

SEPA R.E.D. FACTS

Bendiocarb

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 <u>re</u>registered 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, as well as aggregate exposure of the public to residues of the pesticide from all sources, and the cumulative effects of the pesticide and other compounds with a common mechanism of toxicity. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA reregisters pesticides that meet the safety standard of FQPA and can be used without posing unreasonable risks to human health or the environment.

This fact sheet serves as and explains EPA's Reregistration Eligibility Decision (RED) for Bendiocarb (0409), which consists of a voluntary cancellation of this pesticide. Bendiocarb was scheduled for a reregistration decision in 1999. However, the registrants supporting bendiocarb's registration have requested voluntary cancellation. The public will have 30 days to comment on the voluntary cancellation of bendiocarb when the notice of voluntary cancellation is published in the Federal Register. In addition, the registrants have been granted a 14 month existing stocks provision for products used in or around the home and a 28 month existing stocks provision for other products.

The following information is based on the preliminary review of the existing information on bendiocarb. As a result of the voluntary cancellation, a final review for reregistration will not be completed.

Use Profile

Bendiocarb is a carbamate insecticide used to control household pests, ornamental plant pests, mosquitoes, and fire ants. Bendiocarb is registered for a variety of indoor (homes and commercial establishments), outdoor (ornamental plants, lawns and golf courses) as well as greenhouse uses. Bendiocarb is manufactured into several forms: granular, wettable powder, dust, pellets, pressurized liquid, and pet collars. Bendiocarb is applied by the following methods: broadcast, band treatment, foliar application, dusting, crack and crevice, premise treatment and mound drench.

Regulatory History

Bendiocarb was first registered for use in the United States in 1980. EPA issued a Registration Standard for Bendiocarb in October 1987 (PB540/RS-88-122). A March 1995 and October 1995 Data Call-In (DCI) required additional data for Bendiocarb. Currently, there are 48 bendiocarb products registered.

Human Health Assessment

Toxicity

For oral exposure, bendiocarb is in Acute Toxicity Category I, the highest of four categories for this effect. In addition, bendiocarb is in Acute Toxicity Category II for dermal and inhalation routes of exposure, Acute Toxicity Category III for primary dermal irritation and Acute Toxicity Category IV for primary eye irritation. The existing studies with acute and subacute administration of bendiocarb indicate a rapid onset of cholinesterase inhibition and accompanying symptoms.

The subchronic and chronic toxicity studies demonstrate that bendiocarb inhibits cholinesterease activity in whole blood, plasma, and brain in rats, mice and dogs. Bendiocarb does not produce delayed neurotoxicity in the hen. Bendiocarb is classified as a "Group E" chemical, showing no evidence of carcinogenicity in laboratory animals or in humans. Developmental and reproductive toxicity studies did not show evidence of increased susceptibility of rat or rabbit fetuses following <u>in utero</u> exposure or in offspring following pre- and/or post-natal exposure. There was no evidence of mutagenicity following <u>in vivo</u> or <u>in vitro</u> exposure to bendiocarb. Metabolism studies conducted with rats, mice, hamsters, dogs and humans all indicate that bendiocarb is rapidly absorbed following oral exposure, and the majority of the administered dose is eliminated in the urine.

For occupation and residential short term dermal exposure, the endpoint selected for risk assessment was whole blood cholinesterase inhibition at the lowest observed adverse effect level (LOAEL) of 100 mg/kg/day in a 21-day dermal toxicity study in rats; the short-term no observed adverse effect level (NOAEL) in this study was 50 mg/kg/day. A NOAEL was not established for multiple exposures, therefore an additional uncertainty factor of 3X was applied to both residential and occupational intermediate term assessments. For occupational and residential inhalation exposure, the endpoint was whole blood cholinesterase inhibition at the LOAEL of 0.0013 mg/L in a 90-day rat inhalation toxicity study; the NOAEL was 0.0018 mg/L.

For the chronic dietary risk assessment, the endpoint selected was whole blood cholinesterase inhibition at the LOAEL of 0.25 mg/kg/day in a special 14-day oral toxicity study in rats; the NOAEL in this study was 0.125 mg/kg/day. Thus the reference dose (RfD) for the chronic dietary assessment is 0.00125 mg/kg/day. The

only dietary exposure to bendiocarb may result from crack and crevice use in food service establishments. Bendiocarb has retained the 3-fold FQPA safety factor because of data gaps for acute and subchronic neurotoxicity studies in rats. This factor is applied to dietary and residential assessments. The chronic population adjusted dose (cPAD), which is the reference dose divided by the FQPA safety factor, is 0.0004 mg/kg/day.

Dietary Exposure

Bendiocarb is not registered for use on either food or feed crops. The only food-related use is the spot and crack and crevice treatment of food service establishments. An acute dietary exposure assessment is not required for pesticides having only food handling establishment tolerances. However, a chronic dietary exposure analysis was conducted. The Anticipated Residue Concentration (ARC) for the overall U.S. population represents 3 % of the Population Adjusted Dose (PAD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The most highly exposed subgroup, non-nursing infants less than one year old, has an ARC which represents 13 % of the PAD. This low fraction of the allowable PAD is considered to be an acceptable dietary risk.

Using model estimates, the Agency has calculated drinking water levels of concern (DWLOCs) for bendiocarb. The only estimated environmental concentrations (EECs) of concern were for surface water which exceeded the acute DWLOCs for the general population and children. The estimated peak acute surface water concentrations for ground spray and granular application to turf range from 185 to 202 parts per billion (ppb), respectively.

Occupational and Residential Exposure

Based on the use patterns of bendiocarb, occupational and residential exposures could occur with the granular, wettable powder, dust, pellet, pressurized liquid and pet collar formulations. A total of 43 exposure scenarios were evaluated to estimate potential exposure and risk during mixing/loading, application and post- application activities.

Examples of how bendiocarb products could be applied by a homeowner include: on carpet, furniture, baseboards and floors for treatment of household pests; and on outdoor ornamental plants and turf. The risk assessment showed exposure of the homeowner through several scenarios such as mixing, loading, or applying bendiocarb liquid with a sprayer, dust with a sprinkling can, and granular product with a spreader or an aerosol product. Most of these scenarios indicated risks of concern to the homeowner through both dermal and inhalation routes of exposure. For post-application exposure, children are at risk from exposure to bendiocarb through ingestion by incidental hand to mouth transfer, mostly from treated carpet, furniture, indoor surfaces, and outdoor lawns and as the result of touching treated surfaces and

absorbing bendiocarb through their skin. Workers are exposed to bendiocarb through mixing, loading or applying products in homes and commercial buildings to treat household pests, and through application of bendiocarb products in greenhouses, on turf, and on ornamental plants. Risk estimates for most of these scenarios show risks of concern for workers.

Environmental Assessment

Environmental Fate

Laboratory studies indicate a high degree of mobility; however, field studies indicate that parent bendiocarb generally degrades before leaching through the soil and the major degradate, if detected, is present at low concentrations and remains in upper soil layers. Although parent bendiocarb is sufficiently mobile, screening models indicate that bendiocarb is not likely to move through the soil to ground water.

Bendiocarb can be expected to move to surface water through runoff. Bendiocarb is not likely to accumulate in fish due to its moderate water solubility, and rapid degradation in water.

Ecological Effects

The risk assessment for bendiocarb indicates a single broadcast application of a product on turf could result in high acute risks to birds with levels of concern being exceeded at the registered maximum application rate. Multiple applications are expected to result in repeated acute effects. Due to the lack of data on avian reproduction, chronic effects could not be assessed. The risk assessment indicates acute risks to mammals when bendiocarb is used at the maximum registered application rate. Bendiocarb is highly toxic to bees.

The use of bendiocarb poses acute risks to freshwater fish; however, no chronic risks to freshwater fish are posed by the use of bendiocarb. Bendiocarb use poses both acute and chronic risks to freshwater invertebrates when applied at the registered maximum rate. The risk assessment indicates acute risks to estuarine and marine animals from the use of bendiocarb. Due to the lack of data, chronic risks to estuarine and marine animals were not calculated.

Additional Data Required

There are several outstanding data requirements for bendiocarb. At a minimum, acute and subchronic neurotoxicity studies in rats, a dominant lethal study, several residue chemistry studies, several ecotoxicity studies and an analysis of bendiocarb for dioxin and dibenzofuran contaminants would be required if this chemical were to continue with reregistration.

Conclusion

The terms of the voluntary cancellation include:

- Some products that are not currently marketed are immediately canceled, with no existing stocks provisions;
- The registrant can manufacture the technical product until June 30, 2000; a production cap limits the amount that can be produced to 95,000 pounds per calendar year; and
- End use products used in or around the home can be sold or distributed by the registrant until October 31, 2000. All bendiocarb products will be canceled as of December 31, 2001.

For More Information

For more information about EPA's pesticide reregistration program or the pesticide bendiocarb, please contact Diane Isbell at the Special Review and Reregistration Division (7508C), OPP, US EPA, Washington, DC 20460; telephone 703-308-8154.

Electronic copies of this fact sheet and other REDs are available on the Internet. Please see http://www.epa.gov/REDs.

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, seven days a week. The NPTN website is http://www.ace.orst.edu/info/nptn.