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15136-1

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ACCEPTED
FEB 02 1995
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act,
 as amended, for the pesticide
 registered under
 EPA Reg. No. 15136-1

READY TO USE • NO ACTIVATOR REQUIRED • DILUTE FOR DISINFECTION **30 DAY REPEATED STERILIZATION USE IN MANUAL SYSTEMS** **42 AND 21 DAY REPEATED DISINFECTION USE IN MANUAL SYSTEMS**

WAVICIDE-01

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ACTIVE INGREDIENT:
 Glutaraldehyde (1,5 Pentanedial) 2%
INERT INGREDIENTS..... 98%

Contains a corrosion inhibitor.

SPORICIDAL
VIRUCIDAL*
BACTERICIDAL
TUBERCULOCIDAL**
PSEUDOMONACIDAL
FUNGICIDAL

1:8 Dilution inactivates
 HIV-1 (AIDS Virus)***
 In 1 minute on
 environmental surfaces

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/ OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: Disposable latex gloves should be worn by all personnel engaged in activities that may involve skin contact with potentially infectious fluids, tissues, or cultures. Gowns, masks, and eye covering devices will be needed if there is a risk of generating aerosols, splashes, or spills of potentially infectious materials.

CLEANING PROCEDURE: Blood and other body fluid contaminants must be thoroughly cleaned from surfaces and objects before application of the disinfectant.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluid contaminants should be autoclaved and disposed of according to federal, state, and local regulations.

CONTACT TIME: Although efficiency at a 1 minute contact time has been shown to be adequate against HIV-1, this time would not be sufficient for other organisms. Therefore, for other microorganisms use longer contact time indicated on this label.

FOR PROFESSIONAL USE ONLY
 See bottom for Lot No. and Exp. date

DIRECTIONS FOR USE

PREPARATION: Instruments should be thoroughly cleaned, rinsed and rough dried before immersing in Wavicide-01. Non-ferrous objects and needles should be flushed and filed.

STERILIZATION-FULL-STRENGTH

Final Volume	Vol. Wavicide-01	Water
32 oz.	32 oz.	NONE
64 oz.	64 oz.	USE FULL STRENGTH
128 oz. (1 gal)	128 oz. (1 gal)	USE FULL STRENGTH

Immerse objects to be sterilized in full strength Wavicide-01 as follows:

Contact Time	Temperature
5 Hours	40°C (104°F)
10 Hours	21°C (70°F)

Remove instruments from the Wavicide-01 solution using sterile technique and rinse thoroughly with sterile water. This procedure will also destroy the Hepatitis B virus (HBV). When sterilizing at temperatures above 21°C (70°F) keep solution in closed containers or machine. Do not open to until solution has cooled to room temperature. At 21°C (70°F) full-strength Wavicide-01 can be used and re-used as a sterilant for up to 30 days.

DISINFECTION-1:4 DILUTION

Final Volume	Vol. Wavicide-01	Water
32 oz.	8 oz.	24 oz.
64 oz.	16 oz.	48 oz.
128 oz. (1 gal)	32 oz.	96 oz.

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Contact equipment, wires or objects by mop or immersion with the 1:4 diluted solution (0.5% active ingredient) for 10 minutes at room temperature. After processing, instruments should be rinsed with water that fulfills federal drinking water standards.

This procedure will destroy vegetative organisms including *Staphylococcus aureus*, *Salmonella choleraesuis*, *Escherichia coli*, *Pseudomonas* species, *Klebsiella pneumoniae*, and pathogenic fungi (*Trichophyton mentagrophytes* and *Candida albicans*).

In 10 minutes at 21°C (70°F) the 1:4 diluted (0.5% glutaraldehyde concentration) solution is virucidal after manual re-use for up to 21 days (51 cycle loads) against herpes simplex types 1 and 2, Rotavirus type WA, Poliovirus type 2, Coxsackie virus type B₁, Influenza virus type A (PR8), Rhinovirus type 1A, Respiratory Syncytial virus, and Cytomegalovirus.

In 10 minutes at 23°C (73°F) the undiluted (2% glutaraldehyde concentration) solution is virucidal against the above mentioned viruses after manual re-use for up to 42 days (125 cycle loads).

At room temperature, full-strength, undiluted Wavicide-01 (2% Glutaraldehyde) can be used and re-used as a disinfectant for up to 42 days (six weeks). The Wavicide-01 1:4 disinfecting dilution (0.5% Glutaraldehyde) can be used and re-used up to 21 days (three weeks).

**To destroy *Mycobacterium tuberculosis* at 20°C with the full strength 42 day solution immerse completely for 30 minutes. For single use of full strength solution at 20°C immerse completely for 10 minutes. Remove equipment from the solution and allow to dry thoroughly.

***WAVICIDE-01 is an effective virucidal agent against HIV-1 (AIDS virus) on hard, non-porous surfaces in the presence of a moderate amount of organic soil (5% blood serum) when used at 1:8 dilution (0.25% glutaraldehyde) for a contact time of at least 1 minute at room temperature (20°-25°C) as a previously unused (no re-use) solution.

STORAGE AND DISPOSAL: Do not re-use empty container. Rinse thoroughly with water and dispose of in trash. This product should be stored at room temperature, preferably in a cool place. NOTE: 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.

WARNING: Causes eye irritation. In case of contact with the eye, flush well with water and seek medical aid. Avoid prolonged and repeated contact with skin as possibility of sensitization exists. The use of nitrile rubber gloves when mixing or handling the product is recommended. Avoid contamination of food. The permissible exposure limit (PEL) of glutaraldehyde in the atmosphere is below 0.2 ppm (ie. 0.8 mg/m³).

Recommended for rubber, aluminum, plastic, metals, ferrous, stainless steel instruments, burs, and fiberoscopes.

NET CONTENTS:
 1 U.S. gallon (128 fl. oz.) 3.785 liters
 U.S. PATENTS:
 3,537,222, 3,912,450, 3,958,248 and pending

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