



R.E.D. FACTS

Oryzalin

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 for reregistration case 0186, oryzalin.

Use Profile

Oryzalin is a herbicide that acts by inhibiting cell division in plants. It is used to control annual grasses, broadleaf weeds, woody shrubs and vines in grapes, berries and orchard crops, including both fruits and nuts. It also is used on residential and commercial/industrial lawns and turf, golf course turf, ornamentals and shade trees, Christmas tree plantations, fencerows/hedgerows, nonagricultural rights-of-way, and uncultivated areas including patios, paths, paved areas and power stations. Oryzalin is used most on turf, almond orchards and grapes. Formulation types include granular, wettable powder, water dispersible granules, emulsifiable concentrate, flowable concentrate and liquid.

Regulatory History

Oryzalin was first registered in the U.S. as a pre-emergence herbicide in 1974. EPA issued a Registration Standard for oryzalin in 1987 (NTIS #PB90-174137), and a Data Call-In notice in 1991. Currently, one technical product, two formulation intermediates and 35 end-use products containing oryzalin are registered.

Human Health Assessment Toxicity

In acute toxicity studies using laboratory animals, oryzalin is practically non-toxic by the oral route and has been placed in Toxicity Category IV (the lowest of four categories) for this effect. It is of moderate dermal and inhalation toxicity and causes slight eye irritation, and has been placed in Toxicity Category III for these effects. No skin sensitization occurred in tests on guinea pigs.

In subchronic toxicity studies, oryzalin caused the accumulation of an iron-containing pigment in the kidneys of rats, an increase in the weights of several organs in mice, and blood, bone marrow and liver effects in beagle dogs.

Oryzalin is carcinogenic in rats, based on an increase in mammary gland tumors in females and skin and thyroid tumors in both sexes. It has been classified as a Group C carcinogen--that is, a possible human carcinogen for which there is limited animal evidence.

Another chronic toxicity study using beagle dogs showed effects to the blood, liver, kidneys and thyroid gland. In developmental toxicity studies using rats, oryzalin caused reduced maternal body weight gain as well as decreased fetal body weights, an increase in runts and bone development effects. In rabbits, it caused reduced maternal food consumption and weight gain, fetal effects and reduced litter size. Reproduction studies using rats showed increased liver and kidney weights, and decreased food consumption and body weight gain. Oryzalin was not mutagenic in several studies. A dermal irritation study using the oryzalin technical product is required as confirmatory data.

Dietary Exposure

People may be exposed to residues of oryzalin in the diet when consuming treated food commodities including almonds, avocados, citrus fruits, figs, kiwi fruits, olives, pistachios, pome fruits (apples and pears), pomegranates, small fruits (berries and grapes), stone fruits, tree nuts, guavas and papayas. Tolerances or maximum residue limits are established for these commodities (please see 40 CFR 180.304(a) and (b)), have been reassessed and are acceptable. Tolerances established for several other food crops will be revoked since no registrations for these uses currently exist. A new tolerance has been proposed for green coffee beans.

Available data indicate that residues of oryzalin do not concentrate in processed food or feed; therefore, no food/feed additive tolerances are established or required. If studies currently underway indicate that residues do, in fact, concentrate in processed foods, EPA will not be able to set such tolerances for oryzalin due to the Delaney Clause in Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA), which prohibits the establishment of food/feed additive tolerances for substances that cause cancer in test animals or humans.

No international Codex Maximum Residue Levels (MRLs) have been established or proposed for oryzalin.

EPA has assessed the dietary risk posed by oryzalin. For each of the population groups and subgroups analyzed, chronic dietary exposure is less than 1/5,000th of the Reference Dose (RfD), an amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The dietary excess cancer risk for the entire U.S. population is estimated to be 8.1×10^{-7} , or 8.1 extra incidences of cancer in 10,000,000. When tolerances for unregistered commodities are revoked, the upper bound excess cancer risk estimate will be even lower-- 4.5×10^{-7} , or 4.5 extra cancer cases in 10 million.

Occupational and Residential Exposure

Pesticide handlers (mixers, loaders and applicators) may be exposed to oryzalin during application. EPA conducted a limited exposure/risk assessment based on available data, examining seven major exposure scenarios for private and commercial applicators. Low pressure handwand application was found to have the highest exposure and risk potential. The private applicator using handwand equipment has an excess risk of 2.6×10^{-5} , or 2.6 extra cancer incidences in 100,000. The commercial applicator using handwand equipment, who is exposed more frequently, has the greatest estimated excess cancer risk; that is, 2.6×10^{-4} , or 2.6 extra cancer cases in 10,000. To mitigate these risks, workers will be required to wear chemical-resistant boots during low pressure handwand application. This will reduce exposure below the knees, which is significant.

The Worker Protection Standard (WPS) requires workers handling oryzalin to wear long pants, long sleeved shirts and chemical-resistant gloves. Because the pesticide is a possible human carcinogen, EPA also is requiring the use of coveralls and chemical resistant footwear for all uses of oryzalin (except homeowner uses).

Post-application/reentry exposure also is of concern, and reentry data are not available to calculate a Restricted Entry Interval (REI). For agricultural and ornamental crops where reentry exposure is likely, EPA is requiring an REI of 24 hours instead of 12 hours as imposed by the WPS.

When residential lawns are treated with oryzalin, there is a potential for continued, substantial contact with treated surfaces, especially among children. EPA is concerned about these postapplication exposures because oryzalin is a possible human carcinogen and is persistent. Because of the lack of turfgrass exposure data, however, the safety of this use cannot be evaluated. Such exposure data are required by the RED document. Until they are submitted and evaluated, the residential lawn and turf use of oryzalin is not eligible for reregistration.

Human Risk Assessment

Oryzalin generally is of moderate acute toxicity, but is carcinogenic in animal studies and has been classified as a Group C, possible human carcinogen. Several food crop uses, including grapes and a variety of fruits and nuts, are registered. However, dietary exposure to oryzalin residues in foods is extremely low, as is the cancer risk posed by this pesticide to the general population.

Of greater concern is the risk posed to oryzalin handlers (mixers, loaders and applicators), and to field workers and others who come into contact with treated foliage, crops, lawns or turf following application of this herbicide. Exposure and risk to all applicators will be mitigated by the use of personal protective equipment (PPE) required by the Worker Protection Standard (WPS), supplemented by coveralls and chemical-resistant footwear, as required by this RED.

Post-application reentry workers will be required to observe a 24-hour Restricted Entry Interval (REI), which is twice as stringent as that set forth by the WPS. The residential lawn and turfgrass use of oryzalin is not eligible for reregistration until post-application exposure studies are submitted to EPA and evaluated.

Environmental Assessment

Environmental Fate

Parent oryzalin biodegrades slowly with a half-life of approximately two months. It is not mobile under field conditions and is not volatile. However, up to 20% of the oryzalin degradates may leach. The registrant is conducting a study to determine whether degradate leaching is a major route of dissipation.

Ecological Effects

A preliminary risk screening based on available data indicates that, from an acute toxicity perspective, oryzalin is moderately toxic to freshwater fish and invertebrates, and practically nontoxic to birds, small mammals and honeybees. As would be expected of a herbicide, oryzalin poses an acute risk to non-target plants, including threatened and endangered plants.

Ecological Effects Risk Assessment

Minimal risks to birds are posed from acute and dietary exposure to oryzalin. Chronic risks are not posed at single application rates of 4 pounds active ingredient per acre (4 lb ai/A) or less. However, EPA is unable to determine whether higher application rates pose a serious avian reproduction threat, and is requiring further studies to complete an assessment of chronic avian risks.

Oryzalin does not appear to pose a risk to nonendangered freshwater fish. However, a *Daphnia* life-cycle study is needed to determine the chronic risk to freshwater invertebrates. Acute toxicity studies also are needed to determine the risks to estuarine and marine organisms.

Oryzalin poses a risk to endangered aquatic species in shallow water adjacent to treated areas. It also poses a high risk to nontarget plants, including endangered and threatened plants, from runoff and spray drift. These risks will be addressed through implementation of the Endangered Species Protection Program.

Meanwhile, the technical producer of oryzalin has agreed to take several measures to reduce the pesticide's environmental risks. To mitigate exposure problems associated with spray drift, airplane and helicopter applications will no longer be allowed except to agricultural crops in California. In addition, labeling changes are being required to reflect the maximum amount of oryzalin that may be applied per year, the maximum number of applications and the interval between applications.

Additional Data Required

EPA is requiring the following additional generic studies for oryzalin to confirm its regulatory assessments and conclusions: Avian Reproduction (mallard and quail); Acute Toxicity to Estuarine and Marine Organisms (fish, mollusk and shrimp); Aquatic Invertebrate Lifecycle; Dermal Irritation; Leaching/Adsorption/Desorption (underway); Spray Drift; Storage Stability (apples and grapes, underway); and Processing Studies (citrus and olives, underway). In addition, Mixer/Loader/Applicator Exposure Monitoring studies are required for low pressure handwand application including Estimation of Dermal Exposure at Outdoor Sites and Estimation of Inhalation Exposure at Outdoor Sites. Reentry Protection studies are required for use of oryzalin on residential lawns and turf including: Foliar Dislodgeable Residues; Soil Dislodgeable Residues; Estimation of Dermal Exposure; and Estimation of Inhalation Exposure. The same studies (except Soil Dislodgeable Residues) also are required for Christmas tree and field-grown rose uses of oryzalin.

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSF) and revised labeling for reregistration.

Product Labeling Changes Required

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

Worker Protection Standard (WPS)

POST-APPLICATION REENTRY RESTRICTIONS

- WPS Uses - A 24 hour Restricted Entry Interval (REI) is required for all oryzalin end-use products registered for uses that are within the scope of the WPS.

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- Non-WPS Uses - The following entry prohibitions are required:
 - For Liquids: "Keep all persons, children and pets out of the treated area until sprays have dried."
 - For Dry Formulations: "Keep all persons, children and pets out of the treated area until dusts have settled."
 - For All Other Non-WPS Formulations including Those for Residential Use: "Keep all persons, children and pets out of the treated area until sprays have dried or dusts have settled."

PERSONAL PROTECTIVE EQUIPMENT (PPE) REQUIREMENTS

- WPS Occupational Uses and Non-WPS Uses - The minimum PPE requirements for pesticide handlers are:
 - Coveralls over long-sleeved shirt and long pants;
 - Chemical resistant gloves;
 - Chemical resistant footwear;
 - Chemical resistant headgear for overhead exposures; and
 - Chemical resistant apron (mixers and loaders).
- Homeowner Uses - The minimum PPE requirements are:
 - Long-sleeved shirt and long pants; and
 - Chemical resistant gloves.

WITH ENGINEERING CONTROLS

- When handlers use closed systems, enclosed cabs or aircraft in a manner consistent with the WPS, the requirements above may be modified or reduced. See the WPS for specifics.

USER SAFETY STATEMENTS

- 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.
- Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.
- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing immediately if pesticide gets inside.
- Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing. Wash the outside of gloves before removing.
- For WPS and non-WPS uses, 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.

Precautionary Statement for Fish - To protect fish, all oryzalin end-use product labels must include the following statement:

"This product is toxic to fish. Do not apply this product directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark."

Grazing Restrictions - All oryzalin end-use products must include the following statement:

"Do not graze or feed forage from treated fields or orchards to livestock."

Changes in Directions for Use - All end-use labels must bear specific application rates, number of applications per year, total pounds active ingredient per year, and intervals between applications, as specified in Table 12 of the oryzalin RED document.

Restriction on Aerial Application - All end-use product labels must prohibit aerial application except for agricultural uses in California.

Regulatory Conclusion

EPA has determined that products containing oryzalin are eligible for reregistration **except** products labeled for use on residential lawns and turf.

The use of eligible oryzalin products in accordance with labeling specified in this RED will not pose unreasonable adverse effects to humans or the environment. These products will be reregistered once the required confirmatory generic data, product specific data, Confidential Statements of Formula and revised labeling are received and accepted by EPA. Products which contain active ingredients in addition to oryzalin will be reregistered when all of their other active ingredients also are eligible for reregistration.

EPA does not have enough information at this time to make an eligibility decision for oryzalin products labeled for use on residential lawns and turf. The Agency is requiring additional data in order to develop a more complete database regarding these uses of oryzalin.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for oryzalin 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 oryzalin 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 oryzalin RED, or reregistration of individual products containing oryzalin, 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, from 8:00 am to 6:00 pm Central Time, Monday through Friday.