

MAR 24 1992

Wave Energy Systems, Inc.
One Riverway, Suite 1700
Houston, TX 77056

Attention: Raymond M.G. Bouchen

Gentlemen:

Subject: Wavicide-06
EPA Registration No. 15136-6
Your Amendment Dated January 8, 1990

The amendment referred to above, submitted in connection with registration under FIFRA, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling.
 - a. Under "Recommended for Use In" delete the sanitization claim for air conditioning ducts and coils. Previous approval of the sanitization claim for hard, non-porous surfaces did not include the air conditioning ducts and coil use sites.

Please note that the statements relating to use in air conditioning ducts and coils require exposure data and inhalation toxicity data.

- b. Under "Recommended for Use In," delete the sanitization claim for carpeting. This claim must be substantiated by submitting data to show the product's effectiveness. Refer to DIS/TSS-8 enclosure for the necessary testing parameters.
 - c. Since there are many types of plastics used by the health care industry, the label must indicate the type(s) of plastics with which the product is compatible (e.g., polystyrene, polypropylene, polyvinyl chloride, etc.).

61770:I:DeLaney:C.Disk:KEVRIC:03/11/92:aw:dd:rj

CONCURRENCES

CONCURRENCES							
SYMBOL							
SURNAME							
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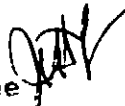
- d. The ingredient section is preferred to be placed directly below the product name.
 - e. Delete the phrase "contains triethylene glycol as a binding agent" from below the ingredient statement unless it is a toxic inert ingredient on list 1 in PR Notice 87-6. However, if you wish to list your inerts, you must list them all.
2. Submit five (5) copies of your final printed labeling before you release the product for shipment.

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 bearing the amended labeling constitutes acceptance of these conditions.

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

If you have any questions concerning this letter, please contact Martha DeLaney at (703) 305-6982.

Sincerely yours,


John H. Lee
Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosure

15136-6

NON-RUSTING • NON-STAINING • LONG-LASTING

WAVICIDE®-06

A TAMED GLUTARALDEHYDE/AN INSTRUMENT DISINFECTANT FOR THE PREP ROOM

BACTERICIDAL

VIRUCIDAL*

TUBERCULOCIDAL**

FUNGICIDAL

PSEUDOMONACIDAL

ACCEPTED
with COMMENTS
to EPA Letter Dated:

MAR 24 1992

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

15136-6

Full Strength Solution
Inactivates HIV-1
(AIDS virus)***
in 1 minute
on pre-cleaned
environmental surfaces.

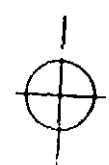
A STABLE, BROAD-SPECTRUM DISINFECTING/SANITIZING SOLUTION FOR USE IN PHARMACEUTICAL, INDUSTRIAL, CLINICAL, VETERINARY, AND MEDICAL FACILITIES, PUBLIC BUILDINGS, AND NURSING HOMES.

KEEP OUT OF REACH OF CHILDREN

CAUTIC † See back panel for additional
precautionary statements
E.P.A. Registration No. 15136-6
Net Contents 1 US Gallon (128 fl. oz.) - 3.785 liters

Patents pending
See bottom for Lot No. and Exp. Date

Manufactured by:
WAVE ENERGY SYSTEMS
E.P.A. Establishment
218 Little Falls Road
Cedar Grove, NJ 07009
800-252-1125



WAVICIDE-06

WAVICIDE-06

REFILL

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 efficacy at 5 minute contact time has been shown to be adequate against HIV-1, this time would not be sufficient for other organisms. Therefore, use a 10 minute contact time for disinfection against all the organisms named

DIRECTIONS FOR USE

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

PREPARATION: Clean or flush objects or surfaces with water to eliminate soil and/or deposits of organic matter. This will insure maximum contact with microbiocidal solution.

DISINFECTION: Contact equipment, wares or objects by mop, spray, or immersion with full strength solution for 10 minutes at room temperature. This procedure will destroy vegetative pathogens including *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *E. coli*, *K. pneumoniae*, *Mycoplasma pulmonis*, *Streptococcus mutans*, and pathogenic fungi (*Trichophyton mentagrophytes* and *Candida albicans*) on inanimate surfaces.

* This procedure will also destroy the following viruses at room temperature in 10 minutes on inanimate surfaces: hydrophilic viruses Polio types 1 & 2, Rotavirus SA and WA (the major causal agents of infectious diarrhea in infants), the bovine Parvovirus type VR 767, and Influenza type A (PR8).

† The full strength solution (0.25% Active Ingredient) inactivates the lipophilic Herpes simplex virus types 1 and 2 in 15 seconds at 23°C on previously cleaned, hard, non-porous surfaces in a single use application

** For tuberculocidal action at 20°C use a 30 minute contact time

*** WAVICIDE-06 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 undiluted (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

SANITIZATION: Mix one part by weight or volume of this solution to one part of potable water for 1:2 dilution. Contact equipment, wares or objects by mop, spray or immersion with 1:2 diluted solution for 5 minutes at room temperature to sanitize surfaces against vegetative organisms (*Staphylococcus aureus* and *Klebsiella pneumoniae*)

DISCARD: Solution used to treat items by immersion should be discarded only as soon as it becomes diluted or soiled

SPECIAL DIRECTIONS: To disinfect or sanitize veterinary laboratories, hospitals, & kennels. Remove all animals and feed from area to be disinfected or sanitized. Clean runs, floors, walls, cages, and attendant equipment thoroughly, then apply solution. Allow solution to dry before repopulating area. To sanitize non-food surfaces and buildings: After cleaning, thoroughly wet all surfaces with the 1:2 diluted solution. Ventilate buildings and other closed spaces. Do not repopulate with animals or use equipment until solution has been dried and removed. Do not re-populate return to a sprayed area until the glutaraldehyde concentration in the atmosphere is below 0.2 ppm (0.8 mg/m³)

To disinfect or sanitize toilet surfaces. Pre-clean all surfaces to be disinfected or sanitized. For outer surfaces, dip a sponge, cloth, or mop into solution. Use on rim, seat tank, and outside of bowl. To disinfect or sanitize inside of bowl, first force scrubbed bowl water over tray with bowl mop, swab, or brush. Pour 2-3 ounces of solution onto mop, swab, or brush, and

completely scrub inner bowl surfaces. Let sit for 10 minutes, then flush.

PRECAUTIONARY STATEMENTS: Hazardous to aquatic life and domestic animals.

CAUTION: Avoid contact with eyes. If solution gets into eyes, flush with plenty of water. If irritation persists, seek medical attention. Do not contaminate food, feed or water. Dispose of solution by diluting with water and pouring down drain or disposal.

When spraying the permissible exposure limit (PEL) for glutaraldehyde in the atmosphere is below 0.2 ppm (i.e., 0.8 mg/m³)

STORAGE AND DISPOSAL: This product should be stored at room temperature—preferably in a cool, dry place. Solution can be discarded on site. Thoroughly clean container and discard in trash.

Recommended for use in: medical, dental, veterinary facilities, hospitals, clinics and offices, nurseries, ambulances, schools, hotels and homes, works on contaminated environmental surfaces including floors and walls, instruments and ware—virtually any exposed area.

Also recommended for rubber, aluminum, plastics, lenses, stainless steel instruments, fiber optics, mirrors, dental tools, otoscope speculums, contact lenses, earlite probe tips, earmolds and contact lenses.

ACTIVE INGREDIENT: Glutaraldehyde (1,5 Pentanedial)

INERT INGREDIENTS: Contains Triethylene Glycol as a binding agent. Nitrite as a corrosion inhibitor.