

015136-00009-062299

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Systems Integration Group, Inc.

33 15/36-9 6/20/99, Pose 173



## U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

Registration Division (H7505C) 401 "M" St., S.W. Washington, D.C. 20460

NOTICE OF PESTICIDE: X Registration

\_\_ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:

Date of Issuance:

15136-9

JUN 2 2 1999

Term of Issuance:

Conditional

Name of Pesticide Product:

Wavicide-06 Plus

Name and Address of Registrant (include ZIP Code):

Medical Chemical Corporation 19430 Van Ness Avenue Torrance, CA 90404

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

- Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
  - Make the following label changes:
    - a. Revise the EPA Registration Number to read, "EPA Reg. No. "15136-9".

Signature of Approving Official:

Marshall Swindell

Product Manager 33

Regulatory Management Branch 1 Antimicrobial Division (7510C)

Date:

JUN 2 2 1999

page 2 EPA Reg. No. 15136-9

- b. In the directions for use for the HIV-1 claims, include a contact time.
- c. In paragraph 2, revised the sentence "This procedure will also destroy the following viruses on inanimate surfaces ..." to read "This procedure will also destroy the following viruses on hard non-porous inanimate surfaces ...".
- 3. Submit two copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

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

Sincerely,

Marshall Swindell

Product Manager (33)

Regulatory Management Branch 1 Antimicrobial Division 7510C)

Enclosure

## 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 fi-ters)

FOR PROFESSIONAL AND INDUSTRIAL USE ONLY

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

Revised Apr. 9, 1999

Manufactured by.

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

EPA Reg. 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, spray non-critical devices with full strength Wavicide-06 Plus at room temperature until saturated. 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. This procedure will also destroy the following viruses on 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. boving 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. <u>Personal protection</u>: Disposable nitrile gloves, eye protection, and face masks should be worn when cleaning and disinfecting soiled equipment. <u>Cleaning procedure</u>. Blood and other bodily fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant. <u>Disposal of Infectious Material</u>: 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 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 preclean 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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JUN 2 2 1999

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

15-136-9

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