



R.E.D. FACTS

Strychnine

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 3133, strychnine.

Use Profile

Strychnine is currently registered for use only below-ground as a bait application to control pocket gophers. The end-use products are formulated as a grain-based bait or a paste. Baiting can be done manually, or with the use of application equipment. Typical application equipment includes a burrow-builder, which digs artificial tunnels; or an impinger, which "injects" bait into the animal's tunnel.

Regulatory History

Strychnine was first registered as a pesticide in the U.S. in 1947. However, strychnine had been used in the U.S. to control vertebrate animals for many years prior to 1947.

All strychnine products, except for those products which contain strychnine at nominal concentrations no greater than 0.5% and which are limited by their labels to manual below-ground applications, were classified as restricted use by the Agency in 1978.

In 1983, the Agency published a Federal Register notice announcing the Agency's intent to cancel certain uses and to limit others. In 1988,

above-ground uses of strychnine were prohibited by a U.S. Court injunction and strychnine products with those uses remain temporarily cancelled.

Since 1988, the U.S. Fish and Wildlife Service has issued several opinions on uses of strychnine products.

Several Data Call-Ins have been issued for strychnine, including requirements for efficacy, benefits, environmental fate and chemistry data, and ecological effects data.

Human Health Assessment Toxicity

The human health assessment for strychnine is based on the acute toxicity for the technical and is described below. Because of the high acute toxicity via the oral and ocular routes, subchronic and chronic data were not required. Strychnine has been placed in Toxicity Category I, indicating the greatest degree of acute toxicity, for oral and ocular effects; inhalation toxicity is also presumed to be high. A confirmatory 21-day dermal study is required to describe the dermal absorption. Additional data are also required to describe the acute toxicity of the end-use products intended for homeowner use.

A substantial number of accidental exposures to strychnine pesticides are reported annually to Poison Control Centers.

Dietary Exposure

Given the below-ground use pattern, strychnine residues on dietary items are not likely.

Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to strychnine during normal use of bait formulations below-ground. Strychnine is highly acutely toxic by the oral and ocular and presumably by the inhalation routes of exposure. In addition, numerous incidents have been reported. Additional information including poisoning incident data and end-use product acute toxicity are required for EPA to reach a decision on eligibility for residential uses.

Human Risk Assessment

Strychnine is generally of very high acute toxicity. However, dietary exposure is not expected because of the below-ground application.

Of greater concern is the risk posed to strychnine handlers, particularly applicators. Exposure and risk to the certified pest control operators will be mitigated by the use of personal protective equipment required in this RED. To mitigate risks to handlers, EPA is requiring personal protective equipment (PPE) including chemical resistant gloves, eye protection, and dust masks. The Agency remains concerned for risks to homeowners and children from strychnines non-occupational uses. Therefore, additional information from poison control center and product-specific acute toxicity data are required to evaluate these risks. In the

interim, all homeowner products containing strychnine are required through this RED to be contained in Child-Resistant Packaging to reduce the potential for accidental exposure to children.

Environmental Fate Assessment

Environmental Fate

Available data satisfy the environmental fate requirements for below-ground uses. In the event that above-ground uses are restored, additional data appropriate to support the registration of these uses will be required.

Ecological Effects

Acute toxicity of strychnine to birds is assumed to be very high. Subacute dietary data indicate that strychnine ranges from slightly to highly toxic to avian species. Strychnine may pose a threat to birds who may be subject to repeated or continuous exposure from spills. Avian reproduction data indicate no treatment related effects in the bobwhite quail. However, in the mallard duck, testes were smaller at the low dose and chick body weights were reduced in the mid dose and high dose groups. Egg production and adult female body weight were also reduced at the high dose.

Mammalian studies indicate that strychnine is very highly toxic to small mammals on both an acute oral basis and dietary basis. The signs of toxicity, including death, occurred within one hour.

Acute freshwater fish data reveal that strychnine ranges from moderately to highly toxic to freshwater fish. Aquatic invertebrate acute toxicity data indicate that strychnine is moderately toxic to aquatic invertebrates.

Ecological Effects Risk Assessment

The Agency believes that the risks to non-target terrestrial animals are minimal when strychnine is used below-ground. When the recommended precautions are followed, below-ground use of strychnine does not constitute a risk to non-target or endangered species.

Risk Mitigation

To mitigate risks of potential toxicity posed by strychnine, EPA is requiring the following risk mitigation measures:

- use of personal protective equipment
- child-resistant packaging for products available to the general public.

Additional Data Required

The Agency is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration. A 21-day dermal study is also required to confirm the assumption that dermal absorption is low.

Additional information is being required prior to making a decision for the use of strychnine products by homeowners. This information includes poison control center data for products used by homeowners to include incident reports for poisoning of children, and end-use product acute toxicity data.

**Product Labeling
Changes
Required**

Manufacturing-use products

The MP labeling must bear the following statement under Directions for Use:

"This product may be used only to formulate end-use rodenticide concentrates of ready-to-use baits which are limited by labeling to below-ground applications to control pocket gophers."

End-use products

All end-use strychnine products will be required to comply with EPA's current pesticide product labeling requirements and with the following.

Restricted-use products must bear the following statement in a prominent location on the front panel of the end-use product labeling:

**"RESTRICTED-USE PESTICIDE
ACUTE ORAL TOXICITY**

For retail sale and use only by Certified Applicators or persons under the direct supervision of a Certified Applicator, and only for those uses covered by the Certified Applicator's certification. Sale to or use by the general public is prohibited."

The minimum (baseline) PPE for strychnine end-use products formulated as a paste is:

"Applicators and other handlers must wear:
--long-sleeved shirt and long pants,
--chemical-resistant gloves*,
--shoes plus socks, and
--protective eyewear.

The minimum (baseline) PPE for strychnine end-use products formulated as grain-based baits is:

"Applicators and other handlers must wear:
--long-sleeved shirt and long pants,
--chemical-resistant gloves*,
--shoes plus socks, and

--dust mask.

* For the glove statement, use the statement established for strychnine through the instructions in Supplement Three of PR Notice 93-7. Although this PR Notice addresses agricultural pesticides, the basis for our decisions for strychnine are similar.

The Agency is requiring the following labeling statements to be located on all end-use products containing strychnine that are intended primarily for occupational use.

Application Restrictions

"Do not apply this product in a way that will contact workers, other persons, pets, or domestic animals."

User Safety Requirements

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

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."

"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

All use sites must be listed on the label. Specifically, these are to include use sites, such as orchards, forests, nurseries, and agricultural crop areas.

**Regulatory
Conclusion**

EPA has determined that products containing strychnine labeled for below-ground use and used by certified applicators are eligible for reregistration. The Agency has not made a determination for those products labeled for sale and use by the general public.

Based on the generic data reviews for strychnine and the use of products below-ground, the Agency has concluded that for the restricted use products it has sufficient information about strychnine's potential to cause adverse effects to humans or the environment. The Agency has concluded that the use of the products classified as restricted use, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable adverse effects to humans or the environment. Therefore, these products are eligible for reregistration. Pesticide handlers of the paste products are to wear the PPE of chemical resistant gloves and protective eyewear to mitigate exposure and risks of acute toxicity from strychnine. A dust mask is required for pest control applicators using the grain-based baits. Also, a 21-day dermal study is required as confirmatory.

However, for the remaining products, those unclassified and available for use by the general public, EPA has concluded that it does not have sufficient information regarding the risks to humans and benefits from the use of these products to make a decision of eligibility. The Agency is requiring that strychnine product registrants provide poison control center data for products used by homeowners, incident reports for poisoning of children, and end-use product acute toxicity. This information will be used to determine if the use of these products below-ground by the general public will result in unreasonable adverse risks to humans or the environment.

After receipt, EPA will review the additional information requested and decide whether additional practical measures are prudent to protect the general public users from the risks of poisonings or whether other regulatory action is appropriate. At that time the Agency will reach a decision on reregistration eligibility for the products intended for use by homeowners.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for strychnine 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 on EPA's gopher server, *GOPHER.EPA.GOV*, or 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 strychnine 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 strychnine RED, or reregistration of individual products containing strychnine, 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.

