

**CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION
PUBLIC REPORT 2007-4**

Chlorhexidine gluconate
Tracking ID Number 214338

DESCRIPTION OF ACTION

Zenith Dental Brand of Foremost Dental LLC (Zenith Dental) submitted an application for California registration of Microsurf, EPA Reg. No. 70467-3-82667. Microsurf is a distributor registration of the Micrylium Laboratories product, Biosurf, EPA Reg. No. 70467-3. Micrylium Laboratories does not intend to register Biosurf in California. Microsurf is a disinfectant labeled for hospital use on hard non-porous surfaces, and contains 0.2% of the new active ingredient chlorhexidine gluconate in combination with ethyl alcohol. Ethyl alcohol is an active ingredient that is registered in California and found in a number of currently registered pesticides.

The Department of Pesticide Regulation (DPR) evaluated the product label and data, and found them acceptable to support registration. Precautionary and first aid statements on the product label, as well as label directions requiring personal protective equipment (PPE) and other protective measures adequately mitigate potential health risks to persons who may come in contact with the pesticide during application. DPR does not expect significant adverse environmental impacts to result from registration of Microsurf.

The U.S. Environmental Protection Agency (U.S. EPA) registered Biosurf conditionally on June 3, 2005. At that time, U.S. EPA identified labeling deficiencies and required Micrylium Laboratories to correct the deficiencies as a condition of registration. Micrylium Laboratories complied with the conditions of registration, and Biosurf was fully registered September 15, 2006. Micrylium Laboratories submitted a notice of Supplemental Distribution of a Registered Pesticide Product (EPA Form 8570-5), to the U.S. EPA, for the supplemental distributor registration of the Zenith Dental product Microsurf, EPA Reg. No. 70467-3-82667. Under the terms of the supplemental registration Zenith Dental must comply with all of the conditions of the basic registration of Biosurf, EPA Reg. No. 70467-3.

BACKGROUND

Registrant: Zenith Dental Brand of Foremost Dental LLC
Chemical name: Chlorhexidine gluconate
Brand name: Microsurf
Uses: Disinfectant for use on hard non-porous surfaces
Pests controlled: Bacteria, fungi, and viruses
Type of registration: Full Registration

Chlorhexidine gluconate belongs to the biguanides chemical group. It is bactericidal, virucidal, and fungicidal, causing cell wall decomposition, leading to the loss of the cell's components. Microsurf is labeled as a disinfectant for use in hospitals on such things as countertops, wheelchairs, metal bed frames, and exteriors of toilets. It is an effective one-step disinfectant on

hard non-porous surfaces at the label recommended undiluted rate in the presence of 5% organic soil with a contact time of one minute.

SCIENTIFIC REVIEW

A. Chemistry

1. **Product Chemistry:** DPR evaluated the submitted chemistry studies for Microsurf. The initial recommendation was against registration of Microsurf because of product chemistry data deficiencies. In response, Zenith Dental submitted the data necessary to upgrade the product chemistry report to acceptable. The results are summarized in Table 1.

Table 1. Physical and Chemical Properties of Technical Chlorhexidine gluconate	
Properties	Values
Physical state	Liquid
Color	Colorless to pale yellow
Specific gravity	1.07
pH (5% solution)	5.5-7.0
Melting point (crystalline form)	132-136°C (crystalline form)
Water solubility	Soluble in water, ethanol, and acetone
Viscosity	2.69 cST at 20°C (end use product)
Storage stability (end use product)	Stable for 1 year @ 20-26°C (end use product)

2. **Residues in Food and Animal Feed:** Microsurf is a disinfectant labeled for use in hospitals on hard non-porous surfaces such as countertops, wheelchairs, metal bed frames, and exteriors of toilets. When used as directed, DPR does not expect chlorhexidine gluconate to come in contact with food or food contact surfaces.
3. **Environmental Fate:** Microsurf is a disinfectant labeled for use in hospitals on hard non-porous surfaces. When used as directed, DPR does not expect chlorhexidine gluconate to be released into the environment. Consequently, environmental fate data are not required at this time.

B. Toxicology

Zenith Dental submitted adequate toxicology studies to conduct a complete toxicological evaluation of Microsurf. DPR evaluated the submitted data to determine the potential for adverse health effects. The acute toxicity parameters for Microsurf are summarized in Table 3.

Table 3. Acute Toxicity of Microsurf		
Type of Study	Acute Toxicity Values*	Acute Toxicity Category
Acute oral	LD ₅₀ > 5000 mg/kg	IV
Acute dermal	LD ₅₀ > 5000 mg/kg	IV
Acute inhalation	LC ₅₀ > 2.03 mg/l	IV
Primary eye irritation	N/A	III
Primary dermal irritation	N/A	IV
Dermal sensitization	N/A	Not a Sensitizer
Signal word	N/A	CAUTION
*Acute Toxicity Values expressed as: LD ₅₀ = Lethal dose that kills 50% of the test population LC ₅₀ = Lethal environmental concentration that kills 50% of the test population N/A = Not applicable		

DPR's evaluation of the acute toxicity studies indicates that the studies are adequate for a complete toxicological evaluation. The product label adequately identifies the potential acute toxicity hazards indicated by the data reviewed. The first aid statements and PPE are adequate for the indicated acute toxicity hazards.

The Medical Toxicology Branch initially recommended against registration of Microsurf because 90-day dermal toxicity and teratogenicity (one species) studies, and a genotoxicity battery were not submitted to support product registration. The registrant submitted a response noting that U.S. EPA has grouped chlorhexidine gluconate with chlorhexidine diacetate for the purpose of assessing the toxicity hazards (see Reregistration Eligibility Document (RED): Chlorhexidine diacetate, U.S. EPA, 1996). In turn, the Medical Toxicology Branch determined that the new active ingredient chlorhexidine gluconate can be grouped with the currently registered active ingredient chlorhexidine diacetate for the purpose of testing under the requirements of the Birth Defects Prevention Act (Food and Agricultural Code section 13121 et seq.). In accordance, Birth Defects Prevention Act data for chlorhexidine gluconate are not required at this time.

DPR prioritizes pesticide active ingredients for risk assessment based on the nature of the potential adverse health effects, number of potential adverse effects, number of species affected, no observable effect levels (NOELs), potential for human exposure, use patterns and other similar factors. Based on these criteria, pesticides with the greatest potential for health problems are placed in high priority, with other chemicals being in moderate or low priority. At this time, chlorhexidine gluconate has not been prioritized by DPR for risk assessment, and toxicity. Because chlorhexidine gluconate is grouped with the currently registered active ingredient chlorhexidine diacetate for the purpose of testing under the requirements of the Birth Defects Prevention Act, toxicity information is not available for chlorhexidine gluconate on DPR's website. However, a summary of toxicology data with chlorhexidine diacetate toxicity information is available on the DPR public website at: <http://www.cdpr.ca.gov/docs/toxsums/pdfs/1144.pdf>.

C. Health & Safety

DPR's evaluation of the medical management information on the Microsurf label and the acute toxicity study results indicate that the product label bears all of the required statements and warnings regarding safety to handlers and other persons who may be exposed to the pesticide. The product label bears an adequate First Aid statement. The label requires applicators to wear safety glasses, and to wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

D. Fish & Wildlife

Microsurf is a disinfectant labeled for use in hospitals on hard non-porous surfaces. When used as directed, DPR does not expect chlorhexidine gluconate to be released into the environment. Consequently, fish and wildlife data are not required at this time.

E. Microbiology

In support of registration Zenith Dental submitted disinfectant test data derived from Microsurf tested against *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Mycobacterium bovis*, *Trichophyton mentagrophytes*, *Trichophyton megninii*, and Canine parvovirus CPV-265. DPR staff evaluated the submitted efficacy data and recommended against registration based on inadequate data to support all label claims. In response, Zenith Dental submitted amended labeling, which negated the need for additional efficacy data. The submitted efficacy data are adequate to support registration of Microsurf.

ALTERNATIVES

Chlorhexidine gluconate is an effective disinfectant against bacteria, fungi, and viruses. Microsurf has a one-minute contact time and is effective in the presence of 5% bioburden. It is a ready-to-use product that does not require mixing. The levels of chlorhexidine gluconate acid residue that may remain on surfaces after application do not pose a hazard. This, in addition to the short contact time required for control of microorganisms makes Microsurf ideal for use in

the hospital environment. A number of other active ingredients are registered as disinfectants for hospital use. However, an effective integrated pest management strategy requires the flexibility of a large number of comparable, but not exactly equivalent, pesticides.

CONCLUSION

DPR evaluated the product label and scientific data submitted to support the registration of Microsurf. The label and data were found acceptable to support registration. The acute health risks to human from exposure to chlorhexidine gluconate are minimal due to its low mammalian toxicity. The precautionary and first aid statements on the product label, and the recommended protective measures mitigate potential health risks to persons who may be exposed to these pesticides. If a risk assessment conducted by DPR determines that exposure to chlorhexidine gluconate may result in unacceptable margins of exposure, further restrictions will be placed on the use of chlorhexidine gluconate at that time.