United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-94-022 September 1994

# R.E.D. FACTS

# M-Cresol and Xylenol

## 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 for m-cresol and xylenol, cases 4027 and 4098, which are formulated together to produce a single pesticide product called Gallex.

## Use Profile

M-cresol and xylenol, when formulated together, have bacteriostatic activity against the causal agents of crown gall and olive knot on fruit, ornamental and shade trees and ornamental woody shrubs and vines and control of the genetic/physiological disorder, burr knot, on apples. The pesticide product that contains these two active ingredients, Gallex, is a ready-to-use liquid that is brushed or painted onto the infected areas of trees and ornamentals. Treatments may be made every 4 to 6 months, or about twice a year. Although usage data are not available, EPA assumes that the volume of use is relatively low.

## Regulatory History

M-cresol and xylenol were first registered for use as pesticides in the U.S. in 1980. Their initial registration was for a use pattern similar to that of the currently registered product, Gallex. Gallex contains the two active ingredients at a very low concentration (only 0.46% of each).

## Human Health Assessment

Cresols (m-cresol and two other isomers) are present at low concentrations in various environmental media including air, car exhaust, wood and coal. Reports that cresols may have tumor promoting activity have not been substantiated by scientific studies. Only acute and subchronic

toxicity and mutagenicity studies are required for reregistration of m-cresol and xylenol because of their current use patterns.

### Toxicity

Technical grade m-cresol causes severe eye and skin irritation and has been placed in Toxicity Category I, indicating the greatest degree of acute toxicity, for these effects. Technical xylenol also is corrosive to the skin, and has been placed in Toxicity Category I for this effect.

The end use product that contains both m-cresol and xylenol has been found to cause slight eye irritation in rabbits and has been assigned to Toxicity Category II for eye effects. It has been found to produce skin sensitization in guinea pigs but does not cause skin irritation in rabbits.

Subchronic toxicity studies by the National Toxicology Program (NTP) of the National Institutes of Health on m-cresol alone and with p-cresol, a related isomer, indicated effects to the kidneys, liver and other organs in rats and mice, particularly at high doses. A dermal study using the formulated product on rabbits showed the product to be corrosive to skin.

M-cresol does not cause developmental toxicity, but causes effects on body and organ weights in reproductive toxicity studies using rats and mice. M-cresol is not mutagenic, and is excreted through urine.

### Dietary Exposure

Since m-cresol and xylenol are applied only to the bases of fruit and nut trees, no residues are expected to remain in food or feed commodities. The Agency is requesting the registrant seek an exemption from tolerance (enforceable residue limit).

### Occupational and Residential Exposure

Applicators may be exposed to m-cresol and xylenol when applying the end-use product Gallex by paint brush to infected areas of trees and ornamentals. Direct dermal and eye exposures to this product are considered potentially significant because the active ingredients have a high degree of acute toxicity to the eyes and skin. The formulated product Gallex is also considered to be a dermal sensitizer. Use of personal protective equipment (PPE) may mitigate the acute toxicity risks to applicators.

Since no more than four consecutive days of occupational/residential exposure are typically expected, a short term occupational/residential margin of exposure (MOE) was calculated for m-cresol based on maternal toxicity. The MOE for the end-use product, estimated to be 1,017, is acceptable. The Agency also considered intermediate term exposure due to the potential that commercial applicators may be exposed to the end-use

product for this interval. The intermediate term exposure assessment was based on a 28-day feeding study. The less likely intermediate term exposure revealed a MOE for the end-use product at 308, an acceptable level. There are no post-application worker exposure concerns.

### Human Risk Assessment

Dietary exposure to m-cresol and xylenol is not a concern since residues of these pesticides do not remain in the fruit or nuts of treated trees. Applicators face acute toxicity hazards to the skin and eyes. However, these risks will be mitigated by use of PPE, as required by the RED. Considering Gallex's use pattern, the low concentration of each active ingredient in the end use product, the toxicity characteristics of these chemicals, and the acceptable MOE, EPA does not expect significant health risks from short term or intermediate term residential/occupational exposure to m-cresol and xylenol, when used properly as directed.

## Environmental Assessment

EPA did not conduct an environmental risk assessment for m-cresol and xylenol and did not require any data on environmental fate or ecotoxicity. The current use pattern of these pesticides and their low volume of use will result in very low environmental exposure, resulting in no threat to wildlife. Non-target organisms including endangered species are not expected to be adversely affected from this use.

## Additional Data Required

EPA is requiring product specific data including product chemistry and acute toxicity studies, a revised Confidential Statement of Formula and revised labeling for reregistration of m-cresol and xylenol.

## Product Labeling Changes Required

The label of the registered pesticide product containing m-cresol and xylenol must comply with EPA's current pesticide labeling requirements. In addition, Personal Protective Equipment (PPE) must be required on product labeling, as follows:

> "Applicators and other handlers must wear: protective eyewear, chemical resistant gloves, long sleeves, long pants, shoes and socks."

## Regulatory Conclusion

Use of the currently registered pesticide product containing m-cresol and xylenol in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these pesticides are eligible for reregistration. The product Gallex will be reregistered once the required product specific data, Confidential Statement of Formula and revised labeling are received and accepted by EPA.

## For More

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for m-cresol and xylenol during a 60-day time

## Information

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.

Following the comment period, the m-cresol and xylenol 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 m-cresol and xylenol RED, or reregistration of the end-use product containing m-cresol and xylenol, 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.