bromacil.

Use Profile

Bromacil is a broad spectrum herbicide used to control weeds in the agricultural food crops citrus and pineapple. In addition, both bromacil and its lithium salt are used to control weeds and brush in nonagricultural areas including utility right-of-ways, railroads, electrical switching stations, and industrial yards.

Formulations include emulsifiable concentrate, granular, liquid ready-to-use, pellets or tablets, pressurized liquid, liquid soluble concentrate, wettable powder, and water dispersible granules (dry flowable).

Bromacil is applied mainly by sprayers including boom, hand-held, knapsack, compressed air, tank-type, and power sprayers. Bromacil is also applied using aerosol, shaker, or sprinkler cans. Solid forms of bromacil

are spread using granule applicators and spreaders. Application using aircraft is allowed only for Special Local Need registrations to control vegetation on the Department of Defense's Yakima Firing Center in the state of Washington.

Use practice limitations include prohibitions on direct application to water, areas where surface water is present or intertidal areas below the mean high water mark. They also prohibit application through any type of irrigation system. Bromacil may not be applied directly to water or wetlands, and should be kept out of lakes, streams, and ponds.

Regulatory History

Bromacil was first registered as a pesticide in the U.S. in 1961. EPA issued a Registration Standard for bromacil in September 1982 (PB87-110276). A Data Call-In (DCI) was issued in September of 1991 requiring additional chemistry, toxicology, ecological, and environmental fate data. As of April of 1996, 95 products were registered. In addition to federal regulation, the states of Florida and California have imposed more stringent regulations on the use of bromacil because of its occurrence in groundwater. 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.

Human Health Assessment

Toxicity

In studies using laboratory animals, bromacil is slightly toxic by the oral, dermal, and inhalation routes and has been placed in Toxicity Category IV (the lowest of four categories) for these effects. Bromacil *per se* is mildly irritating to the eyes (Toxicity Category III). The lithium salt of bromacil, however, is moderately irritating to the eyes (Toxicity Category II).

In a chronic feeding study using beagle dogs, bromacil caused decreased body weight gain. In another chronic study using rats, effects in addition to reduced body weight gain include (1) increased incidence of thyroid cysts in the high dose males; (2) enlargement of the thymus in high dose females; and (3) dose-related incidence of thyroid tumors in the males.

Bromacil has been evaluated for potential carcinogenic activity in rats and mice. Bromacil is classified as a Group C possible human carcinogen based on increases in incidence of liver tumors in male mice, and positive trends in thyroid tumors in male rats, and, to a lesser extent, structural activity relationship to similar compounds.

Bromacil 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 bromacil. Therefore, the Agency does not consider bromacil a developmental toxicant.

Dietary Exposure

People may be exposed to residues of bromacil through the diet. Tolerances or Maximum Residue Limits (MRLs) have been established for citrus and pineapple at 0.1 ppm (see 40 *Code of Federal Regulations* 180.210). EPA has reassessed the bromacil tolerances in accordance with FQPA and found that both are acceptable.

No MRLs for bromacil have been established by Codex for any agricultural commodity. Therefore, no compatibility issues exist with respect to U.S. tolerances.

Occupational Exposure

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to bromacil during and after normal use in agricultural and other settings.

Because bromacil is a possible human carcinogen and systemic toxicity may result from intermediate exposure (one week to several months), EPA assessed risk to workers using several major exposure scenarios.

Human Risk Assessment

Bromacil generally is of low acute toxicity, but demonstrates thyroid, adrenal, eye, and thymus effects in animal studies and has been classified as a Group C, possible human carcinogen. EPA has reassessed the dietary risk posed by bromacil's uses on citrus and pineapple and has concluded the cancer and chronic toxicity risks posed to the general population are very low. Dietary chronic risk is not of concern because present tolerances for bromacil result in a Theoretical Maximum Residue Concentration which represents less than one percent of the Reference Dose (the amount believed not to cause adverse effects if consumed daily over a 70-year lifetime) for the U.S. general population. This low fraction of the allowable RfD is considered to be an acceptable dietary exposure risk.

Of greater concern is the risk posed to bromacil handlers, particularly mixers/loaders/applicators. Margins of Exposure (MOEs) for subchronic systemic effects are unacceptable (less than 100) for mixers/loaders of the wettable powder and dry flowable formulations. Exposure and risk to workers will be mitigated by the use of Personal Protective Equipment (PPE) required by the Agency's Worker Protection Standard, supplemented by chemical resistant gloves for all formulations and a dust mask for the wettable powder formulation, as required by this RED. PPE requirements will be confirmed using the 28-day dermal study currently being developed

by the registrant. Post-application reentry workers will be required to observe a 12-hour (bromacil) or a 24-hour (bromacil lithium salt) Restricted Entry Interval.

EPA conducted additional risk analyses using available data in response to the new FQPA requirements. The Agency found that the bromacil data base for pre- and post-natal effects is complete based on current requirements, and that these studies indicate no special sensitivity of young organisms to bromacil. EPA concludes that no additional safety factor is warranted in assessing risks to infants and children. The EPA considered aggregate exposures from all sources of bromacil (food and drinking water) and concluded that aggregate risks for infants and children and the general population resulting from bromacil uses are not of concern. Based on available information, bromacil does not appear to have a common mode of toxicity with other substances and therefore cumulative effects are not anticipated.

Environmental Assessment

Environmental Fate

Parent bromacil is persistent and highly mobile, and has been detected in groundwater. Bromacil is stable to hydrolysis under normal environmental conditions. The primary routes of dissipation appear to be photolysis in water under alkaline conditions and microbial degradation in anaerobic soil. Bromacil's persistence is demonstrated by half-lives of 124 to 155 days in the field dissipation studies.

Ecological Effects

Acute toxicity to bromacil ranges from practically nontoxic to slightly toxic for birds, mammals, honey bees, fish, and estuarine and marine species. New studies are required to determine its chronic toxicity to nontarget species. Bromacil is toxic to non-target plants.

Ecological Effects Risk Assessment

Acute as well as chronic exposures to nontarget organisms can result from direct application, spray drift, and runoff from treated areas.

Agency levels of concern (LOCs) have been exceeded for acute toxicity to birds, reptiles, and mammals at the historic higher application rates which were as high as 32 pounds of active ingredient per acre (lbs ai/A). In addition, the concentration of bromacil that is estimated to occur in puddles or shallow irrigation ditches exceeds the fish and amphibian LOCs at most application rates. For non-target plants, the LOCs are exceeded by very large margins in virtually all use situations.

The Agency was unable to complete its assessment of the chronic and reproductive effects from exposure to bromacil since it lacked the necessary studies to assess risk. Potential for exposure to bromacil for non-target terrestrial and aquatic animals is considered to be high because it is persistent in soil and water, and may be applied repeatedly throughout the year.

Risk Mitigation

To lessen worker risk, and ecological and water quality risks posed by bromacil, EPA is requiring the following mitigation measures from registrants of bromacil-containing products.

- For all risk concerns:

Reduce the maximum rate of application from 32 lbs ai/A to 12 lbs ai/A (except for undersurface treatment of toxic-waste holding ponds at 25 lbs ai/A).

- To protect workers:

Additional PPE are being required for workers mixing, loading, and applying bromacil. Chemical resistant gloves are required for most of the formulations during mixing and loading. A dust mask is required for the wettable powder formulation.

The total number of acres that may be treated by a worker in one day is being restricted to five for the toxic-waste holding pond liner treatment.

- To protect non-target organisms:

Continue existing label warnings addressing the potential exposure of very sensitive areas, such as wetlands, to bromacil. Remove label instructions that allow direct application to water (e.g. treating ditchbanks).

- To protect water resources, the Agency is requiring that registrants:

Develop training materials to explain management practices that can reduce potential for contamination of water resources;

Standardize use rates for certain weed control situations (i.e. for use in citrus orchards or to control specific problem weeds); and

Change labels to specify the time of application.

In addition, the Agency supports risk mitigation measures taken by the states of California and Florida to protect their groundwater resources. These include the ban on use of bromacil on the Central Ridge of Florida and the creation of Pesticide Management Zones for bromacil in California.

Additional Data Required

EPA is requiring the following additional generic studies for bromacil 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)]
- Dermal toxicity study [82-2]
- Groundwater monitoring studies [166-1]

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 bromacil end-use products must comply with EPA's current pesticide product labeling requirements and with the following.

- Remove the statement: "It is permissible to treat the berm of ditches, seasonally dry flood plains, deltas, marshes, swamps, bogs, and transitional areas between upland and lowland sites."

- PPE/Engineering Control Requirements for Pesticide Handlers

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

For **multiple-active-ingredient** end-use products that contain bromacil, the handler personal protective equipment 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.

Products Intended Primarily for Occupational Use (WPS and non WPS)

Minimum (Baseline) PPE Control Requirements

EPA is establishing minimum (baseline) PPE requirements for some occupational uses of bromacil end-use products. The following is the minimum (baseline) PPE for all occupational uses of bromacil end-use products formulated as a liquid, wettable powder, or dry flowable:

"Applicators and other handlers must wear:

- long-sleeved shirt and long pants,
- chemical-resistant gloves*, and
- shoes plus socks."

In addition, while mixing and loading the wettable powder formulation, pesticide handlers are required to wear a dust mask.

* For the glove statement, use the statement established for bromacil through the instructions in Supplement Three of PR Notice 93-7.

EPA is not establishing minimum (baseline) PPE requirements for bromacil end-use products formulated as granules and pellets.

Determining PPE Requirements for End-use Product Labels

The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient-based minimum (baseline) personal protective equipment specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Placement in Labeling

The personal protective equipment requirements 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 bromacil, 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 bromacil, 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."

Products Intended Primarily for Agricultural Occupational Use

WPS Uses

Restricted-entry interval:

A 24-hour restricted-entry interval (REI) is required for uses within the scope of the WPS on all lithium-salt bromacil end-use products. A 12-hour restricted-entry interval (REI) is required for uses within the scope of the WPS on all other (non-lithium-salt) bromacil end-use products.

Early-entry personal protective equipment (PPE):

The PPE required for early entry is:

- coveralls,
- chemical-resistant gloves, and
- shoes plus socks.

For the lithium salt of bromacil, protective eyewear also is required.

Placement in labeling:

The REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7. The PPE required for early entry must be inserted into the standardized early-entry PPE statement required by Supplement Three of PR Notice 93-7.

NonWPS uses

Entry restrictions:

The Agency is establishing the following entry restrictions for nonWPS occupational uses of bromacil end-use products:

For liquid applications:

"Do not enter or allow others to enter the treated area until sprays have dried."

For dry applications:

"Do not enter or allow others to enter the treated area until dusts have settled."

Placement in labeling:

If WPS uses are also on label -- Follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box, and place the appropriate nonWPS entry restrictions in that box.

If no WPS uses are on the label -- Place the appropriate nonWPS entry restrictions in the Directions for Use, under the heading "Entry Restrictions."

■ **Other Labeling Requirements**

Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing bromacil that are intended primarily for occupational use.

Application Restrictions

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

Engineering Controls

"When handlers use closed systems (including water-soluble packets), enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

User Safety Requirements

For products with labeling which requires handlers to wear coveralls:

"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."

For all products:

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions are provided for washables, use detergent and hot water. Keep and wash PPE 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 PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

Skin Sensitizer Statement

"This product may cause skin sensitization reactions in some people."

■ **Application Rates, Amounts, and Timing**

Labels must be revised to reduce the maximum allowed rates to 12 ai/A. If the state of Florida lifts the current ban on bromacil, the Agency will not allow application above the rate of 1.6 lb ai/acre in

that state. Registrants are required to reduce rates on citrus in Texas from 6.4 to 2.4 lb ai/A.

DuPont is required to change labels of products for undersurface treatment for toxic-waste holding ponds to restrict the number of acres that may be treated by a worker to a maximum of five acres per day. Registrants must submit labels that specify the timing of applications. Registrants must specify appropriate rate of application for control of Russian thistle and kochia.

Regulatory Conclusion

The use of currently registered products containing bromacil in accordance with approved labeling as specified in the RED will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Bromacil 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 bromacil 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 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 bromacil 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 bromacil RED, or reregistration of individual products containing bromacil, 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 9:30 am and 7:30 pm Eastern Standard Time, Monday through Friday.

