



R.E.D. FACTS

Zinc Phosphide

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 that 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 0026, zinc phosphide.

Use Profile

Zinc phosphide is a rodenticide used to control gophers, mice, rats, lagomorphs (e.g. jack rabbits), prairie dogs, and squirrels. Zinc phosphide has indoor and outdoor uses, which are classified as food and non-food depending upon the application method and label restrictions. Food uses of zinc phosphide include: grapes, rangeland grasses, sugarcane and regional uses on artichokes and sugar beets. Non-food uses include: indoor and outdoor residential and agricultural areas (including in and around homes, on lawns, around bulbs, indoor and outdoor commercial or institutional premises, golf courses, alfalfa, barley, berries (dormant), oats, sugar maple, wheat, no-till corn, orchards/groves (postharvest and dormant), timothy (hay).

Formulations include solid baits, tracking powders and dusts intended for mixing into baits. Zinc phosphide is applied by hand, machine spreader,

cyclone seeder, and aircraft. Use practice limitations are numerous and vary by site, including a prohibition against livestock feeding in treated areas.

Regulatory History

Zinc phosphide was first registered as a pesticide in the U.S. in 1947. EPA issued a Registration Standard for zinc phosphide in June 1982 (PB85-102499). A Data Call-In Notice (DCI) was issued in 1987 and another in 1991 requiring further data for reregistration. Following the issuance of the 1991 DCI, the Zinc Phosphide Consortium was formed. The consortium is made up of technical, formulator, as well as end-use product registrants. The USDA APHIS (Animal and Plant Health Inspection Service) is the consortium leader. Currently, 59 zinc phosphide products are registered.

Benefits

Toxic rodenticides are the most efficient available means for controlling existing infestations of large numbers of pest rodents. These agents also may be the method of choice in controlling certain smaller rodent infestations and often are needed to control rodents that cannot be removed by use of traps. When buildings, including residences, are heavily infested, poisoning generally is an integral component of successful abatement programs.

Rodents transmit various diseases either directly or indirectly, via ectoparasites such as fleas, ticks or mites, or bodily waste products and secretions. Approximately 14,000 humans are bitten by rats each year.

"Field" rodents such as ground squirrels, voles, and native mice and rats cause significant damage to crops and rangelands. Certain crops, such as sugarcane, are heavily damaged in the field by rats and mice. Zinc phosphide plays an important role in the management of rodents associated with agricultural crops.

Human Health Assessment

Toxicity

In studies using laboratory animals, zinc phosphide is Toxicity Category I (the highest of four categories) for acute effects via the oral or inhalation route of exposure, Toxicity Category III (the second lowest of four categories) for the dermal route, and Toxicity Category IV (the lowest of four categories) for eye irritation.

Dietary Exposure

Although zinc phosphide is used in and around food crops, people are expected to be exposed to minimal residues of zinc phosphide through the diet because of its rapid degradation and restrictive application methods. Based on application method and label use restrictions, artichokes (globe), grapes, rangeland grasses, sugar beets and sugarcane are considered food uses. Tolerances or maximum residue limits have been established for these

commodities (please see 40 CFR 180.284). EPA has reassessed the zinc phosphide tolerances and found that all are acceptable, and that a new tolerance must be established for grasses, hay.

No Codex Maximum Residue Limits have been established for zinc phosphide, therefore, issues of compatibility between Codex MRLs and U.S. tolerances do not exist.

Because zinc phosphide residues on food are expected to be minimal to non-existent, EPA has not assessed the dietary risk posed by zinc phosphide. If additional uses be submitted for registration in the future that result in residues on food, then a risk assessment will be conducted at that time.

Occupational and Residential Exposure

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

Human Risk Assessment

Although zinc phosphide is primarily used in agricultural and non-residential settings, rodenticides, in general, that are used in and around the home are responsible for a high number of accidental exposures each year. EPA is concerned about the continued risk of exposure to humans, especially children, from rodenticides used in residential settings as well as the cost and trauma associated with treating those who might have been accidentally exposed. Although few reported incidents are associated with zinc phosphide, the Agency believes that the common use pattern should be the primary determining factor shaping the regulatory decision regarding these rodenticides used in and around the home. Additionally, a margin of exposure (MOE) of 0.5 was calculated for zinc phosphide based on an acute neurotoxicity study and accidental ingestion of the bait formulation by a child. Generally, the Agency seeks to ensure that exposures have an MOE of 100 or greater. The Agency has also determined that a single swallow of zinc phosphide bait may be fatal to a young child.

Zinc phosphide has not been classified for carcinogenicity. Since dietary exposure to zinc phosphide residues in foods is negligible, no cancer risk is expected for the general population.

Although the Agency has not identified any endpoints of concern from which to perform a handler exposure and risk assessment, it is concerned for inhalation exposure of occupational workers to the particulate fines or dust that may be generated from the mixing and loading of the dust-concentrate or wettable-powder formulations and from applying the pellet and bait formulations. The Agency is confident that current labeling restrictions, when combined with those required by this document, are adequate and will require these formulation-specific protections for all appropriate products.

Exposure to workers will be mitigated by the use of PPE required by this RED, including: long-sleeve shirt and long pants, shoes plus socks, chemical-resistant gloves made of any waterproof material, and a dust/mist filtering respirator (for mixers and loaders, MSHA/NIOSH approval number prefix TC-21C).

FQPA Considerations

No drinking water risk assessment was performed for zinc phosphide because no residues are expected in either ground or surface water due to the pesticide's rapid degradation and limited usage.

Although zinc phosphide may share a common mode of toxicity (the generation of phosphine gas) with other chemicals, the Agency has determined that any future cumulative risk determination involving these chemicals will not include the uses of zinc phosphide discussed in this document. This determination is based on the fact that exposures to phosphine from zinc phosphide in food or water are negligible due to zinc phosphide's rapid degradation and limited use patterns.

Tolerances with amendments and changes specified in the RED document meet the FQPA safety standard for the general population and infants and children.

Environmental Assessment

Environmental Fate

The Agency has determined that a review of available literature is sufficient to assess the environmental fate of zinc phosphide, therefore, few guideline studies were required. The major route of degradation/dissipation of zinc phosphide is hydrolysis, which results in the formation of volatile phosphine and zinc ions. Zinc phosphide and its residues appear to be non-persistent under most environmental conditions and relatively immobile (zinc ions and dissolved phosphorus readily sorb onto soil) in laboratory and field data. When applied to dry soil environments, zinc phosphide may be moderately persistent ($\approx 40\%$ of applied remaining at 30 days post-treatment). The rates of hydrolysis and volatilization of phosphine appear to be pH and soil moisture dependent with the hydrolysis rate increasing as the pH increases or decreases from neutrality. Zinc phosphide and its degradation products appear to have a low potential for ground water or surface water contamination.

Ecological Effects

The Agency has determined that zinc phosphide is highly toxic to avian species (Bobwhite quail) on an acute oral and on a subacute dietary basis. The results from studies also indicate that zinc phosphide is highly to very highly toxic to small mammals on an acute oral basis. Due to the fatal nature of zinc phosphide poisonings, chronic studies are not necessary.

The Zinc Phosphide Consortium is currently conducting two terrestrial field studies. One study is to determine the residues available on alfalfa following broadcast applications of a 2% bait in flood irrigated and sprinkler irrigated alfalfa fields. The other study is to determine nontarget hazards to pheasants in alfalfa fields that have been treated with a broadcast application of 2% zinc phosphide. The testing is expected to be completed within a year.

Environmental Risk Characterization

The Agency has concluded from the studies reviewed, many of which are not guideline studies, that the use of zinc phosphide in agricultural fields will likely kill nontarget birds and mammals. Zinc phosphide is a very toxic substance and will kill most animals to which it is administered. Rodents are more sensitive than carnivores. Gallinaceous birds (pheasants, turkeys, other large terrestrial birds) are more sensitive than other avian species, however, some passerines (songbirds) are also sensitive.

The Agency also concludes that predators or scavengers who eat a target animal that has been killed by zinc phosphide will not die, however, they may become ill, listless, and regurgitate.

Risk Mitigation

To mitigate the potential risk to children from accidental ingestion of baits, the Agency is requiring several mitigation measures to be implemented in two phases. During Phase I the Agency will require zinc phosphide products, as well as those of several other rodenticides, to incorporate indicator dye (to help identify whether a child or pet has actually consumed the pesticide) and bittering agents into their formulations. These formulation changes are required of all zinc phosphide products, except for those used exclusively in an agricultural setting. In addition, registrants must update their product labels to include the protective statements addressed in Section V of the RED. During Phase II EPA will form a stakeholder group (including industry, states, various poison control centers, rodent control experts, the medical community and other interested parties) to develop additional means of significantly reducing exposures to children and pets. It is the Agency's intent that within nine months or less from the issuance of the RED, the stakeholder group will conclude with recommendations to the Agency on how to mitigate risk to children and pets. Possible outcomes of this group include: requiring all rodenticide baits used in residential settings to be placed in disposable, child-resistant bait stations or equivalently protective mechanisms; develop an exhaustive educational and outreach program for consumers and enhanced training for certified applicators; tamper-resistant bait stations; and additional labeling improvements. To monitor the effectiveness of the mitigation measures implemented during both phases, the Agency is requiring registrants to submit annual National Poison Control Center Data for years 1999 through 2009. Registrants are encouraged to share the cost of generating data and new technologies, whenever appropriate.

To mitigate the potential exposure of the rodenticide to non-target animals in an agricultural setting, the Agency is retaining the requirement that all zinc phosphide products labeled for field use (except those limited to underground baiting for pocket gophers and moles) must be restricted to use by pesticide certified applicators, or persons under their direct supervision.

Because the use of zinc phosphide will still present a hazard to non-target animals, the Agency is seeking ways to minimize exposure to these animals. The Agency is especially concerned about the broadcast use of zinc phosphide as it allows large tracts of land to be treated. However, the available data do not show that hand-baiting will necessarily result in reduced exposure to non-target animals. Rather than impose specific use restrictions at this time, the Agency is continuing its evaluation of the risks associated with hand baiting versus broadcast applications and may impose additional data requirements or label amendments at a later date.

Additional Data Required

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

- 72-1a Acute Fish Toxicity (bluegill sunfish)
- 72-1c Acute Fish Toxicity (rainbow trout)
- 72-2 Acute Aquatic Invertebrate Toxicity
- 171-4e Storage Stability
- 171-4k Crop Field Trials

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 zinc phosphide end-use products must comply with EPA's current pesticide product labeling requirements and with the comprehensive list of labeling requirements required in Section V of the zinc phosphide RED document.

End-Use Products 8-Month Submission

All registrants of zinc phosphide products must submit revised Confidential Statement of Formula (CSF) and draft labeling to the Agency reflecting all changes noted in Section V, except for changes in formula or labeling related to indicator dye, bittering agent or special child risk warning. The details of these requirements, which do not apply to products used exclusively in agricultural settings, will be an outgrowth of a meeting held 30 days after the issuance of the RED document.

Stakeholder Meetings

The Agency is planning to hold the initial stakeholders meeting within 120 days from the issuance of this RED in Washington, DC. As mentioned earlier, these meetings will provide an open forum to develop workable mitigation measures to adequately protect children from accidental rodenticide exposures. For these meetings to be most efficient and successful, all interested parties and viewpoints will be welcomed and considered. The outcomes of these meetings will affect all rodenticide products with residential uses, including those that were previously reregistered and those that have been registered more recently and, hence, are not subject to reregistration.

Regulatory Conclusion

The use of currently registered products containing zinc phosphide 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.

Zinc phosphide 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 zinc phosphide 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/REDS>.

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 zinc phosphide RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-605-6000.

For more information about EPA's pesticide reregistration program, the zinc phosphide RED, or reregistration of individual products containing zinc phosphide, 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 6:30 am to 4:30 pm Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week.