

US EPA ARCHIVE DOCUMENT

EPA R.E.D. FACTS

Ziram

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 Ziram one of four chemicals in reregistration case 2180.

Use Profile

Ziram is an agricultural fungicide registered to control fungal diseases on a wide range of crops including stone fruits, pome fruits, nut crops, vegetables and commercially grown ornamentals. In addition, it is formulated as a rabbit repellent for outdoor foliar applications to ornamentals and as an additive in industrial adhesives, caulking, and latex paints. The total annual domestic use of ziram is approximately 1.9 million pounds of active ingredient.

Regulatory History

Ziram was first registered in the United States in 1960 as a broad spectrum use fungicide to control the scab in apples and pears, leaf curl in peaches, and anthracnose and early blight in tomatoes. In 1981, additional uses were added to the label for controlling leaf blight and scab in almonds, shot-hole in apricots, brown rot and leaf spot in cherries, scab and anthracnose in pecans, and leaf spot, rust and powdery mildew in ornamentals. Other registered uses of ziram include homeowner application on residential ornamentals as a rabbit repellent and

industrial application as a preservative in exterior latex paint, caulking, sealants and wall boards.

Human Health Assessment Toxicity

The mechanism of toxicity for ziram has not been fully investigated; however the primary target organs appear to be the nervous system, liver, and thyroid. Ziram has moderate acute toxicity. It has been placed in a toxicity category II/III for oral and dermal exposure, in category II for inhalation exposure, in category I for eye irritation, and in category IV for skin irritation. Ziram is a moderate skin sensitizer, and is classified as “suggestive of carcinogenicity” to humans.

Dietary Exposure (Food and Water)

EPA has assessed dietary risk by estimating exposure to ziram residues from consumption of food and drinking water. Both chronic and acute food risks, as measured by the Population Adjusted Doses (PAD) are below the Agency’s level of concern. Since ziram residues are primarily found on the surface of the fruit and are not systemic in nature, applying a washing reduction factor (0.15) to the acute residues was a practical way to refine the residues in fruits. When a washing reduction factor of 0.15 was applied to the residues of all commodities (except nuts and berries) the maximum acute dietary estimates were below the Agency’s level of concern for all population subgroups. The chronic (non-cancer) food exposures, even without applying the washing reduction factor were below the level of concern for all population subgroups. Drinking water risk estimates are based on surface and groundwater screening models. The PRZM/EXAMS and the SCI-GROW models were used on surface and ground water respectively. The drinking water level of comparison (DWLOCs) for all population subgroups, are higher than the surface and groundwater estimated drinking water concentration (EDWC). Therefore, the chronic and acute drinking water exposures are not of concern to the Agency.

Aggregate Risk

Under the Food Quality Protection Act of 1996, the Agency considers contributions to risk from various exposure sources, specifically food, drinking water, and non-occupational sources. Residential exposure and risk from the use of ziram was limited to short-term exposure scenarios (dermal and inhalation) because intermediate-term and chronic residential exposure to ziram from the rabbit repellent and its use in paint are not expected to occur.

Occupational and Residential Exposure

Occupational exposure is of concern to EPA for workers handling ziram in agricultural settings and commercial painters. Workers can be exposed during mixing/loading and applying formulations containing ziram on agricultural,

ornamental and commercial/industrial settings or re-entering the treated areas. Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE), which determines how close the exposure comes to a No Observable Adverse Effect Level (NOAEL). Generally, MOEs greater than 100 are not of concern.

Agricultural workers are primarily exposed to the dry flowable, liquid, and wettable powder formulations. Both dermal and inhalation exposures are expected to mixers, loaders, and applicators. The MOEs for agricultural workers ranged from 8 to 170 while the target MOE was 100. The proposed mitigation is expected to result in an acceptable level of risk for agricultural workers.

EPA's residential risk assessment indicates concern from outdoor use of latex paints usually applied either with an airless sprayer or a brush. As a result, dermal and inhalation exposures can result to homeowners. Only short-term exposures were calculated because the Agency does not believe that homeowners who apply paints with ziram will be exposed to the product for more than seven days. Lowering the concentration of ziram in paints should result in acceptable levels of risk. The Agency applied an uncertainty factor of 100 along with a FQPA safety factor of 3x for a target MOE of 300. This additional factor was applicable due to the quantitative evidence of increased susceptibility in the developmental neurotoxicity study in rats. The combined dermal and inhalation MOEs are 74 for the airless sprayer and 351 for the paint brush.

Tolerances

The tolerances for ziram and the other dithiocarbamates are enforced by a common moiety method that determines carbon disulfide. The Agency is recommending that the tolerances for ziram and all other dithiocarbamates be changed to be expressed in terms of carbon disulfide. This recommended change in tolerance expression allows harmonization of US tolerances with Codex MRLs.

Tolerances (refer to 40 CFR §180.116) or maximum residue limits are summarized here. There are approximately 41 proposed revocations and 7 proposed new tolerances for ziram. The majority of the tolerances have remained the same while some have decreased.

Environmental Assessment

Environmental Fate

The major routes of dissipation of ziram are hydrolysis, photodegradation and aerobic soil metabolism. Ziram's high susceptibility to degradation under neutral and acidic environments reduces residues of ziram significantly in soil and water, thereby minimizing the probability of prolonged exposure of terrestrial and aquatic organisms to the chemical.

Ecological Effects

EPA has identified ecological risks of concern from ziram use, particularly to birds, mammals, and aquatic organisms. Ziram showed low acute toxicity for mammals, is moderately toxic to avian species and highly toxic to aquatic organisms. Exposure is determined by modeling residue concentrations on foodstuffs for terrestrial animals and in water for aquatic organisms.

Risk Mitigation To mitigate risks to homeowners and commercial painters:

- Reduce the concentration of ziram in latex paints from 3% to 1%.

To mitigate risks to agricultural workers:

- Upgrade personal protective equipment (PPE) for mixer/loaders of liquid formulations from baseline to minimal.
- Require all wettable powder formulations to be packaged in water soluble bags.
- Require pilots to use planes with enclosed cockpits when applying aerially.
- Cancel aerial applications on blackberries, blueberries, apples grown East of the Rockies, cherries grown East of the Rockies, grapes grown East of the Rockies, peaches grown East of the Rockies, nectarines, pears, pecans, and tomatoes.

To mitigate ecological risks:

- Reduce application rates on apples, cherries grown East of the Rockies, pears, nectarines, and peaches grown West of the Rockies.
- Reduce the maximum numbers of applications to apricots, cherries, nectarines, peaches, and pecans.

Additional Data Required

EPA is requiring the following additional generic studies for Ziram to confirm its regulatory assessments and conclusions:

- 830.7840 Additional water solubility studies using column elution or shake flask method
- 830.1750 Certification of Limits
- 830.1620 Description of Production Process
- 830.7050 UV/Visible Absorption
- 835.4100 Aerobic soil metabolism with one soil type near neutral pH
- 835.6100 Terrestrial field dissipation - upgrade existing study or submit new study

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- 850.1300 Chronic toxicity study for freshwater aquatic invertebrates
 - 850.1350 Chronic toxicity study for estuarine/marine aquatic invertebrates
 - 850.1400 Early Life Stage Freshwater Fish
 - 850.1450 Early Life Stage Estuarine Fish
 - 850.1500 Fish life cycle study for freshwater and estuarine/marine fish
 - 850.2300 Avian reproduction with mallard duck
 - 850.4225 Seedling Germination and Seedling Emergence
 - 850.4250 Vegetative Vigor
 - 850.4400 Aquatic plant toxicity study (Tier 2)
 - 860.1300 Nature of residue - plants, livestock and processed food/feed commodities
 - 860.1500 Additional residue data required for blackberries, blueberries, grapes, and tomatoes
 - 860.1540 Additional reduction of residue data for orchard fruits, including washing and processing studies (cooking data suggested)
 - 870.3465 90-day inhalation study in rats
 - 870.5395 In-vitro Mammalian Cytogenetics Tests
 - 870.6300 Morphometric analyses of brain tissues and statistical analyses of neurobehavioral data in the developmental neurotoxicity study
 - 870.7485 Metabolism and pharmacokinetics study in rats

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 Ziram 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 Ziram RED document.

**Regulatory
Conclusion**

The use of currently registered products containing Ziram 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.

Ziram 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 Ziram 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 Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

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

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 1-800-490-9198; fax 513-489-8695.

Following the comment period, the Ziram 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 Ziram RED, or reregistration of individual products containing Ziram, please 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 pm Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week. Their internet address is <http://npic.orst.edu>.