United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-97-016 January 1998

R.E.D. FACTS

Paranitrophenol

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 reregistration case 2465, Paranitrophenol.

Use Profile

Paranitrophenol, a nitrated benzene, is a nonfood use chemical that is registered for use as a fungicide to control fungal mold on leather and specialty industrial products used by the military. The treatment process is for protection of military leather shoes, leather combat boots, and other leather items while in storage in the field, and for specified cork insulations on Air Force equipment. Paranitrophenol-treated cork is used in missile silo construction. A single product containing 99.5% paranitrophenol, formulated as a flaked solid, is registered.

Regulatory History

Paranitrophenol was first registered in the United States in 1963 as a fungicide incorporated into leather products and hides as a preservative. A second fungicidal product was registered in 1967. Both products contained a second active ingredient, salicylanilide. However, the registrations for all registered products containing salicylanilide as an active ingredient have been canceled.

Currently, one pesticide product is registered containing paranitrophenol as an active ingredient. This registration, granted in 1980, is for use of paranitrophenol as a fungicide incorporated into leather for military use, at a concentration not to exceed 0.7% on the basis of dry finished leather weight. In 1983, this registration was amended to add use of the product for incorporation into cork insulation for military use.

Human Health Assessment

Toxicity

Paranitrophenol is a corrosive eye irritant (Toxicity Category I, indicating the greatest degree of acute toxicity) and a potential dermal irritant. Paranitrophenol is acutely toxic (Toxicity Category II) via the oral route and moderately toxic (Toxicity Category III) via the dermal route.

A subchronic oral toxicity study in rats showed an increased incidence of acute mortality, while a dermal study in mice resulted in dermal irritation and mortality. Chronic toxicity has not been conclusively evaluated. Paranitrophenol has been classified as Group D for carcinogenicity, indicating that there is inadequate information to determine its cancer potential.

Paranitrophenol is not believed to cause reproductive or developmental toxicity, but additional studies are needed to confirm these tentative findings. The data available on mutagenicity are not complete.

Additional toxicity studies or information are needed to support reregistration of paranitrophenol. Required studies using the technical active ingredient include: rat acute inhalation toxicity study (81-3); primary dermal irritation study in rabbits (81-5); dermal sensitization potential study in guinea pigs (81-6); rabbit developmental toxicity study (83-3b) (exposure via dermal route is required); and in vivo bone marrow cytogenetics assay (84-4). In addition, an acute inhalation toxicity study in rats using the formulated end-use product at the minimum dilution specified on product labels is required.

Dietary Exposure

No dietary exposure is expected from the pesticide uses of paranitrophenol since no food or feed uses are registered.

Occupational and Residential Exposure

There is a potential for dermal and inhalation exposure to handlers during usual paranitrophenol use patterns, that is, while treating leather or cork for military use, or handling dry hides or cork to which paranitrophenol has been added. Post-application exposure also may occur, when working near a vat where paranitrophenol was added or while wearing treated military boots or shoes.

At this time, EPA lacks information about probable dermal and inhalation exposures to primary and post-application handlers, and is unable to assess worst-case risks to these workers. Exposure data for primary handlers are required, as are acute inhalation toxicity data. Since paranitrophenol is classified as Toxicity Category I for eye irritation potential and since data on skin irritation potential are not available, the Agency is imposing risk reduction measures including use of personal protective equipment (chemical-resistant gloves and apron, and protective eyewear) as well as a long sleeved shirt, long pants, shoes, and socks.

EPA believes that inhalation and ocular exposures for secondary handlers are minimal, and that the risk from secondary post-application exposure, wearing treated footwear, is not significant.

Human Risk Assessment

Paranitrophenol is corrosive to the eyes, is a potential skin irritant, and its inhalation toxicity is not known. It is of relatively high acute toxicity by the oral route. No food uses are registered so dietary risk is not anticipated. However, based on reviews of the generic data, EPA has some concerns about potential handler dermal and inhalation exposure during treatment of leather and cork products for use by the military. Lacking adequate exposure and toxicity data, the Agency is unable to conduct a quantitative risk assessment. In order to assess the risk and support the continued registration of paranitrophenol, additional acute toxicity, developmental toxicity, and mutagenicity studies would be required. EPA is requiring use of personal protective equipment to reduce possible eye and skin exposures and risks to primary handlers of paranitrophenol.

FQPA Considerations

Paranitrophenol is not registered for food uses, nor is it available for use by homeowners in residential settings. However, military personnel could be exposed from wearing paranitrophenol-treated leather shoes or boots. Developmental and reproduction studies do not indicate any pre-natal effects, but these findings should be confirmed by an new rabbit developmental study.

Environmental Assessment

Paranitrophenol is slightly to moderately toxic to birds and aquatic animals. Wild animals or plants are not likely to be exposed to paranitrophenol, however, since it is not applied outside of a factory. Paranitrophenol thus is not expected to pose a risk to nontarget organisms.

Risk Mitigation and Regulatory Conclusion

EPA's reregistration eligibility decision for paranitrophenol is to accept its voluntary cancellation. All uses of the sole registered pesticide product containing paranitrophenol will be voluntarily canceled as of May 30, 2002.

A number of studies are needed to more fully assess the risks and support the reregistration of paranitrophenol. EPA contacted the sole registrant, the U.S. Department of the Army, about obtaining the necessary data. Subsequently, EPA received a request from the Army to cancel the

registration of the sole product containing paranitrophenol, effective May 30, 2002. In requesting cancellation, the registrant noted that there are no supplies of paranitrophenol in stock; that the product would be used only in a national security emergency situation; and that they would rely on available alternative fungicides registered for use in treating leather and cork products and would pursue efficacy testing of these alternative products.

EPA has decided to accept the voluntary cancellation request because:

- The weight of evidence from all available toxicological data does not suggest a potent threat to handlers and others from dermal and inhalation exposure.
- Exposure to paranitrophenol is believed to be very limited. Its uses are confined to leather and cork treatments applied by military contractors to a few products used by the military. The worker population exposed during treatment is likely to be small. The only large population potentially exposed is military personnel wearing treated footwear. EPA was able to quantitatively estimate their risk and found it to be acceptably low, even using protective assumptions.
- During the five year phase-out period, workers using and handling paranitrophenol solutions and freshly treated products are required to wear chemical-resistant aprons and gloves.

Revised product label language is required to reflect the phase out date, personal protective equipment requirements, and additional handler safety requirements, as set forth in the RED document and summarized below.

Product Labeling Changes Required

The paranitrophenol end-use product must comply with EPA's current pesticide product labeling requirements and with the following. For a comprehensive list of labeling requirements, please see Section V of the paranitrophenol RED document.

- Personal Protective Equipment (PPE) Requirements

"Mixers, loaders, applicators and other handlers must wear:

-- Long-sleeve shirt and long pants,

-- Shoes plus socks,

-- Protective eyewear,

-- Chemical-resistant full front apron, with attached full sleeve chemical resistant gloves."

Since this product is toxicity category II for acute inhalation toxicity, a respirator requirement also must be added, based on the product’s vapor pressure.

In addition to the minimum PPE specified above, the following specific PPE requirement must be added to labels:

"Handlers participating in hands-on operations, including introduction of materials to and removal from the dip and handling leather or cork still wet with the treatment, must wear chemical-resistant full-front aprons with attached full-sleeve gloves."

- Application Restrictions

"Do not use this product in a way that will contact workers or other persons."

- Restrictions For Use Statement

"This product can not be used after May 30, 2002."

- 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."

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for paranitrophenol during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. A notice announcing receipt of the voluntary cancellation request for the only registered paranitrophenol product also will be published, and comments may be submitted for a 30-day period. 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), 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 45242-0419, telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the paranitrophenol 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 paranitrophenol RED, or reregistration of individual products containing paranitrophenol, please contact the Special Review and Reregistration Division (7508W), OPP, 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.