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FEB - 6 1989

Wave Energy Systems, Inc.  
Research & Development  
1500 Sage Plaza, Suite 1537  
5151 San Felipe  
Houston, TX 77056

Attention: Dr. R.M.G. Boucher

Gentlemen:

Subject: Wavicide-01  
EPA Registration No. 15136-1  
Your Amended Application Dated January 27, 1988

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling.
  - a. Refer to the enclosed Efficacy Evaluation and Technical Efficacy Review - II, and revise your labeling in accordance with the labeling comments outlined there.
  - b. Refer to the enclosed document "Label Requirements for Antimicrobial Pesticides Used on Hard Surfaces Against HIV-1 (AIDS Virus)" for EPA's current labeling policy for efficacy claims. Your labeling must be revised in accordance with the requirements outlined in this policy notice.
2. Submit five (5) copies of your final printed labeling before you release the product for shipment.

50396:I:Lee:LL-07:KENCO:12/21/88:02/06/89:aw:EK:CT:

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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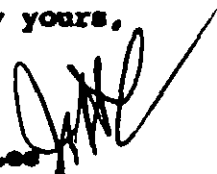
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Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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

Sincerely yours,



John M. Lee  
Product Manager (31)  
Antimicrobial Program Branch  
Registration Division (TS-767C)

Enclosures

30 DAY REPEAT

# WAVICIDE-01

## DIRECTIONS FOR USE

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

**PREPARATION:** Instruments should be thoroughly cleaned, rinsed and drained before immersing in Wavicide-01. Hollow objects, e.g., needles should be flushed and filled.

**STERILIZATION:** Immerse objects to be sterilized in full-strength Wavicide-01 (2% Active ingredient) solution observing one of the following sets of conditions: 5 hour contact time at 40°C (104°F) or 1 hour contact time at 70°C (170°F). Remove instruments from the Wavicide-01 solution using a sterile technique and rinse thoroughly with sterile water. This procedure will also destroy the Hepatitis B virus (HBV). When sterilizing at temperatures above 70°C (170°F) keep solution in covered container or machine. Do not permit hot solution to be cooled to room temperature. At 21°C (70°F) full strength undiluted Wavicide-01 can be used and reused as a sterilant for up to 30 days.

**DISINFECTION:** Mix one part by weight or volume of the product to three parts of sterile water for 1:4 dilution (0.5% Active ingredient). Contact equipment, wires or objects by mop spray 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*, *Cholera*, *Escherichia coli*, *Pseudomonas* species, *Klebsiella pneumoniae* and pathogenic fungi, *Trichophyton mentagrophytes* and *Candida albicans*.

In 10 minutes at 23°C (73°F) the 1:4 diluted (0.5% glutaraldehyde concentration) solution is virucidal after manual reuse for up to 42 days (126 cycle loads) against Herpes simplex types 1 and 2.

Rotavirus type WA, Poliovirus type 2, Coxsackie virus type B, Influenza virus type A (PR), 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 reuse for up to 42 days (126 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 for up to 21 days (three weeks).

\*\*To destroy *Mycobacterium tuberculosis* at 20°C with the full strength 42 day solution or with the 21 day (1:4) solution immerse completely for 30 minutes. For single use of fresh solution (full strength or 1:4 dilution) at 20°C immerse completely for 15 minutes. Remove equipment from the solution and rinse thoroughly.

**STORAGE AND DISPOSAL:** Do not reuse 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 rubber gloves when mixing or handling the product is recommended. Avoid contamination of food.

EPA Registration No. 15136-1

See Bottom for Lot no. and exp. date

FOR PROFESSIONAL USE ONLY

# WA

A RAPID ACTION

SPORICIDAL

VIRUCIDAL\*

BACTERICIDAL

TUBERCULOCIDAL

PSEUDOMONICIDAL

FUNGICIDAL

KEEP OUT OF REACH OF CHILDREN

WARNING:

See Left Panel For Additional Precautions

BEST AVAILABLE COPY

IN MANUAL SYSTEMS:

42 AND 21 DAY REPEATED DISINFECTION USE IN MANUAL SYSTEMS

# DE-01 WAVICIDE-01

DISINFECTING SOLUTION.

on inactivates AIDS virus in one minute  
on environmental surfaces

NO ACTIVATOR  
REQUIRED  
READY TO USE  
DILUTE FOR  
DISINFECTION

ALLOWED



Manufactured by  
WAVE ENERGY SYSTEMS, INC.  
EPA Establishment No. 15136-NJ1  
216 Little Falls Road  
Cedar Grove, NJ 07009

**RECOMMENDED FOR:**

Rubber, aluminum, plastic objects, lenses, stainless steel instruments, and fiberoptics

**ACTIVE INGREDIENTS:**

Glutaraldehyde (1.5 Pentanedal) 7%

**INERT INGREDIENTS**

93%

Inert ingredients contain non ionic ethoxylates of nonionic linear alcohols as synergistic agent

$CH_3 - (CH_2)_n - CH_2 - (CH_2)_m - CH_3$

$O - (CH_2CH_2O)_n H$  with  $n = 6 - 12$

Contains Sodium Nitrate as a corrosion inhibitor

**COVERED BY U.S. PATENTS**

3,697,222; 3,912,450; 3,968,746

**NET CONTENTS:**

1 U.S. gallon (128 fl. oz.) - 3.785 liters

ACCEPTED  
with COMMENTS  
in EPA Letter Dated

Distributed by

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

15136-1

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