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R.E.D. FACTS

Fenbutatin-oxide

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 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 0245, fenbutatin-oxide or Vendex.

Use Profile

Fenbutatin-oxide is a miticide or acaricide used to control mites, aphids, thrips, mealybugs, whiteflies and scale on citrus, apples, stone fruits, nut trees, several other food crops and ornamentals. Marketed under the trade name Vendex, fenbutatin-oxide is used in the U.S. primarily on orange and grapefruit crops.

Fenbutatin-oxide is formulated as a wettable powder, emulsifiable concentrate and soluble concentrate. It is applied aerially or through airblast or groundboom equipment two to nine times per year, depending on the site.

Regulatory History

Fenbutatin-oxide was first registered as a pesticide in the U.S. in 1974. The first end-use product was registered in August 1975. EPA issued a Registration Standard for fenbutatin-oxide in March 1987 (NTIS #PB87-190690). Currently, 10 pesticide products containing this active ingredient are registered.

Human Health Assessment

Toxicity

Fenbutatin-oxide generally is of low acute toxicity. However, it is a severe eye irritant in rabbits and has been placed in Toxicity Category I, indicating the highest degree of acute toxicity, for eye irritation effects.

In a subchronic dermal toxicity study using rabbits, fenbutatin-oxide caused redness of the skin and swelling at a low dosage but did not cause systemic toxicity.

Fenbutatin-oxide does not cause chronic toxicity and has been classified as a "Group E" carcinogen--a chemical showing evidence of non-carcinogenicity for humans.

In a developmental toxicity study using rats, fenbutatin-oxide caused no compound-related effects in treated dams. A similar study using rabbits resulted in anorexia, gastric lesions and abortions. In a reproductive toxicity study using rats, decreased body weight and food consumption were observed in parents, and pup body weights also were reduced during lactation. Fenbutatin-oxide is not mutagenic.

Metabolism studies indicate that the potential for bioaccumulation of fenbutatin-oxide is minimal. Approximately 1% of the pesticide is absorbed from the gastrointestinal tract when it is administered orally.

A reference dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime, has been established for fenbutatin-oxide at 0.05 mg/kg/day (milligrams per kilogram per day). This RfD is based on the reproductive toxicity study which caused reduced body weight and food consumption in both generations of rats.

Dietary Exposure

People may be exposed to residues of fenbutatin-oxide through the diet. Tolerances or maximum residue limits have been established for citrus, apples, many stone and other fruits, tree nuts and several vegetables (please see 40 CFR 180.362(a) and (c)); for milk fat, eggs and the meat, fat and meat byproducts of cattle, goats, hogs, horses, poultry and sheep (please see 40 CFR 180.362(b); for dried prunes and raisins (please see 40 CFR 185.3550); and for apple and grape pommace, citrus oil and pulp, and raisin waste (please see 40 CFR 186.3550). EPA has reassessed these fenbutatin-oxide tolerances and found that a number of changes are needed, as detailed in the RED document.

International maximum residue limits (MRLs) have been established by Codex for many food commodities. However, because of the differences in tolerance expression between the MRLs and U.S tolerances, compatibility between the two is not achievable. In addition, the U.S. tolerances are higher than the corresponding Codex MRLs. Established U.S. agricultural practices for application of fenbutatin-oxide are unlikely to be changed. Therefore, U.S. tolerance levels probably cannot be lowered to achieve compatibility with Codex MRLs.

EPA has assessed the dietary risk posed by fenbutatin-oxide. For the overall U.S. population, exposure from all current tolerances represents 136% of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. This value likely overstates the risk, however, because it assumes all crops have tolerance-level residues and 100% of all crops with tolerances are treated.

Information on actual anticipated residue levels and percent of crop treated with fenbutatin-oxide was included to more accurately estimate dietary exposure. The resulting Anticipated Residue Contribution (ARC) for the overall U.S. population represents 4% of the RfD, and the ARC for the most highly exposed subgroup, children age one to six, is 8% of the RfD. Chronic dietary risk from exposure to fenbutatin-oxide is believed to be minimal.

Occupational and Residential Exposure

Occupational and residential exposure can be expected based on the use patterns of currently registered products containing fenbutatin-oxide. The Worker Protection Standard for Agricultural Pesticides (WPS) established an interim 48-hour restricted entry interval (REI) based on fenbutatin-oxide's Toxicity Category I eye irritation potential. EPA has determined that the 48-hour REI should be retained for all WPS sites as a prudent measure to mitigate risk to workers entering treated areas after application. The personal protective equipment (PPE) required for early entry includes coveralls, chemical-resistant gloves, shoes, socks and protective eyewear.

Uses of fenbutatin-oxide that are outside the scope of the WPS including occupational and residential use products are required to add strengthened entry restrictions to their labels.

Human Risk Assessment

Fenbutatin-oxide generally is of low acute toxicity but is a severe eye irritant. It poses no significant chronic health risks and is classified as a Group E carcinogen, indicating that it poses no known cancer risk for humans.

Although people may be exposed to residues of fenbutatin-oxide in many fruits and other foods, the chronic dietary risk from such exposure is minimal. Workers and other users may be exposed to fenbutatin-oxide during and after application to food crops and ornamentals. To mitigate the risk of eye irritation during these activities, EPA is requiring a 48-hour REI and use of PPE including protective eyewear for all agricultural uses within the scope of the WPS, and more stringent entry restrictions for non-WPS occupational and residential uses.

Environmental Assessment

Environmental Fate

Fenbutatin-oxide is persistent in the environment, with no major route of dissipation. It is relatively unsusceptible to hydrolysis or photodegradation in water or on soil. Microbial degradation of fenbutatin-oxide in soil also is very slow.

Fenbutatin-oxide is relatively immobile in the environment. It is slightly soluble in water, has a low vapor pressure and binds strongly to soil. Therefore, it is not expected to leach.

Although fenbutatin-oxide is persistent, residues do not tend to accumulate in crops planted in previously treated soil. Fenbutatin-oxide does accumulate in fish tissues.

In the field, fenbutatin-oxide exhibits the same characteristics of persistence and immobility as in the laboratory. Calculated half-lives range from 271 days to 1367 days in different States and soils. This long half-life causes residue levels to increase with each successive application.

Ecological Effects

Fenbutatin-oxide is practically nontoxic to birds on an acute and subacute dietary basis, and has no effect on their reproduction. It also is practically nontoxic to mammals and honey bees. However, fenbutatin-oxide is very highly toxic to freshwater, estuarine and marine fish and invertebrates.

Ecological Effects Risk Assessment

Although no acute hazard is expected, use of fenbutatin-oxide at current rates does present the potential for chronic hazard to birds and mammals. Hazards to bees and nontarget plants are not anticipated.

Acute risk to freshwater fish is expected for all major uses of fenbutatin-oxide at current application rates. Acute risk to freshwater invertebrates is only expected for the citrus use, and acute risk to estuarine invertebrates is expected from both the citrus and the apple uses.

A significant potential for chronic risk to fish exists from the use of fenbutatin-oxide on citrus. No chronic risk is anticipated for freshwater and estuarine invertebrates.

Acute risk to endangered birds and mammals is not expected, but there is a potential for chronic hazard to these organisms. Acute risk to endangered freshwater fish and invertebrates is expected from all major uses. Use of fenbutatin-oxide on citrus presents significant potential for chronic hazard to endangered freshwater and estuarine fish.

Additional Data Required

EPA is requiring the following additional generic data for fenbutatin-oxide to confirm its regulatory assessments and conclusions: Discussion of formation impurities, Ph, bioaccumulation in fish, droplet size spectrum, and drift field evaluation.

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 fenbutatin-oxide end-use products must comply with EPA's current pesticide product labeling requirements, and with the following:

Use Directions (Restricted Use Classification)

All uses of fenbutatin-oxide are declared Restricted, and products reregistered under this RED must bear a restricted use legend at the top of the front panel of the label. No other wording or symbols may appear above the legend and it must begin with the heading,"RESTRICTED USE PESTICIDE," followed by a brief statement of the reason for the restricted use classification (ie, "DUE TO VERY HIGH TOXICITY TO AQUATIC ORGANISMS"). Following this, the terms of the restriction must be stated as, "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification."

Entry Restrictions and Personal Protective Equipment (PPE)

For occupational end-use products, EPA is establishing a 48-hour restricted entry interval (REI) for each use that is within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The PPE required for early entry permitted by the WPS is coveralls, chemical-resistant gloves, shoes plus socks, and protective eyewear.

All end-use products with non-WPS occupational uses must bear the following entry restriction:

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

All residential use products must bear the following entry restriction:

> "Do not allow persons or pets to enter the treated area until sprays have dried."

Other Labeling Restrictions

EPA is requiring the following labeling statements on all end-use products 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."
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> 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 no such instructions exist 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."

Type of Respirator: If the acute inhalation toxicity of the end-use product is in category I or II, then a respirator is required for pesticide handlers. A dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) is the only type of respirator that is appropriate to mitigate fenbutatin-oxide inhalation concerns.

Toxicity Statement

Due to the toxicity of fenbutatin-oxide to birds, mammals and aquatic organisms, all end-use product labels must bear the following statement:

"This pesticide is toxic to birds, mammals, fish, and aquatic invertebrates. 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."

Drift Reductions

To mitigate risks posed due to fenbutatin-oxide's high toxicity to aquatic organisms, all end-use product labels with aerial applications must bear the following statements for citrus use in Florida:

1) Do not apply within 125 feet of bodies of water such as lakes, reservoirs, rivers, permanent streams, natural ponds, marshes or estuaries.

2) Do not apply when gusts or sustained winds exceed 8 mph.

3) The boom length must not exceed 3/4 of the wing or rotor length (ie, the distance of the outer-most nozzles on the boom must not exceed 3/4 or the length of the wingspan or rotor).

4) Do not apply at a height greater than 10 feet above the top of the target plants unless a greater height is required for aircraft safety.

5) Nozzles must always point backward and never be pointed downwards more than 45 degrees.

6) Do not apply in less than 10 gallons of final spray per acre.

7) Do not apply east of US Highway #1, south and east of State Road #846 or south of West Palm Beach Canal.

All end-use products using airblast applications must bear the following statements for citrus use in Florida:

1) Citrus groves may be planted close to bodies of water. Do not apply within 25 feet of bodies of water such as lakes, reservoirs, rivers, permanent streams, natural ponds, marshes or estuaries.

2) For all plantings within 75 feet of bodies of water as described above, spray trees only form outside the planting away form the bodies of water.

3) Shut off the sprayer when turning at row ends.

4) Do not apply when gusts or sustained winds exceed 12 mph.

Regulatory Conclusion

To ensure that the potential risks of this pesticide are not unreasonable, EPA is classifying fenbutatin-oxide as a Restricted Use Pesticide and is requiring the registrant to implement certain risk mitigation measures. Provided that these measures are implemented, all products containing fenbutatin-oxide as an active ingredient are eligible for reregistration.

The Restricted Use Pesticide classification is appropriate for all uses of fenbutatin-oxide because many of its use sites are located on or near bodies of water, and this pesticide is very highly toxic to freshwater and estuarine aquatic organisms. Fenbutatin-oxide persists in the environment long after initial application. The potential for serious contamination of the ecosystem is substantial.

The required risk mitigation measures are designed to reduce the risk to freshwater and estuarine aquatic organisms found near Florida's citrus groves. Measures include reduced application rates, label amendments with instructions to minimize spray drift, development of more accurate aquatic modeling, and monitoring to determine if fenbutatin-oxide levels accumulate over multiple years of use.

Fenbutatin-oxide products will be reregistered once the confirmatory generic data, product-specific data, revised Confidential Statements of Formula and revised labeling (including the Restricted Use Pesticide classification) are received and accepted by EPA, assuming that the required risk mitigation measures also are implemented.

For More

EPA is requesting public comments on the Reregistration Eligibility

Information

Decision (RED) document for fenbutatin-oxide 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 fenbutatin-oxide 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 fenbutatin-oxide RED, or reregistration of individual products containing fenbutatin-oxide, 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.