

US EPA ARCHIVE DOCUMENT



R.E.D. FACTS

ORTHO-BENZYL-P- CHLOROPHENOL

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 2045, Ortho-benzyl-para-chlorophenol.

Use Profile

Ortho-benzyl-para-chlorophenol and its salts are used as disinfectants/antimicrobials for controlling variety of bacteria, fungi, algae, and viruses. The use sites include swimming pool water related surfaces such as decks, and other hard surface areas surrounding swimming pools refuse/solid waste sites, air washer water systems, evaporative condenser water systems and industrial processing water, and commercial/industrial water cooling systems.

Ortho-benzyl-para-chlorophenol and its salts are also used as disinfectants for farm premises, poultry houses, food processing plants, eating establishments, and federally inspected meat and poultry processing

plants. Labeling for disinfectants registered for use in federally inspected meat, poultry, and egg processing plants, as well as for phenolic-based products used as disinfectants in food preparation, storage, and serving establishments/areas, requires that food products and packaging materials are removed or carefully covered prior to application and that a potable water rinse is employed after treatment. Phenolic-based products recommended for use as disinfectants on food contact surfaces in eating establishments and homes are limited to sites such as counter tops, stoves, and refrigerators, which followed by a potable water rinse would allow their classification as a nonfood use. Application of these products as disinfectants on eating utensils, glassware, and similar items would be considered a food use and would require a tolerance or an exemption from the requirements of a tolerance prior to approval, however specific label directions are provided in Section V, of the RED document which result in the classification of farm premise and poultry house disinfectants as non-food use products.

Regulatory History

Ortho-benzyl-para-chlorophenol, potassium and sodium 2-benzyl-4-chlorophenate salts were first registered in the United States in 1948 as disinfectants. They are currently registered as disinfectants, bacteriostats, sanitizers and microbiocides. Additionally, the salts are currently registered for use as tuberculocides, virucides and fungicides.

There are currently 143 products registered by the Environmental Protection Agency containing ortho-benzyl-para-chlorophenol active ingredients.

Human Health Assessment

Toxicity

Ortho-benzyl-para-chlorophenol is Category III for acute oral and dermal toxicity, and Category IV for acute inhalation toxicity. Ortho-benzyl-para-chlorophenol is severely irritating to the eye (Category I), and is corrosive with repeated contact to the skin. The requirement for a dermal sensitization study was waived due to the corrosive nature of ortho-benzyl-para-chlorophenol. In chronic studies, ortho-benzyl-para-chlorophenol induces increases in kidney nephropathy and has been classified as a Group C, possible human carcinogen. This was based on increases in renal tubule combined adenomas/carcinomas in male B6C3F1 mouse and in renal transitional cell carcinomas in female F344/N rat. However, renal tubular carcinomas in the mouse and renal transitional cell tumors in the rat are rare.

Dietary Exposure

No dietary exposure is expected from the pesticide uses of ortho-benzyl-para-chlorophenol since no food or feed uses are registered.

Ortho-benzyl-para-chlorophenol and its salts when registered for use as sanitizers on food-processing equipment and utensils, and on other food-contact articles are under the purview of FDA (21 CFR Part 178.1010 (20)). EPA accepts FDA's approval and acceptance of the chemical(s) use pattern.

Occupational and Residential Exposure

The Agency has determined that regulatory action regarding the establishment of active ingredient-based minimum PPE requirements for occupational handlers must be taken for ortho-benzyl-para-chlorophenol. The Chemical Manufacturers Association (CMA) exposure data used to assess the risk resulting from three of the use-scenarios were based on the handlers in these use-scenarios wearing chemical-resistant gloves. Therefore, chemical-resistant gloves shall be required for occupational handlers of ortho-benzyl-para-chlorophenol for the following use-scenarios: mixing and pouring a soluble liquid, transferring (pumping) liquid, and pouring powdered or flaked solid product. Since the chronic MOE for hand-wiping (ungloved) was less than 300, chemical resistant gloves are required to reduce/mitigate the potential risk to applicators. For exposures related to indoor fogging applications, EPA is requiring the use of a full-face canister-style respirator to mitigate ocular and inhalation concerns.

The high-pressure spray application use-scenario, which is an intermediate exposure scenario, had an MOE of less than 100. The CMA exposure data used to assess the risk from this use-scenario was based, in some replicates, on the handlers wearing chemical-resistant gloves and rainsuits, there are no additional PPE options available that would adequately mitigate the risk. Furthermore, there are no practicable engineering controls for this use-scenario. Due to uncertainties in the data used to calculate exposure, the Agency will consider the high pressure spray scenario conditionally acceptable until new exposure data are available.

Human Risk Assessment

Since ortho-benzyl-para-chlorophenol has no food or feed uses, dietary risk is not expected.

Environmental Fate

The Agency expects that the registered uses of ortho-benzyl-para-chlorophenol should not result in significant exposure to the environment.

The environmental fate data indicated that the two salts rapidly degrade into the acid in the environment. Therefore, the data supporting the acid also can be used to support the potassium and sodium salts.

Ecological Effects Risk Assessment

The Agency requires only a limited set of ecotoxicology and environmental fate studies for microbiocides. The chemical, ortho-benzyl-para-chlorophenol, is nontoxic to birds and highly toxic to freshwater fish and aquatic invertebrates. While the hazard to aquatic organisms from ortho-benzyl-para-chlorophenol has been characterized, a quantitative risk assessment has not been conducted. The risks to aquatic environments from the uses of ortho-benzyl-para-chlorophenol are regulated under the NPDES permitting program of the Office of Water. The Agency currently requires that labels for all ortho-benzyl-para-chlorophenol products require that discharges to aquatic environments comply with a NPDES permit. Because terrestrial use of ortho-benzyl- para-chlorophenol and its potassium and sodium salts is limited to refuse/solid waste sites, exposure to wildlife is not expected to be significant.

Additional Data Required

EPA is requiring product-specific data including product chemistry and information to upgrade the acute toxicity studies, and data to satisfy the mammalian cells in culture forward gene mutation assay (specifically a mouse lymphoma assay, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration of products containing Ortho-benzyl-para-chlorophenol and its salts.

Product Labeling Changes Required

All end use products containing ortho-benzyl-para-chlorophenol and it salts must comply with EPA's current pesticide product labeling requirements.

PPE/Engineering Control Requirements for Pesticide Handlers

For **sole-active-ingredient** end-use products that contain ortho-benzyl-para-chlorophenol, the product labeling must be revised to adopt the handler personal protective equipment/engineering control 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 ortho-benzyl-para-chlorophenol, the handler personal protective equipment/engineering control 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 on which requirements are considered more protective, see PR Notice 93-7.

Minimum (Baseline) PPE/Engineering Control Requirements

EPA is establishing active-ingredient-based minimum (baseline) PPE/engineering control requirements for ortho-benzyl-para-chlorophenol end-use products that are intended primarily for occupational use for the following use-scenarios: (1) mixing and pouring soluble liquids, (2) transferring (pumping) liquids, (6) hand-wiping, (7) pouring powdered or flaked formulations, and (8) applying fogs to enclosed areas. The minimum (baseline) PPE for such occupational uses of ortho-benzyl-para-chlorophenol end-use products are:

"Applicators and other handlers must wear:

- long-sleeve shirt and long pants,
- socks plus shoes, and
- chemical-resistant gloves*.

"In addition, for applicators and other handlers exposed to the fog during fogging applications and until the fog has dissipated and the enclosed area has been thoroughly ventilated must wear:

- a full-face respirator with a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)"

*For the glove statement, use the statement established for ortho-benzyl-para-chlorophenol through the instructions in Supplement Three of PR Notice 93-7.

EPA is not establishing active-ingredient-based minimum (baseline) PPE for occupational handlers in the following use-scenarios: (4) low-pressure spray, and (5) mopping (ungloved).

In addition, for a comprehensive list of labeling requirements, please see the ortho-benzyl-para-chlorophenol RED document.

Regulatory Conclusion

The use of currently registered products containing ortho-benzyl-para-chlorophenol 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.

Ortho-benzyl-para-chlorophenol 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 ortho-benzyl-para-chlorophenol 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 ortho-benzyl-para-chlorophenol 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 ortho-benzyl-para-chlorophenol RED, or reregistration of individual products containing ortho-benzyl-para-chlorophenol and its salts, 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.