United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-96-025 September 1996

# R.E.D. FACTS

# Chlorhexidine diacetate

## 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 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 3038, chlorhexidine diacetate.

## Use Profile

Chlorhexidine diacetate is a disinfectant used to control bacteria on agricultural premises, egg handling and packing equipment, and meat and poultry processing plants, and certain viruses in veterinary settings.

End-use products contain 2% of the active ingredient and are formulated as soluble concentrates or liquids.

Chlorhexidine diacetate is applied by open-pour loading of liquid formulations, hand-wiping surfaces, dipping tools/implements into diluted disinfectant solution, mopping of surfaces, using hand-held high- and low-pressure spray equipment, and with fogging devices. Use practice limitations prevent exposure to food items.

## Regulatory History

Products formulated with chlorhexidine diacetate as an active ingredient were first registered in the U.S. as early as 1955 for use as a farm premise disinfectant/virucide.

Currently, two products (each containing 2% chlorhexidine diacetate) are registered for use as hard surface-treatment disinfectants/virucides.

## Human Health Assessment

### Toxicity

In acute toxicity studies using laboratory animals, the Agency concluded that chlorhexidine diacetate is mildly to moderately toxic when administered by inhalation, oral and dermal routes. However, in repeat primary eye irritation studies, the chemical is severely toxic.

In a subchronic dermal rabbit toxicity study systemic effects included degenerative changes in the livers of females. In a developmental toxicity study in rats, no observable malformations nor signs of developmental toxicity were found at any dose level tested. A battery of mutagenicity studies were negative for mutagenic effects.

### Dietary Exposure

Chlorhexidine diacetate is registered for use on processing surfaces in federally inspected meat, poultry, egg, and rabbit processing plants as a disinfectant. The labeling for these products directs the user to remove or carefully cover the food products prior to application, and to use a potable water rinse after treatment. The U.S. Department of Agriculture and the EPA have determined that disinfectants, when applied to federally inspected meat, poultry, egg, and rabbit processing plants as described above, do not present dietary exposure risks (USDA, FSIS publication #1419, "List of Proprietary Substances and Nonfood Compounds").

### Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to chlorhexidine diacetate during and after normal use of products containing this active ingredient. An exposure assessment is appropriate because of the toxicological endpoint from the subchronic dermal study.

Several exposure scenarios are possible, including open pouring, wiping, dipping of implements, mopping, spraying, and fogging. Data are not available to calculate exposures for the fogging scenario. For the remaining scenarios, EPA's exposure assessment, which considered combined dermal and inhalation exposures, suggests that short- and intermediate-term exposures are greatest for the open pouring scenario while chronic exposures are greatest from wiping activities. However, the calculated margins of exposure (MOEs) for these uses were greater than 100. MOEs of greater than 100 are considered acceptable.

Because the exposure data used to calculate these risks were generated for workers wearing personal protective equipment (PPE), these PPE are required as described in the product labeling section of this fact sheet.

The potential for exposures to chlorhexidine diacetate exists following application. However, the Agency believes that exposures from post-application are significantly lower than exposures during application,

provided entry into treated areas is restricted immediately following application. The Agency is concerned for workers exposed to chlorhexidine diacetate from their entry into the fogged area. To protect these workers, PPE, including gloves and a respirator, is required.

### Human Risk Assessment

Chlorhexidine diacetate generally is of low to moderate acute toxicity, but is highly acutely toxic when applied to the eye. It causes liver effects in animal studies.

The Agency is concerned for risks posed to chlorhexidine diacetate handlers and workers reentering areas recently treated with the pesticide. To mitigate these risks, PPE is established for both handlers and workers in early-entry situations.

## Environmental Assessment

For chlorhexidine diacetate, like other pesticides whose uses are limited to indoor sites, the Agency required a limited set of ecotoxicology and environmental fate studies. The Agency does not routinely conduct full environmental assessments on such pesticides since minimal to no environmental exposure is expected from the indoor use patterns. Only a limited set of studies are necessary to characterize the pesticide's hazard potential in the case of unanticipated environmental exposures caused by transportation accidents, spills, or improper disposal or use.

### Ecological Effects

Chlorhexidine diacetate is slightly toxic to avian species on an acute and subacute oral dietary basis, moderately to highly toxic to fish, and very highly toxic to aquatic invertebrates. Current uses of chlorhexidine diacetate are expected to result in minimal exposure or risk to the environment. Therefore, no environmental risk mitigation measures are imposed at this time.

## Additional Data Required

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 chlorhexidine diacetate end-use products must comply with EPA's current pesticide product labeling requirements and with the following.

Minimum (Baseline) PPE Requirements

The minimum (baseline) PPE for persons applying chlorhexidine diacetate by mopping and hand wiping is:

"Applicators and other handlers must wear:

- Long sleeve shirt and long pants
- Socks plus shoes."

The minimum (baseline) PPE for occupational uses of chlorhexidine diacetate end-use products with the exception of the wet-mist fogging is:

"Applicators and other handlers must wear:

- Long-sleeve shirt and long pants
- Chemical-resistant gloves
- Socks plus shoes."

For the wet-mist fogging, the following PPE is required:

"Applicators and other handlers exposed to the fog during wet-mist fogging applications and until the fog has dissipated and the enclosed area has been thoroughly ventilated must wear:

- Long-sleeve shirt and long pants
- Chemical-resistant gloves
- Socks plus shoes."

## Regulatory Conclusion

The use of currently registered products containing chlorhexidine diacetate in accordance with approved labeling and as specified in the RED will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Chlorhexidine diacetate 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 [name] 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 [name] 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 [name] RED, or reregistration of individual products containing [name], 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.