



R.E.D. FACTS

Pesticide Reregistration

p-Chloro-m-cresol

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 3046, p-chloro-m-cresol.

Use Profile

p-Chloro-m-cresol is a microbicide used to control slime-forming bacteria and fungi that might develop in industrial adhesives, industrial coatings, emulsions, leather processing liquors, metal cutting fluids, paints (in can), specialty industrial products, oil drilling muds/packer fluids, and wet-end adhesives/industrial processing chemicals. Products are applied by open pouring.

Use practice limitations prohibit discharging effluent containing p-chloro-m-cresol to bodies of water without an NPDES license and/or into treatment plants without first notifying the sewage treatment plant authority.

Regulatory History

p-Chloro-m-cresol was first registered as a pesticide in the U.S. in 1968. Currently, three p-chloro-m-cresol products are registered including two manufacturing-use products and one end-use product. Through the Antimicrobial Data Call-In (DCI) of 1987 and the Reregistration Phase IV DCI of 1991, EPA required additional data to complete p-chloro-m-cresol's data base for reregistration. The U.S. Food and Drug Administration has established tolerances or maximum residue levels for p-chloro-m-cresol in

food grade adhesives and paper coatings which may contact foods. These tolerances are specified in the 21 CFR.

Human Health Assessment

Toxicity

In most acute and subchronic toxicology studies using laboratory animals, p-chloro-m-cresol has been shown to be slightly toxic to practically non-toxic. It is, however, very highly toxic (Toxicity Category I) when applied to the skin or the eye. It is not a skin sensitizer, and inhalation exposure is not expected since p-chloro-m-cresol is a chunky solid and respirable particles are unlikely. In a developmental toxicology study using rats decreases of body weight and food efficiency, increased water intake, decreased urinary protein, and changes in organ weights were noted at the highest dose level. In a chronic feeding study using rats decreases in body weight and food efficiency, increased water intake, decreased urinary protein, and changes in organ weights were noted at the lowest dose. Carcinogenicity and mutagenicity studies were negative for effects. The Agency thus classified p-chloro-m-cresol as a Group D carcinogen, that is, a chemical with insufficient or no information to be classified.

Dietary Exposure

There is no direct application of p-chloro-m-cresol to food; however, indirect exposure may occur from its use in paper coatings and adhesives. Tolerances are established by FDA for these indirect food additive exposures.

Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to p-chloro-m-cresol during and after use of products containing this active ingredient. Occupational exposures may occur to workers from open-pouring the solid end-use product. Assessments for short- and intermediate-term and chronic exposures are appropriate because of the toxicological endpoints from the developmental toxicology and chronic feeding studies.

EPA's exposure assessment included dermal and inhalation exposures for handlers applying product used in industrial preservatives and metal-working/cutting fluids. The Agency also considered exposures to other workers in industrial settings and people in residential settings who handle products treated with p-chloro-m-cresol. The Agency believes that, with the exception of workers using metal-working/cutting fluids and paints, these secondary exposures are not greater than the handler exposures described above.

Exposures are likely to workers in industrial settings and to people in residential settings where p-chloro-m-cresol-treated products have been applied, for example, exposures from working in a recently-painted room. These post-application exposures are expected to be of short duration and result from products with diluted concentrations (0.02 to 5.0%) of p-chloro-m-cresol. These exposures are expected to be less than those described for the handler of the concentrated p-chloro-m-cresol end-use product.

For estimating short- and intermediate-term risks to workers, EPA compared the no observed effect level from the developmental study to the worker exposure estimates. The margins of exposures (MOEs) for short and intermediate term exposures to workers, except painters, are not of concern to the Agency. The calculated MOEs are well above 100, a level the Agency generally considers adequate protection.

Chronic risk was estimated for the handler applying the end-use product as a general preservative. This MOE was greater than 300 and therefore is not of concern to the Agency.

Risks to commercial painters from short- and intermediate-term and chronic exposures were of concern to the Agency. To minimize these risks, the registrant has agreed to reduce the concentration of p-chloro-m-cresol in finished paints to 0.05%.

The Agency has concerns for the metal-working/cutting fluid worker, and has made this document available to OSHA for their use in regulating these workers.

Human Risk Assessment

p-Chloro-m-cresol is very highly toxic to the skin and eyes (Toxicity Category I), but otherwise is of low acute toxicity. No dietary exposure is expected as a result of its pesticide uses. Food additive uses, in paper coatings and adhesives, are regulated by FDA.

To minimize risks to commercial painters, the registrant has agreed to reduce the concentration of p-chloro-m-cresol in finished paints to 0.05%. Personal protective equipment (PPE), including chemical-resistant gloves and protective eyewear, is required for occupational users.

Environmental Assessment

Ecological Effects

p-Chloro-m-cresol is slightly toxic to avian species in both acute oral and subacute dietary toxicity studies. It is highly toxic to freshwater fish and moderately toxic to freshwater invertebrates in acute studies.

Environmental Fate

The currently registered uses of p-chloro-m-cresol are not likely to result in significant environmental exposures. Therefore, the Agency required only limited data to describe dissipation in the environment.

Ecological Effects Risk Assessment

Current uses of p-chloro-m-cresol are expected to result in minimal exposure or risk to the environment, and effluent from these uses is regulated under the NPDES program. Therefore, no environmental risk mitigation measures are imposed at this time.

Risk Mitigation

EPA is requiring the following risk mitigation measure to lessen the risks posed by p-chloro-m-cresol:

- Reduction of maximum application concentration of p-chloro-m-cresol in paints to 0.05%.
- Personal protective equipment (PPE) for handlers as described below.

Additional Data Required

All p-chloro-m-cresol end-use products must comply with EPA's current pesticide product labeling requirements and with product-specific data requirements including product chemistry and acute toxicity studies, and revised Confidential Statements of Formula for product reregistration.

Product Labeling Changes Required

The Agency is requiring revised labeling for reregistration of end-use products:

- Registrants must specify on labeling the complete directions for use for each use pattern: site of application, type of application, timing of application, equipment used for application, and the rate of application.
- The maximum application concentration of p-chloro-m-cresol in paints must be revised to 0.05%.
- The following statement is required to appear in the Environmental Hazards section of the label, in accordance with 40 CFR 156.10: "This pesticide is highly toxic to fish."
- To clarify the intent of the oil recovery drilling mud/packer fluid use (as an aquatic or terrestrial site), the following statement must be added to the labels for terrestrial oil drilling muds and packer fluids: "For use in (terrestrial or aquatic) wells only."

PPE Requirements for Pesticide Handlers

For sole active-ingredient end-use products that contain p-chloro-m-cresol, the product labeling must be revised to adopt the handler personal protective equipment requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For multiple active-ingredient end-use products that contain p-chloro-m-cresol, the handler PPE requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance see PR Notice 93-7. Although this PR Notice addresses products within the scope of the Worker Protection Standard (WPS), that is products that are generally for agricultural use, certain parts of the guidance in this PR Notice are applicable to all pesticide products.

The Agency is establishing the following active ingredient-based minimum (baseline) PPE requirements for p-chloro-m-cresol end-use products that are intended primarily for occupational use:

Applicators and other handlers must wear:

- long-sleeved shirt, long pants,
- socks and shoes, and
- chemical-resistant gloves

Any necessary PPE for each p-chloro-m-cresol occupational end-use product will be established on the basis of the end-use product's acute toxicity category. The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active ingredient-based minimum (baseline) PPE specified above, and the more protective PPE must be placed on the product labeling.

- The Agency is requiring the following labeling statements to be located on all end-use products containing p-chloro-m-cresol:
 - "Do not apply this product in a way that will contact workers or other persons."
 - "Follow manufacturer's instructions for cleaning/maintaining personal protection equipment (PPE). If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

Regulatory Conclusion

The use of currently registered products containing p-chloro-m-cresol, used in accordance with required labeling, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

p-Chloro-m-cresol 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 p-chloro-m-cresol 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 p-chloro-m-cresol 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 p-chloro-m-cresol RED, or reregistration of individual products containing p-chloro-m-cresol, 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.