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R.E.D. FACTS

Pendimethalin

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 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 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 0187, pendimethalin.

Use Profile

Pendimethalin is a selective herbicide used to control broadleaf weeds and grassy weed species in a number of crop and noncrop areas and on residential lawns and ornamentals. Formulations include liquid, solid, granular, emsulsifiable concentrate, and dry flowables. Pendimethalin is applied by broadcast, chemigation, conservation tillage, containerized plant treatment, soil incorporation, and directed spray.

Regulatory History

Pendimethalin was first registered as a pesticide in the U.S. in 1972. EPA issued a Registration Standard for pendimethalin in March 1985 (PB86-172814). A October 1990 Data Call-In (DCI) required additional product and residue chemistry, toxicology, ecological effects and environmental fate data. Currently, 58 pendimethalin products are registered.

Human Health Assessment

Toxicity

In studies using laboratory animals, pendimethalin generally has been shown to be of low acute toxicity. It is slightly toxic by the oral and eye route and has been placed in Toxicity Category III (the second lowest of four categories) for these effects. It is practically non-toxic by the dermal and inhalation routes and has been placed in Toxicity Category IV (the lowest of four categories).

Dietary Exposure

People may be exposed to residues of pendimethalin through the diet. Tolerances or maximum residue limits have been established for pendimethalin (please see 40 CFR 180.361). EPA has reassessed the pendimethalin tolerances and found that data for cotton gin by-products and tobacco are required. The need for additional tolerances will be determined upon receipt and evaluation of these data.

EPA has assessed the dietary risk posed by pendimethalin. For the overall U.S. population, exposure from all current pendimethalin tolerances represents less than 1% of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The exposure level of the most highly exposed subgroup, non-nursing infants, represents less than 2% of the RfD. Actual risks using anticipated residue information would be considerably less than 1% of the RfD for all population subgroups. Therefore, it appears that chronic dietary risk is minimal.

Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to pendimethalin during and after normal use of pendimethalin formulations.

Human Risk Assessment

Pendimethalin generally is of low acute toxicity, but causes thyroid follicular cell adenomas in male and female rats and has been classified as a Group C, possible human carcinogen. Many food and feed crops are registered; however, dietary exposure to pendimethalin residues in foods is extremely low, as is the cancer risk posed to the general population.

Of greater concern is the risk posed to occupational handlers involved in food, feed, fiber, ornamental, turf, rights-of-way and other noncrop treatments; and homeowner handlers making applications to residential turf.

Occupational/Short and Intermediate Term:

Agency calculations indicate that Margins of Exposure (MOEs) for handlers wearing baseline attire (long-sleeve shirt, long pants, shoes and socks) are acceptable (over 100) for all but three scenarios: (1) mixing/loading liquid for aerial applications and irrigation systems, (2) mixing/loading liquid for rights-of-way spraying, and (3) mixing/loading liquid for groundboom applications. These MOEs range from 1.5 to 59.

The risks to handlers in these scenarios are reduced to an adequate level (MOEs range from 110 to 33,333) when chemical-resistant gloves are added to the baseline attire.

Occupational/Post Application:

The Agency has determined that there are risks following applications to commercial or research food, feed, fiber, turf, and ornamental crops. Restricted Entry Intervals (REIs) can allow sufficient time to pass for residues to dissipate to levels that result in adequate MOEs. Pending the development of pendimethalin specific data, the Agency is requiring that the 12-hour interim REI be increased to 24 hours for all pendimethalin uses within the scope of the Worker Protection Standard (WPS).

However, REIs are generally not feasible as a mitigation measure for occupational exposures in noncrop areas (such as rights-of-way). Therefore, as a risk mitigation measure, the Agency is requiring a reduction in the maximum use rate from 3 lbs active ingredient(ai)/acre to 2 lbs. ai/acre. The registrant agreed to this reduction in the maximum application rate.

Residential/Post Application:

Again, REIs are not practical or feasible for residential or recreational turf; consequently, the Agency is requiring a reduction in the maximum use rate to 2 lbs. ai/acre.

FQPA Considerations

EPA has determined that the established tolerances with amendments and changes as specified in this document, meet the FQPA safety standard for the general population. In reaching this determination, EPA has considered the available information on aggregate exposures (both acute and chronic) from non-occupational sources, food and drinking water.

Pendimethalin has both food and non-occupational uses; therefore, the considerations for aggregate exposure are those from food, drinking water, and residential non-occupational sources.

Chronic dietary risks utilizing tolerance level residues and 100% crop treated (TMRC) are <1% of the RfD for the general population.

Based on limited ground water monitoring data (data from 8 states with 2 states with detectable residues), the maximum level found was 0.9 ppb. The maximum level of pendimethalin found in surface water is 17.6 ppb. Based on this information, the estimated risks from water are <2% RfD for all population subgroups, including those most highly exposed to pendimethalin residues.

In evaluating the potential for cumulative effects, EPA does not have, at this time, available data to determine whether pendimethalin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which

EPA has followed a cumulative risk approach based on common mechanism of toxicity, pendimethalin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that pendimethalin has a common mechanism of toxicity with other pesticides.

Environmental Assessment

Environmental Risk Characterization

Pendimethalin dissipates in the environment by binding to soil, microbially-mediated metabolism and volatilization. It is essentially immobile in soil.

Based on laboratory studies and limited field study information, pendimethalin is slightly to moderately persistent in aerobic soil environments. Persistence decreases with increased temperature, increased moisture and decreased soil organic carbon.

Additional terrestrial field dissipation studies for major pendimethalin uses (cotton and soybeans) are requested to fully characterize the fate of pendimethalin.

Pendimethalin may contaminate surface water from spray drift associated with aerial and ground spray application, or in runoff from rainfall events and through irrigation waters (chemigation). However, its high affinity to bind to soil and sediment particles should limit concentrations of pendimethalin in surface waters.

Although pendimethalin has been detected in ground water (at very low levels), the potential for ground water contamination from pendimethalin residues is low.

Pendimethalin would not represent a high acute risk to birds or a high acute or chronic risk to mammals. The chronic risk to birds could not be determined because avian reproduction studies have not been submitted. These studies are required.

Chronic risk Levels of Concern (LOCs) for fish were exceeded by a small margin. But it is presumed that overall, pendimethalin does not represent a high risk to aquatic animals and plants, including estuarine organisms.

The use of pendimethalin may adversely effect endangered species of terrestrial and semi-aquatic plants, aquatic plants and invertebrates including mollusks, fish, and birds (specifically grazers).

The risk to nontarget terrestrial and semi-aquatic plants is expected to be moderate.

Risk Mitigation

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

For occupational handlers/use sites:

- increase restricted entry interval from 12 to 24 hours;
- add chemical resistant gloves;
- engineering controls--all WP formulations must be contained in water-soluble packaging.

For residential lawns and sod farm use sites:

- reduce maximum application rate from 3 lbs. ai/acre to 2 lbs. ai/acre for residential and sod farm use sites

To reduce risks to nontarget plants:

- Add spray drift best management practices.

Additional Data Required

EPA is requiring the following additional generic studies for pendimethalin to confirm its regulatory assessments and conclusions: post application reentry studies (guidelines 132-1a, b), physical/chemical properties for the 86.8% and 60% FIs (61-1 through 61-3, 62-2, 62-3), magnitude of residue for tobacco and cotton gin byproducts (171-4k), processing for rice (171-4l), avian chronic (71-4), field dissipation for cotton and soybeans (164-1), and aquatic dissipation for rice (164-2).

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 pendimethalin end-use products must comply with EPA's current pesticide product labeling requirements and with the following. For a comprehensive list of labeling requirements, please see the pendimethalin RED document.

The Agency is establishing minimum (baseline) **engineering controls** for occupational uses of pendimethalin end-use products formulated as wettable powders. All wettable powder formulations must be contained in water-soluble packaging.

Products Intended for Occupational Use- WPS Uses

The **minimum (baseline) PPE** for occupational uses of pendimethalin end-use products are:

For emulsifiable concentrate formulations:

Mixers and loaders must wear:

-- long-sleeved shirt and long pants,

-- chemical-resistant gloves, and

-- shoes plus socks

For water-dispersible granule, wettable powder, and emulsifiable concentrate formulations whose use directions reasonably permit application using hand-held sprayers:

Commercial Handlers (mixers, loaders, and applicators) who apply this product using hand-held equipment or hoses (not including hoses attached to truck-mounted equipment) must wear:

-- long-sleeved shirt and long pants,

-- chemical-resistant gloves, and

-- shoes plus socks

Restricted-entry interval:

A 24-hour restricted-entry interval (REI) is required for uses on food, feed, fiber, ornamental, forestry, and turf crops within the scope of the WPS on all pendimethalin end-use products.

Exception: if the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

The labels of all pendimethalin end-use products must be revised to bear the following application rate for the respective uses:

For residential lawn and sod farm uses:

"Maximum application rate of 2.0 lbs. active ingredient per acre."

NonWPS uses

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."

Products Intended Primarily for Homeowner Use

Entry restrictions:

The Agency is establishing the following entry restrictions for all homeowner uses of pendimethalin end-use products (NOTE: This presumes the registrant reduces the maximum application rate for turf at residential sites and parks and recreation areas to two pounds active ingredient per acre.):

For liquid applications:

"Do not allow people or pets to touch treated plants until the sprays have dried."

For dry applications:

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

Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing pendimethalin 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, 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."

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."

Products Intended Primarily for Home Use

Application Restrictions

"Do not apply this product in a way that will contact any person or pet, either directly or through drift. Keep people and pets out of the area during application."

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."

Environmental Hazards Statement

"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 washwaters."

Application Rates

The labels of all pendimethalin end-use products must be revised to bear the following application rate for the respective uses:

For residential lawn and sod farm uses:

"Maximum application rate of 2.0 lbs. active ingredient per acre."

Spray Drift

A spray drift labeling advisory is required for labels of all products that can be applied aerially.

Regulatory Conclusion

The use of currently registered products containing pendimethalin 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.

Pendimethalin 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 pendimethalin 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 45242-2419, telephone 1-800-490-9198, fax 513-489-8695.

Following the comment period, the pendimethalin 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 pendimethalin RED, or reregistration of individual products containing pendimethalin, 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.