

PM 33

15136-9

8-13-99

1 of 2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 13 1999

Medical Chemical Corporation  
19430 Van Ness Avenue  
Torrance, CA 90501

Attn: Patrick Braden

Subject: Wavicide-06 Plus  
EPA Registration No. 15136-9  
Letter Dated July 21, 1999

The Agency is in receipt of your submitted final printed label based on the previously accepted draft label dated June 22, 1999. The final label has not been reviewed in accordance with PR Notice 82-2 but placed in your product registration file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,



Marshall Swindell  
Product Manager (33)  
Regulatory Management Branch 1  
Antimicrobial Division (7510C)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

# Wavicide-06 Plus™

## HARD SURFACE DISINFECTANT SPRAY

### ACTIVE INGREDIENTS:

Glutaraldehyde (1,5 Pentanedial) . . . 0.25%

Ethanol . . . . . 50%

INERT INGREDIENTS: . . . . . 49.75%

Contains a corrosion inhibitor

Bactericidal

Virucidal

Tuberculocidal

Fungicidal

Pseudomonacidal

KEEP OUT OF REACH OF CHILDREN

DANGER

Net contents one US gallon (3.79 liters)

FOR PROFESSIONAL AND INDUSTRIAL USE ONLY

US patents: 5,004,757; 5,219,890 and pending

Revised Jul. 21, 1999

Manufactured by:

Medical Chemical Corp.  
19430 Van Ness Ave.  
Torrance, CA 90501  
(800)424-9394

EPA Reg. Number 15136-9  
EPA Est. No. 8654-CA-1

## DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling. Recommended for the disinfection of hard non-porous surfaces such as: counter tops, tables, chairs, cages and other environmental surfaces in hospitals, laboratories and other institutions. Wavicide-06 Plus is compatible with rubber, latex, aluminum and stainless steel when used according to instructions.

Preclean all surfaces to be disinfected. This will insure maximum contact with the disinfection solution. DO NOT DILUTE. For effective disinfection, saturate non-critical devices with full strength Wavicide-06 Plus at room temperature. Surfaces should be kept moist for 10 Minutes. Dry surfaces with a clean cloth. This procedure will destroy vegetative pathogens including Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa and pathogenic fungi (such as Trichophyton mentagrophytes) on hard, non-porous, inanimate surfaces. A ten minute contact time with this procedure will also destroy the following viruses on hard non-porous inanimate surfaces: Polio virus type 2, HIV-1, Adenovirus type 2 and Herpes simplex virus type 1.

Tuberculocidal at room temperature (22° C) and a 10 minute contact time (tested against M. bovis using the quantitative test method).

**Special instructions for cleaning and decontaminating against HIV on surfaces/objects soiled with blood/body fluids.** Observe universal precautions as defined by the CDC for surfaces soiled with blood/body fluids. Observe Universal Precautions As Defined By The CDC For Medical Instruments Or Equipment Soiled With Blood/Body Fluids. **Personal protection:** Disposable nitrile gloves, eye protection, and face masks should be worn when cleaning and disinfecting soiled equipment. **Cleaning procedure:** Blood and other bodily fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant. **Disposal of Infectious Material:** Blood and other bodily fluids should be disposed of according to approved hospital procedures.

**STORAGE AND DISPOSAL:** Store at room temperature. **CONTAINER DISPOSAL:** Thoroughly rinse container and discard in trash. **PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**PRECAUTIONARY STATEMENTS:** Hazardous to humans and domestic animals. This product is a sensitizer. **DANGER.** Corrosive. Causes irreversible eye damage. Do not get into eyes or on clothing. Wear goggles or face shield. Prolonged or repeated skin contact may cause allergic reaction in sensitive individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. **FLAMMABLE LIQUID.** Contains alcohol. Keep away from heat, flame or other sources of ignition.

**STATEMENT OF PRACTICAL TREATMENT:** If swallowed, call a physician or poison control center. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol. If in eyes, hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention. **Note to physician:** Probable mucosal damage may contraindicate the use of gastric lavage.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

See bottom of bottle for Lot No. and expiration date.

NOT REVIEWED

In Accordance with PR Notice 82-2.  
Based on Draft Labeling Dated

2092