



R.E.D. FACTS

Rodenticide Cluster

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. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce 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 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 2755, brodifacoum; case 2760, bromadiolone; case 2765, bromethalin; case 2100, chlorophacinone; case 2205, diphacinone and its sodium salt, and, case 2810, pival and its sodium salt.

Use Profile

These chemicals are for the control of mammal pests, particularly commensal rats and mice but also a variety of field rodents [note: commensal rodents are Norway rat, roof rat, and house mouse.] Products can be used in and around buildings, alleys, transport vehicles (trains, ships, aircraft) and related port terminals, or in sewers. A few diphacinone labels allow applications in wet or damp sites such as dumps, irrigation ditches, along fences, and in gullies. Other products have limited uses. Bromadiolone products can be applied only indoors in non-urban areas. Diphacinone sodium salt liquid (i.e., drinking) bait can be applied only indoors, and diphacinone and chlorophacinone tracking powders can only be used indoors and in rodent burrows along the outside walls of buildings.

Most rat and mouse products are formulated as pelletized baits. Some products are sold in place packs (pellets contained in small plastic or paper bags applied unopened) and others, especially those for use in sewers, as paraffinized bait blocks. Current labels for rat and mouse baits used outdoors require that baits be applied in protective bait stations or placed in areas inaccessible to nontarget wildlife (e.g., in burrows).

Both chlorophacinone and diphacinone have section 3 and Special Local Needs (SLNs) registrations for field uses. Each has one product for hand-applied, underground baiting of pocket gophers. Chlorophacinone has one product for underground baiting of moles. Diphacinone has one product for field control of ground squirrels. Twenty states have one or more SLNs for vole control, predominantly in dormant fruit orchards, and nine states have SLNs for control of ground squirrels. Other SLNs target various rat species (CA, FL), deer mice (CA), pocket gophers (CA), moles (OR, WA), chipmunks (CA), muskrats (CA), woodrats (CA), jackrabbits (CA, OR), and mongoose (HI).

Most products are 0.005% active ingredient or 0.01% active ingredient food pellets; others include treated whole grains, paraffinized food blocks, a chlorophacinone orchard spray for voles, meat bait for mongoose, and treated artichoke bracts for voles in California artichoke fields. Many of the orchard applications for voles include aerial broadcasting of food bait.

Regulatory History

The Agency's predecessor, the U.S. Department of Agriculture (USDA), first regulated vertebrate control agents after Congress passed FIFRA in 1947. Since then, additional rodenticides have been registered including diphacinone which was registered in 1960 followed by the registration of its sodium salt in 1962. Chlorophacinone and brodifacoum were registered in 1971 and 1979, respectively, followed by bromadiolone in 1980 and bromethalin in 1984. This RED covers 243 of the currently registered 406 products, including Section 3 and 24(c) used to control vertebrate pests by baits and tracking powders. The decisions made in this RED will affect many of the remaining 182 vertebrate controlled products, which were the subject of past REDs as well as those subject to future reregistration.

Human Health Assessment

Toxicity

In studies using laboratory animals, brodifacoum, bromadiolone, bromethalin, chlorophacinone, and diphacinone and its sodium salt generally

have been shown to be highly acutely toxic. All chemicals, with the exception of bromethalin, are in categories I for oral, inhalation and dermal exposure. Bromethalin is category II for dermal exposure.

Dietary Exposure

The Agency considers the uses of brodifacoum, bromadiolone, bromethalin, chlorphacinone, and diphacinone and its sodium salt to be nonfood. Based on current use patterns and exposure profiles, residues in and on food and/or feed are not expected to occur. Therefore, a dietary risk assessment is not required.

Occupational and Residential Exposure

EPA is concerned about the likelihood of risk of human exposure, resulting from continued use of rodenticides in residential settings. The number of human incidents reported has increased greatly in recent years with the advent of a new reporting network. In 1988, more than 10,000 rodenticide incidents were reported in the American Association of Poison Control Center's National Data Collection System. About 90% of these cases involved children under six years of age. Nearly all of such exposure incidents are classed as accidents. The human exposure incidents that are reported may represent less than half of those which actually occur. Well over 80% of reported human rodenticide exposures involve anticoagulant compounds.

The Agency has determined that there is potential exposure to applicators and/or other handlers during typical use patterns associated with these chemicals. Specifically, the Agency is concerned about potential dermal and inhalation exposures to handlers during the loading and application of these chemicals. Based on the use patterns and potential exposures, major handler scenarios were identified such as (1) placing bait packs; (2) loading bait boxes or bait stations with meal bait, grain bait, bait pellets, or other food-based bait from larger containers; (3) breaking paraffinized blocks into pieces and placing the pieces in bait stations; (4) securing large paraffin blocks in bait stations used in sewers; (5) applying bait by hand; and (6) applying bait, e.g. pellets in broadcast treatments using ground and (6) spray.

Human Risk Assessment

Rodenticides are acutely toxic to humans. Margins of Exposure (MOEs), when bait is ingested, are less than one. Generally, the Agency

considers a MOE of 100 or above to be protective of the public's health. The Agency, for example, has calculated the dose a 10 kg child receives from a 43 gram packet (standard commercial package). The Agency's calculation resulted in a MOE of 0.5.. Because of improved data collection, it appears that the high number of human unintentional or accidental exposures to rodenticides remain constant each year, or may be increasing. From the number of exposures to children, it is clear that children under six years-old are disproportionately more at risk to the continued use of these products in and around the home. EPA is therefore concerned about the risk from accidental exposures to these chemicals from residential users, particularly children.

Environmental Assessment

Environmental Fate

While generally the rodenticides are very similar in their environmental fate characteristics, there are a few exceptions. The rodenticides are generally stable to hydrolysis, except for diphacinone at pH 5 (which has a half-life of 44 days), moderately persistent to persistent to aerobic soil degradation (half-lives of 26 to 178 days) and, except for bromethalin can generally be considered to be immobile in the soil ($K_{ds} = 5.4$ to 1000, and found in the upper soil layer of column leaching studies).

Generally the potential for these chemicals to reach ground water is low. They probably reach surface waters through adsorption to eroding soil, as opposed to dissolution in runoff water. Because of their generally high adsorption coefficients and/or demonstrated lack of movement in soil leaching columns they would have a good probability of partitioning into the suspended and bottom sediments instead of the water column after reaching surface waters.

Based on the available data, little if any contamination of surface and ground waters is expected for brodifacoum, bromadiolone, chlorophacinone and diphacinone. These chemicals, although persistent, tend to be relatively immobile in soil and fairly insoluble in water. Most are applied as a pelleted bait in and around buildings and mostly in protective bait stations when used outdoors. Because of the lack of leaching data, the environmental fate of bromethalin is uncertain at this time. Leaching data is being requested for bromethalin in the RED.

Ecological Effects

Primary toxicity to mammals is very high for all five of these products. Primary toxicity to birds is mostly high to very high for the single-feeding compounds (brodifacoum, bromadiolone, bromethalin), but

mostly moderate for the multiple-feeding compounds (diphacinone, chlorophacinone). Toxicity to aquatic organisms ranges from moderate to very high.

Available laboratory and/or field data indicate that rodents poisoned with brodifacoum and bromadiolone baits can kill avian and mammalian secondary consumers. Sufficient data also exists to indicate that 0.01% a.i. diphacinone bait is secondarily hazardous to birds and mammals and that 0.01% a.i. chlorophacinone bait is hazardous to mammalian predators.

Ecological Effects Risk Assessment

The Agency believes that there is a high risk of secondary poisoning, especially to mammals, from the use of these rodenticides outdoors (i.e., “around” buildings) in rural and suburban areas. The available data indicate that brodifacoum, bromadiolone, and 0.01% a.i. chlorophacinone and diphacinone baits may pose a secondary hazard to avian and/or mammalian predators that feed on poisoned rodents. Brodifacoum and bromadiolone likely pose the greatest secondary risks, because they are more acutely toxic, especially to birds, more persistent in animal tissues, and can be lethal in a single feeding. In contrast, chlorophacinone and diphacinone tend to be less toxic to birds, less persistent in the tissues of primary consumers, and must be eaten over a period of several days to cause mortality. Therefore, a predator feeding only once on a poisoned carcass may not die if the rodent was poisoned with diphacinone or chlorophacinone, but is more likely to die if the rodent was poisoned with brodifacoum or bromadiolone. Data is being requested in the RED for bromethalin in order to determine secondary risks.

The Agency recently became aware of incident data which suggests that there may be a potential incident problem specifically involving the active ingredient brodifacoum. At this time the Agency is reviewing the data; no final conclusions have been reached. Additionally, through the “Notice of Availability” for this document, the Agency requests state incident data for all rodenticides to better understand the extent of this potential problem. After review, the Agency may impose additional restrictions on the use of brodifacoum and/or other active ingredients.

Risk Mitigation

To address the risks posed by the rodenticides bromadiolone, bromethalin, brodifacoum, chlorophacinone, diphacinone and its sodium salt, EPA has developed a two-phased approach to minimize exposure particularly to infants and children.

During Phase I the Agency will require the products covered in the rodenticide cluster to incorporate an indicator dye (to help identify whether a child or pet has actually consumed the pesticide) and a bittering agent into the formulations. The Agency is aware that all mitigation measures required during Phase I may not be feasible within the 8-month time frame usually accorded by the RED process to submit labeling changes. While registrants will still be required to submit revised labeling within the 8-month time frame, the Agency recognizes that the formulation changes required by the add-on of the indicator dye and bittering agent may take longer. The timing for the incorporation of the dye and bittering agent in rodenticide products will be an outcome of the initial stakeholder meeting. In Phase II, EPA will form a stakeholder group that will include representatives from 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.

In addition to the mitigation measures discussed above, EPA is requiring a number of label revisions to rodenticides used in and around the home as well as requiring registrants, under the authority of FIFRA, section 3(c)(2)(B), to submit data from the American Association of Poison Control Center. The data will be for the years 1999 through 2009. Restricted Use classifications will also continue to be maintained.

Additional Data Required

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

Brodifacoum

- 21-Day Dermal - rabbit/rat [82-2)
- Estimation of Dermal Exposure at Outdoor Sites [231]
- Estimation of Inhalation Exposure at Outdoor Sites [232]
- Estimation of Dermal Exposure at Indoor Sites [233]
- Estimation of Inhalation Exposure at Indoor Sites [234]

Bromadiolone

- Leaching/Adsorption/Desorption [163-1]
- Estimation of Dermal Exposure at Outdoor Sites [231]
- Estimation of Inhalation Exposure at Outdoor Sites [232]
- Estimation of Dermal Exposure at Indoor Sites [233]
- Estimation of Inhalation Exposure at Indoor Sites [234]

Bromethalin

- General Metabolism [85-1]
- Leaching/Adsorption/Desorption [163-1]
- Estimation of Dermal Exposure at Outdoor Sites [231]
- Estimation of Inhalation Exposure at Outdoor Sites [232]
- Estimation of Dermal Exposure at Indoor Sites [233]
- Estimation of Dermal Exposure at Outdoor Sites [234]
- Secondary Poisoning, Mammal [70-A-SS]*
- Protocol
- Secondary Poisoning, Bird [70-B-SS]*
- Protocol
- Whole Body Residue, Target Species [70-C-S]*
- Protocol

*Studies are not required for “indoors and along the outside walls of buildings”, but are required for any other uses.

Chlorophacinone

- Avian Reproduction, Quail [71-4(a)]*
- Avian Reproduction Duck [71-4(b)]*
- Estimation of Dermal Exposure at Outdoor Sites [231]
- Estimation of Inhalation Exposure at Outdoor Sites [232]
- Estimation of Dermal Exposure at Indoor Sites [233]
- Estimation of Dermal Exposure at Outdoor Sites [234]
- Secondary Poisoning, Mammal [70-A-SS]**
- Protocol
- Secondary Poisoning, Bird [70-B-SS]**
- Protocol
- Whole Body Residue, Target Species [70-C-S]**
- Protocol

*Required to support Product CAS 90023.

**Studies are not required for “indoors and along the outside walls of buildings”, but are required for any other uses.

Diphacinone, and Salt

- General Metabolism[85-1]

- Hydrolysis [161-1]
- Leaching/Adsorption/Desorption [163-1]
- Estimation of Dermal Exposure at Outdoor Sites [231]
- Estimation of Inhalation Exposure at Outdoor Sites [232]
- Estimation of Dermal Exposure at Indoor Sites [233]
- Estimation of Dermal Exposure at Outdoor Sites [234]
- Secondary Poisoning, Mammal [70-A-SS]*
- Protocol
- Secondary Poisoning, Bird [70-B-SS]*
- Protocol
- Whole Body Residue, Target Species [70-C-S]*
- Protocol

*Studies are not required for “indoors and along the outside walls of buildings”, but are required for any other uses.

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 brodifacoum, bromadiolone, bromethalin, chlorophacinone and diphacinone and its sodium salt 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 Rodenticide Cluster RED document.

Labeling Requirements:

1. Incorporate the word “POISON” (in Spanish and English), and skull and cross bones icon on the labels.
2. The section on labels for pets must include a hazard to pet statement, first aid treatment for pets, and a note to veterinarians.
3. To clarify that bait can be applied only as specified on the label the following must be added: “Do not apply this product by any method not specified on this label”.
4. Specific information regarding use sites and use directions should be included on SLN labels to help avoid inappropriate use of these products.

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- 5 Dust masks/respirators and water-proof gloves are required for commercial handlers (Mixer/loader/applicator) when handling rodenticide chemicals not already in place packs.
 - 6 All products intended primarily for occupational use must contain the following statement: “Do not contaminate water, food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment”.
 7. Products intended primarily for consumer use (OTC) must contain the following stat: “Do not apply this product in a way that will contact any person or pet. Keep people and pets out of the area during application.
 8. All products must contain an environmental hazard statement stating: “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, wash water, or rinsate”.
 9. All tracking powders must limit treatment areas to concealed, inaccessible places such as spaces between floors and walls. Powder may not be applied along walls, in corners or in open floor areas of rooms in which food or feed is handled or stored.
 - 10 All rodenticide products labeled for field use, except those limited to manual underground baiting for pocket gophers and moles, will be restricted use.
 11. Where applications for the control of mice and rats in non-urban and rural settings are not limited indoors and against the outside walls of buildings, labels shall state to place baits:
“indoors and along the outside walls of buildings.”
 12. The second sentence of the “Environmental Hazards” precautionary labeling on all food bait products should read as follows: “Predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten the bait.”
 13. For chlorophacinone orchard spray products, the statement should be modified to read:
“Predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have been poisoned by this product.

Regulatory Conclusion

With the exception of pival and its sodium salt, the Agency has concluded that the uses, as prescribed in the RED document, with additional labeling requirements and a number of risk mitigation measures, will not cause unreasonable risks to humans or the environment.

The Agency has determined that all uses of brodifacoum, bromethalin, and bromadiolone are eligible for reregistration.

The Agency has determined that all uses of chlorophacinone and diphacinone and its sodium salt are eligible for reregistration, with the exception of certain field bait uses. The Agency has determined that field-bait uses containing .005% chlorophacinone and diphacinone and its sodium salt are eligible for reregistration.

The Agency has determined that field-bait uses containing *more than* .005% chlorophacinone and diphacinone and its sodium salt are ineligible for reregistration. Field tests have adequately demonstrated that products with lower-concentrations of these active ingredients are sufficiently efficacious for target pest species, and that the uses with higher concentrations have the potential to cause unnecessary secondary poisonings to avian and mammalian consumers.

The EPA has determined that all uses of pival and its sodium salts are ineligible for reregistration. Pival and its sodium salt was suspended by the Agency in December 1994 for failure of the registrant, Motomco, Incorporated, to respond to the Agency's Data Call-In Notice (DCI) and submit the required data to support the continued registration. In the future, EPA may seek cancellation of the registration for pival and its sodium salt.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for brodifacoum, bromadiolone, bromethalin, chlorophacinone and diphacinone and its sodium salt, 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 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the Rodenticide Cluster 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 brodifacoum, bromadiolone, bromethalin, chlorophacinone, and diphacinone and its sodium salt RED, or reregistration of individual products containing brodifacoum, bromadiolone, bromethalin, chlorophacinone, and diphacinone, 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.