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EPA R.E.D. FACTS

Benfluralin

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 (FQPA) 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 current human health and safety standards and can be used without posing unreasonable risks to human health and the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Document (RED) document. This fact sheet summarizes the information in the RED document for benfluralin (Chemical Code No. 084301; Case No. 2030).

Use Profile

Benfluralin is a pre-emergent dinitroaniline herbicide used to control grasses and other weed species. Annual usage is approximately 700,000 pounds active ingredient. The majority of benfluralin use is on commercial and residential turf. Benfluralin is also used on alfalfa, lettuce, birdsfoot trefoil, clover, non-bearing fruit and nut trees, non-bearing berries, non-bearing vineyards, ornamentals, rights of way (including industrial sites, utility substations, highway guardrails, sign posts, and delineators), fence rows/hedgerows, and Christmas tree plantations. The use for peanuts has been voluntarily canceled by the registrant and the tolerance for peanuts will be proposed for revocation by the Agency. Benfluralin is formulated as emulsifiable concentrate, granules, soluble concentrate/liquid, water dispersible granules (dry flowable). Benfluralin is used alone and is also commonly formulated with trifluralin and oryzalin.

Regulatory History

Benfluralin was registered in the United States in 1970. During the second phase of reregistration, the Agency conducted a review of the scientific data base underlying pesticide registrations and identified missing or inadequate studies. Subsequent Data Call-Ins (DCIs) were issued in 1991 and 1995 for benfluralin. There are approximately 120 products containing benfluralin, registered under Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Currently, there are no Section 18 (Emergency Exemption) uses, or Section 24(c) (Special Local Needs) uses registered for benfluralin.

Human Health Assessment

Toxicity

In acute studies, benfluralin is practically non-toxic (Toxicity Category IV) by the oral and dermal routes. For primary skin and eye irritation, benfluralin has low acute toxicity (Toxicity Category III). In guinea pig studies, technical benfluralin was found to be a dermal sensitizer.

In longer-term studies, benfluralin is toxic to the kidneys and liver, and is toxic to the thyroid at high dose levels. Rats show a lowest observed adverse effect level (LOAEL) based on kidney toxicity. Dogs show a LOAEL based on liver toxicity and mice show a LOAEL based on liver and kidney toxicity. Other dinitroaniline pesticides show a mixture of kidney, liver, hematological, and thyroid toxicity at their respective LOAELs.

In accord with the Agency's Draft Guidelines for Cancer Risk Assessment (July, 1999), the Agency classified benfluralin into the category "suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential," based on studies in two species (mice and rats).

Suggestive evidence of neuropathy occurring only in rats and only at study termination was evaluated by the Agency. This neuropathy was considered to be due to normal age related neuropathy in aging rats at excessive dose levels.

Benfluralin shows no developmental toxicity in two studies (in the rat and rabbit) at maternally toxic doses. Also, no obvious endocrine related effects were noted on the organs of reproduction. Thyroid toxicity in rats was seen at the highest dose, but whether or not these thyroid effects were directly related to endocrine modulation by benfluralin can not be determined based on the data submitted.

Dietary Exposure and Risk

Benfluralin's dietary risk assessment considered both acute and chronic risks from residues in food based on field trials. The acute and chronic dietary (food) risks are less than 100% of the Acute Population Adjusted Dose (aPAD) and Chronic Population Adjusted Dose (cPAD) for all population subgroups and are not of concern.

The Agency estimates potential surface water and ground water pesticide contamination using models. All modeled surface water EECs (< 3.5) and ground water EECs (< 0.07) are less than the drinking water levels of concern (DWLOCs) (50 or greater) and therefore are not of concern. The available monitoring data indicates that benfluralin is found at a lower level in surface water than the modeling estimates indicate. All detections are well below the DWLOCs and are not of concern.

Residential Exposure and Risk

Residential handlers may be exposed to benfluralin during and after application on home lawns and ornamental plants; or after applications at golf courses, parks, and schools. Benfluralin products are marketed for homeowner use on residential lawns

and landscape ornamental plants. Benfluralin containing products are also marketed for use by professional applicators (Lawn Control Operators, or LCOs) on residential turf, golf courses, other turf such as recreational or commercial areas, and on ornamental plantings.

For the residential use of benfluralin, EPA is concerned about any Margin of Exposure (MOE) less than 100, which incorporates a Food Quality Protection Act (FQPA) safety factor of 1. Benfluralin is not assessed for systemic dermal toxicity (because no systemic toxicity was observed from a dermal toxicity study in rats), but is assessed for systemic inhalation toxicity. All residential handler MOEs are greater than 100 and therefore risks to residential handlers are not of concern.

For the residential postapplication assessment, children are the population group most likely to be significantly exposed. Since systemic toxicity was not observed in a dermal toxicity study, up to a dose level of 1,000 mg/kg/day, the only risk addressed in the assessment is the possible oral exposure of small children from treated turf, or from treated soil (i.e., soil ingestion, granule ingestion, and hand-/object-to-mouth transfer). A Margin of Exposure of 100 (or more) is considered protective for this assessment. The oral MOE from all ingestion exposures to children is above 100, and therefore these risks are not of concern. Postapplication inhalation exposure is expected to be minimal.

Occupational Exposure and Risk

Based on current use patterns, occupational handlers (mixers, loaders, and applicators) may be exposed to benfluralin during and after normal use. The Agency identified 13 handler scenarios resulting from mixing/loading and applying benfluralin for crop and non-crop uses. Of the 13 scenarios, all short- and intermediate-term exposures resulted in an MOE above 100 and are therefore not of concern.

FQPA Considerations

The Agency has concluded that the FQPA Safety Factor for benfluralin should be removed (equivalent to 1X) based on a complete database for FQPA consideration and a conclusion that there is no increased susceptibility following pre- and/or postnatal exposure. The FQPA Safety Factor recommendation assumes that the exposure databases (food, drinking water, and residential) are complete, the risk assessment for each potential exposure scenario includes all metabolites and/or degradates of concern, and does not underestimate the potential risk for infants and children. These criteria have been met in the benfluralin risk assessment.

Tolerance Reassessment

The tolerances for benfluralin meet the FQPA safety standards for the U.S. population and sensitive populations, including infants and children. The technical registrant has requested voluntary cancellation of the peanut use. A Federal Register Notice was published on June 25, 2003, announcing the receipt of this voluntary use cancellation request. The cancellation was effective on December 22, 2003 (68 FR 37811). The tolerance will be proposed for revocation.

Environmental Assessment

Environmental Fate

Available data indicates that benfluralin is of variable soil persistence with different mechanisms of degradation. Benfluralin has low mobility in soils. Acceptable field dissipation studies observed in three different locations indicate moderate half-lives of 22 to 79 days. Benfluralin volatilizes rapidly, as indicated in laboratory volatility studies.

Parent benfluralin is not expected to leach into ground water, based on its low mobility in soil. However, degradate 2,6 dinitro-4-trifluoromethyl-phenol was formed at 6% of parent in the soil metabolism study. Based on limited environmental fate information, it has the potential to contaminate groundwater, and was included in the drinking water assessment. Trifluoroacetic acid (TFA) was not found in environmental fate studies, but was noted as a plant metabolite.

Based on its measured bioaccumulation factor in whole fish (1580), parent benfluralin is considered to be bioaccumulative. The depuration rate was 0.54 per day for whole fish.

Ecological Toxicity

Benfluralin is considered to be practically non-toxic to birds on an acute and subacute basis. However, benfluralin caused reproductive effects in chronic avian studies. The endpoint from the bobwhite quail study cannot be assumed conservative, as effects were observed at the lowest dose tested of 96 ppm. Another quail study is needed to establish a No Observed Adverse Effect Concentration (NOAEC) for reproductive effects.

Benfluralin is classified as practically nontoxic to small mammals on an acute oral basis. Although no data are available on the toxicity of benfluralin to wild mammals, adverse effects were observed in a reproduction study on rats.

Benfluralin has been found to be very highly toxic to freshwater fish on an acute basis. No acceptable data is available to assess risk to freshwater invertebrates. Also, no acceptable data is available to determine toxicity to estuarine fish. Available acute toxicity data on technical benfluralin indicate that it is very highly toxic to estuarine/marine invertebrates.

A honey bee acute toxicity study indicated that technical benfluralin is practically non-toxic to the honey bee. The Agency is unable to assess risk to non-target plants due to a lack of toxicity data on non-target plants.

Additional data is being required to assess risk to birds, freshwater invertebrates, freshwater and estuarine fish, and non-target plants.

Risks to Terrestrial and Aquatic Organisms

The Agency conducted a screening level ecological risk assessment to determine the potential impact of benfluralin use on non-target terrestrial and aquatic organisms. The Agency used modeling to evaluate ecological risks for benfluralin.

Most ecological risk quotient (RQ) values are 9 and below, including RQ values for acute risk to freshwater fish, freshwater invertebrates, and estuarine invertebrates, and for chronic risk to birds, mammals, and freshwater fish. The highest RQ value for non-cropland areas at the maximum application rate of 12 lb ai/A per year is 24 for chronic risk to mammals. The RQs for non-target terrestrial and aquatic plants have not been calculated due to lack of toxicity data.

The Agency's screening level risk assessment for benfluralin concluded that there is a potential for risk to endangered species. Reductions in application rates and/or number of applications will reduce overall risk. The rates for non-cropland sites, ornamentals, and Christmas tree farms are being reduced. The use of benfluralin on alfalfa and lettuce is limited in terms of application rate, frequency of application and the states that use it for these crops. The endangered species assessment on all use sites will be refined using data that will be submitted as a result of this RED. After the new data are reviewed, the risk assessment will be refined, and exceedences of the levels of concern for risks for endangered species will be addressed.

Risk Mitigation

To lessen the risks posed by benfluralin, EPA is requiring the following ecological risk mitigation measures:

- The yearly maximum use rate for benfluralin has been reduced at several use sites. For field-grown ornamentals, container-grown ornamentals, non-bearing berries, non-bearing fruit trees, non-bearing nut trees, and non-bearing vineyards, the maximum yearly rate has been reduced from 9 lbs ai/acre to 6 lbs ai/acre; for landscape ornamentals and Christmas trees, the maximum yearly rate has been reduced from 8 lbs ai/acre to 4 lbs ai/acre; and for non-cropland areas (Industrial Sites, Utility Substations, Highway Guardrails, Sign Posts, and Delineators) the maximum yearly use rate has been reduced from 12 lbs ai/acre to 4 lbs ai/acre.

Additional Data Required

EPA is requiring multiple confirmatory data requirements for benfluralin, including acute fish toxicity, acute aquatic invertebrate toxicity, acute estuarine/marine toxicity in fish and mollusk, fish life cycle, avian reproduction, aquatic plant growth, vegetative vigor, aerobic aquatic metabolism, 90-day inhalation in rat, and carcinogenicity in mouse, among others. For a complete listing of required studies with corresponding guideline number, see Section V of the Benfluralin RED document.

Product Labeling Changes Required

All benfluralin end-use products must comply with EPA's current pesticide product labeling requirements and with the following:

- For Manufacturing Use Products with greater than 60% active ingredient benfluralin, the labeling statement "Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals."
- Directions for watering-in granular formulations used on turfgrass.

- A 12-month plant back interval for crops other than the crops listed on the label.
- Label amendments to minimize the potential for spray drift are required.

For a comprehensive list of labeling requirements, please see Section V of the Benfluralin RED document.

Regulatory Conclusion

EPA has determined that all products containing benfluralin as the active ingredient are eligible for reregistration, provided changes specified in the Benfluralin RED are incorporated into the label and additional data identified in Section V of the RED confirm this conclusion.

Electronic copies of the RED and this fact sheet are available on the Internet. See http://www.epa.gov/pesticides/reregistration/status.htm or http://www.epa.gov/edockets.

Printed copies of the RED and fact sheet can be obtained from EPA's National Service Center for Environmental Publications (EPA/NSCEP), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-553-6847; fax 513-489-8695.

The Benfluralin RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 1-800-553-6847, or 703-605-6000.

For more information about EPA's pesticide reregistration program, the Benfluralin RED, or reregistration of individual products containing benfluralin, contact the Special Review and Reregistration Division (7508C), 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 Pesticide Information Center (NPIC). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 am Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week. The NPIC internet address is http://npic.orst.edu.