

US EPA ARCHIVE DOCUMENT



R.E.D. FACTS

Pesticide Reregistration

Bentazon

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 document for reregistration case 0182, bentazon, which includes bentazon technical and sodium bentazon, the active ingredient in end-use pesticide products.

Use Profile

Bentazon, also known by its trade name Basagran, is a selective herbicide that is used after seedlings have emerged to control broadleaf weeds and sedges among food and feed crops including alfalfa, beans, corn, peanuts, peas, peppers, peppermint, rice, sorghum, soybeans and spearmint. Bentazon also is registered for use on ornamental lawns and turf. Most bentazon used in the U.S. (73%) is applied to soybean crops.

Bentazon may be applied either aerially or using ground equipment (except to lawns and turf, which may be treated using ground equipment only). Formulations include a flowable concentrate and a soluble concentrate/liquid. Use practice limitations prohibit applying bentazon through any type of irrigation system; discharging effluent containing the product into sewage systems or bodies of water; using treated plants for feed or forage; and treating crops/sites within 30 to 75 days of harvest or 12 to 50 days of grazing.

Regulatory History

EPA issued a Registration Standard for bentazon in September 1985 (NTIS #PB86-159563). An August 1990 Data Call-In (DCI) required additional data on terrestrial and aquatic animal effects, environmental fate, toxicology, residue chemistry, and plant protection. Products currently

registered contain bentazon alone or in combination with atrazine.

Human Health Assessment Toxicity

Bentazon is slightly acutely toxic by the oral, dermal and inhalation routes, and has been placed in Toxicity Category III (the second-to-lowest of four categories) for these effects. It is a skin sensitizer in guinea pigs.

In a subchronic toxicity study using rats, bentazon caused a variety of effects at the highest dose tested including reductions in body weight gain, an increase in blood clotting times, and increased kidney and liver weights.

A chronic toxicity study in beagle dogs produced adverse effects at the two highest dose levels including clinical signs of toxicity, anemia-like changes in blood, depressed body weight gains, intestinal inflammation and congestion of the small intestine and spleen.

In two combined chronic toxicity and carcinogenicity studies using rats and mice, bentazon caused no compound-related increases in tumors. Numerous other adverse effects were observed at the highest dose levels, however, including effects on blood clotting and to the testes, pancreas and liver, changes in kidney, thyroid and pituitary gland weights, reduced body weight gain, and hemorrhage in the liver and heart. Based on these studies, bentazon was classified as a "Group E" carcinogen, that is, a compound that shows evidence of non-carcinogenicity for humans.

In a developmental toxicity study using rats, bentazon did not cause maternal toxicity but at the highest dose tested caused an increase in postimplantation loss and effects on bone development in fetuses. In rabbits, bentazon caused some evidence of both maternal toxicity and developmental toxicity. In a reproductive toxicity study using rats, at the highest dose levels, bentazon caused a decrease in body weights of pups during lactation and reductions in food consumption and weight gain, as well as kidney and liver effects in parents. Bentazon is not mutagenic.

Dietary Exposure

People may be exposed to residues of bentazon through the diet. Tolerances or maximum residue limits have been established for raw agricultural commodities including various types of beans, corn, mint, peanuts, peas, peppers, rice, sorghum and soybeans (please see 40 CFR 180.355(a)); for animal commodities including milk, eggs, and the fat, meat and meat byproducts of cattle, goats, hogs, poultry and sheep (see 40 CFR 180.355(b); and for the processed commodity spent mint hay (see 40 CFR 186.375). A tolerance for rice hulls is proposed. EPA has reassessed the existing bentazon tolerances and found that several changes and corrections are needed, as explained in the RED document.

EPA has assessed the acute and chronic dietary risks posed by bentazon. In the chronic risk analysis, the Agency used a Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime, of 0.03 mg/kg bwt/day (milligrams/kilogram of bodyweight/day).

This RfD is based on a No Observed Effects Level (NOEL) of 3.2 mg/kg bwt/day established in the dog feeding study described earlier, plus an uncertainty factor of 100. For the overall U.S. population and 22 subgroups, exposure from all current tolerances represents 2.2% of the RfD. The exposure level of the most highly exposed subgroup, non-nursing infants less than one year old, represents 8.1% of the RfD. Based on these estimates, chronic dietary risk is not of concern.

In the acute dietary risk analysis, EPA used a NOEL derived from the developmental toxicity study in rats, described earlier. The subgroup of most interest in terms of developmental toxicity, females aged 13 and above (women of child bearing age), have a margin of exposure (MOE) of 500. This means they receive approximately 1/500th the amount that represents the NOEL in animals. Thus, acute dietary risk from bentazon is not of concern.

Occupational and Residential Exposure

Based on current use patterns, workers may be exposed to bentazon during and after applications in agricultural and other settings. The Agency was concerned about developmental toxicity effects resulting from this exposure. Margins of Exposure (MOEs) were estimated for short and intermediate term exposure scenarios involving mixing, loading and applying bentazon using both ground and aerial application methods. The resulting MOEs ranged from 1,714 to 100,000; all are well over 100, the margin regarded as acceptable from a safety standpoint. Therefore, the personal protective equipment (PPE) required for early entry is the minimum PPE required under the Worker Protection Standard (WPS): coveralls, chemical-resistant gloves, shoes and socks.

The risk to homeowners who handle bentazon is expected to be lower than that of people who handle the pesticide occupationally.

Human Risk Assessment

Bentazon is slightly acutely toxic by all routes (Toxicity Category III) and is a skin sensitizer. It is classified as a "Group E" carcinogen--a chemical showing evidence of non-carcinogenicity to humans, but causes some developmental toxicity effects in rats and rabbits.

Bentazon is used on a variety of food crops, and people may be exposed to residues through their diets. Based on EPA's acute and chronic dietary risk assessments, however, dietary exposure to the bentazon uses supported for reregistration is not of concern.

Although the Agency has concerns about possible developmental toxicity effects among workers exposed to bentazon, these concerns are minor based on our assessment that worker risks are low. There are no concerns that warrant the establishment of personal protective equipment (PPE) requirements beyond those required by the Worker Protection Standard (WPS) or appearing on existing product labels for non-WPS uses.

Environmental Assessment

Environmental Fate

Dissipation of bentazon is dependent on microbe-induced degradation, leaching and surface water runoff. Bentazon is moderately resistant to degradation in aerobic mineral soils. Degradation in aquatic environments is dependent on photolysis. Degradation in soil is controlled by processes involving microbes in the presence of oxygen. Bentazon has a low binding affinity to soil and therefore may leach into ground water and runoff into surface waters. Leaching did not appear to be a major route of dissipation in field studies, however. Bentazon dissipates rapidly under typical use conditions.

The soil degradates of bentazon include AIBA, which is very mobile but not persistent, and N-methylbentazon which is not mobile. These compounds should not pose a threat to ground water.

Environmental Fate Assessment

EPA concludes that, in addition to surface runoff, leaching through the soil profile also is a major route of dissipation for bentazon in the environment. Bentazon exceeds levels of concern for ground water quality, and also may impact the quality of surface water. Possible chronic effects of long-term drinking water exposure prompted EPA's Office of Water to establish a lifetime Health Advisory (HA) of 20 parts per billion (ppb), which will likely be increased to 200 ppb soon. However, bentazon is not regulated under the Safe Drinking Water Act (SDWA), no Maximum Contaminant Level (MCL) has been established, and water supply systems are not required to sample or analyze for its residues.

Bentazon has been detected in well water in four out of eight states sampled including California (with the greatest number of detections, extending over 11 counties), Florida, Missouri and Virginia. EPA is requiring a small-scale prospective ground water monitoring study to establish the conditions under which bentazon is prone to leach to ground water during normal agricultural use. The Agency also is requiring a ground water label advisory for bentazon to minimize its adverse effects on ground water. The registrant has agreed to prepare educational materials for end users, dealers and distributors regarding ground and surface water protection.

EPA also is requiring spray drift studies as confirmatory information, and in the future may require drift-related labeling statements for bentazon products applied aerially to agricultural crops.

Ecological Effects

Bentazon is slightly toxic to birds on an acute oral and subacute dietary basis, and exceeds the level of concern for avian chronic effects. Bentazon is slightly toxic to small mammals on an acute basis, and is practically nontoxic to honeybees. Bentazon also is practically nontoxic to cold and warm water fish, aquatic invertebrates and estuarine/marine organisms. Bentazon poses a low risk to aquatic plants but may represent a hazard to terrestrial and semi-aquatic plants.

Ecological Effects Risk Assessment

EPA concludes that the use of bentazon as an herbicide will not pose a serious environmental threat. Bentazon poses a chronic reproductive health risk to birds. However, the registrant has agreed to lower the maximum seasonal application rate from four to two pounds per acre, to reduce the potential for this risk. Although it is slightly toxic to birds and small mammals on an acute and subacute basis, bentazon is expected to pose minimal acute/subacute risks to both endangered and nonendangered birds and mammals as a result of its current uses. Since it is a herbicide, bentazon is expected to pose a risk to non-target terrestrial and semi-aquatic plants near treated sites. No hazard to aquatic animals or honeybees is anticipated.

Additional Data Required

EPA is requiring additional generic product chemistry, residue chemistry, toxicology, environmental fate and ecological effects studies to confirm its regulatory assessments and conclusions regarding bentazon. 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 bentazon end-use products must comply with EPA's current pesticide product labeling requirements. The following statements, some of which may be on some existing product labels, are now required on all labels as specified below.

Environmental Hazard Statement

Non-residential end-use product labeling must bear the following statement for crayfish and catfish commercial farms:

"For terrestrial uses only, do not apply directly 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 washwater or rinsate."

Ground Water Label Advisory

To minimize bentazon contamination of ground water, the following statement is required on all end-use product labeling:

"This chemical is known to leach through soil into groundwater under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination."

Worker Protection Requirements

- The following entry restriction is required for all non-WPS occupational uses of bentazon:

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

dried."

- The following entry restriction is required for all homeowner products:
"Do not allow persons or pets to enter the treated area until sprays have dried."
- The following labeling statements are required for all bentazon products intended primarily for occupational use, including uses both within and not in the scope of the WPS.

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, 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:

"Follow manufacturer's instructions for cleaning/maintaining PPE. If there are no such instructions 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."

- Because bentazon is a skin sensitizer, the following statement must be placed in the "Hazards to Humans and Domestic Animals" section of the Precautionary Statements on the labeling of all end-use products:

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

Reduction in Application Rate

All bentazon labels must be amended to reflect a maximum seasonal application rate of 2 lbs ai/a (2 pounds active ingredient per acre).

Products Registered for Residential Use Only

The following label statement is required for all products intended for use on lawns and turf:

"Do not apply directly to water. Do not contaminate water when disposing of equipment washwater or rinsate."

**Regulatory
Conclusion**

The use of currently registered pesticide products containing bentazon 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.

Bentazon products 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 that contain the active ingredient atrazine in addition to bentazon will be reregistered when atrazine also is eligible for reregistration.

**For More
Information**

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for bentazon 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 bentazon 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 bentazon RED, or reregistration of individual products containing bentazon, 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.