



R.E.D. FACTS

Chloroxylenol

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 years ago 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 imposes any regulatory controls that are needed to effectively manage 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 announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 3045, chloroxylenol or chloro-m-xyleneol.

Use Profile

Chloroxylenol is an antimicrobial used to control bacteria, algae and fungi in adhesives, emulsions, paints and wash tanks. It also is used to sanitize bathroom premises, diaper pails, laundry equipment, human bedding and pet living quarters in households, hospitals and other institutions. Formulations include a soluble concentrate/liquid (applied using a squirt bottle) and a pressurized liquid (aerosol), as well as a technical formulation and a formulation intermediate.

Use practice limitations include a prohibition against discharging effluent containing the pesticide into lakes, streams, ponds, estuaries, oceans or public waters unless specifically addressed in an NPDES permit, and a warning not to discharge the pesticide to sewer systems without previously notifying the sewage treatment plant authority.

Regulatory History

Chloroxylenol was first registered as a pesticide in the U.S. in 1959, for use as a fungicide. Products used as disinfectants and sanitizers have subsequently been registered. EPA issued an antimicrobial Data Call-In Notice in March 1987 to obtain chronic and subchronic toxicity data for the chloroxylenol manufacturing use product. Technical chemistry data were obtained through a Dioxin/Furan Data Call-In issued in 1988. Currently, two

manufacturing use products and five end use products containing this active ingredient are registered.

Physical Chemistry Assessment

EPA was concerned with the potential formation of dioxins and chlorinated dioxin impurities during the manufacture of chloroxylenol, and with the effect of these impurities on human health and the environment. The Agency has required the registrant to fully satisfy technical chemistry data requirements addressing this concern. These data have been submitted and do not suggest that dioxins or chlorinated dioxin impurities are present in technical chloroxylenol.

Human Health Assessment

Toxicity

Chloroxylenol generally is of moderate to low acute toxicity, but causes severe eye irritation and has been placed in Toxicity Category I (indicating the greatest degree of acute toxicity) for eye irritation effects. Chloroxylenol is of low acute toxicity via the inhalation route and causes only slight skin irritation, so it has been placed in Toxicity Category IV (the lowest of four categories) for these effects. It is slightly toxic by the oral and dermal routes, and has been placed in Toxicity Category III for acute oral and dermal effects.

In a subchronic dermal study using rabbits, chloroxylenol caused redness, toughness and cracking of the skin at the highest dose level. In a developmental toxicity study using rats, chloroxylenol caused maternal effects including decreased weight gain and food consumption. Deaths occurred at the highest dose. The No Observed Effect Level was the highest dose administered. Chloroxylenol is not mutagenic.

Dietary Exposure

Since no food or feed uses are registered, the Agency anticipates no dietary exposure to chloroxylenol. A food additive tolerance has been established by the Food and Drug Administration (FDA) allowing use of chloroxylenol as a preservative in food packaging adhesives (please see 21 CFR 175.105(c)(5)). However the safety of that use is under FDA's regulatory purview.

Occupational and Residential Exposure

Based on current use patterns, the potential dermal and inhalation exposures to applicators, mixers and loaders may be significant when chloroxylenol is applied as a medical disinfectant using spray application methods, or as a preservative using the open pouring application method. Secondary exposure of residents and others to chloroxylenol after application of end-use products is significantly less than workers' exposure.

Human Risk Assessment

Since chloroxylenol is not applied to food or feed crops and is not used in food handling establishments, no dietary risk is expected. FDA regulates the use of this pesticide as a food packaging adhesive.

No toxicological endpoints of concern have been identified for chloroxylenol except eye irritation. Personal protective equipment (PPE) may be required for some end-use products on a case-by-case basis, but is not required for all chloroxylenol products at this time.

Environmental Assessment

Environmental Fate and Assessment

Chloroxylenol is hydrologically stable and is a weak acid. EPA does not anticipate significant environmental exposure to this pesticide since it has only one limited outdoor use, on pet living quarters.

Ecological Effects

Chloroxylenol's toxic effects range from low to high, depending on the species. The pesticide is practically non-toxic to bobwhite quail on an acute oral basis and to birds on a dietary basis. However, it is highly toxic to freshwater fish and moderately toxic to aquatic invertebrates on an acute basis. Plants and non-target insects are not expected to be exposed to chloroxylenol since it is used mostly indoors.

Ecological Effects Risk Assessment

Chloroxylenol is practically non-toxic to birds, moderately toxic to freshwater invertebrates and highly toxic to fish. However, exposure to terrestrial and aquatic organisms is extremely minimal since chloroxylenol has almost all indoor uses. The sole outdoor use, on pet living quarters, will not result in significant environmental exposure. Therefore, when used according to label directions, chloroxylenol poses only a minimal risk to terrestrial and aquatic organisms.

Additional Data Required

No additional generic data for chloroxylenol is required at this time. 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.

Product Labeling Changes Required

All chloroxylenol end-use products must comply with EPA's current pesticide product labeling requirements, and with the following:

Products with the Outdoor Use - Products with the pet living quarters use on their labeling must bear the following statement:

"This pesticide is toxic to fish. Do not apply directly to water. Do not contaminate water when disposing of equipment wash waters or rinsate."

Non-Residential Products with Indoor Nonfood and/or Medical Uses - Must bear the following statement:

"This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant

Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

All end-use products must specify their formulation type and percent of active ingredient on their labels.

Regulatory Conclusion

The use of currently registered pesticide products containing chloroxylenol in accordance with approved labeling is not expected to pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Products containing chloroxylenol will be reregistered once the product-specific data, revised Confidential Statements of Formula and revised labeling are received and accepted by EPA. Products containing chloroxylenol and other active ingredients will be reregistered only after the other active ingredients also are eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for chloroxylenol 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, and also can be reached on the Internet via *FEDWORLD.GOV* and EPA's gopher server, *EARTH1.EPA.GOV*.

Following the comment period, the chloroxylenol RED document 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 chloroxylenol RED, or reregistration of individual products containing chloroxylenol, 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 8:00 am and 6:00 pm Central Time, Monday through Friday.