

SEP 11 1986

Wave Energy Systems, Inc.
Research and Development
200 East 64th Street, 12D
New York, New York 10021

Attn: Raymond M.G. Boucher, Ph.D.

Subject: WAVICIDE - 01
EPA Reg. No. 15136-1
Amended Appl. dated May 28, 1986

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

1. Submit to us the identification of the neutralizer solution employed in the submitted test report.
2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:
 - a. With regard to the claim "New 42 and 21 Day Repeated Disinfection Use In Manual Systems", the word "new" may be claimed only for a period of six months following approval of the label.
 - b. Since the claims and directions for use in the Ultrasonic Cleaner/Decontamination machine have been deleted, the claim "Can be Used In Ultrasonic Cleaners" must also be deleted.
 - c. The claim ". . . for up to 42 days (six weeks) or 163 cycle-loads . . ." must be revised to read ". . . for up to 42 days (six weeks) or 126 cycle-loads . . .". This discrepancy is apparently due to an error in the previous review and our letter of February 13, 1986.

2/3

d. In the directions for tuberculocidal efficacy, the statement "For single use of fresh solution at 20°C immerse during 15 minutes" should be revised to read "For single use of fresh solution at 20°C immerse completely for 15 minutes".
(See Technical Support Section Efficacy Review-II)

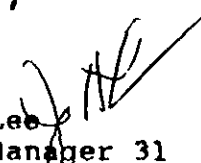
e. The new address of your company 200 East 64th Street, 12D, New York, N. Y. 10021, as stated on your amended application, must appear on the label. Note, if you wish to use the company address of 1 Madison Street, East Rutherford, N. Y. 07073 with the new New York City street address as your business mailing address you must submit an amended application for this change.

4. Submit five (5) copies of your final printed labeling before you release the product for shipment.

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,


John H. Lee
Product Manager 31
Disinfectants Branch
Registration Division (TS-767C)

Enclosure

3/3

NEW 42 AND 21 DAY REPEATED DISINFECTION

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 and 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: 60 minutes contact time at 60°C (140°F) or 5 hours contact time at 40°C (104°F) or 10 hours contact time at 25°C (77°F). Remove instruments from the Wavicide-01 solution using a sterile technique and rinse thoroughly with sterile water. Use fresh solution for each sterilization procedure. When sterilizing at temperatures above 25°C (77°F) keep solution in covered containers or machine. Do not open lid until solution has cooled to room temperature.

DISINFECTION: Mix one part by weight or volume of this solution to three parts of potable water for 1:4 dilution (0.5% Active Ingredient). Contact equipment, wares 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 fully meets 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*).

FOR PROFESSIONAL USE ONLY.
EPA Registration No. 15136-1

*For virucidal action at room temperature use the 1:4 dilution (0.5% Active Ingredient) to destroy Herpes simplex types I and II, Rotavirus type WA, and Rotavirus type II on nonporous surfaces.

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) or 163 cycle-loads, whichever comes first. The Wavicide-01 1:4 disinfecting dilution (0.5% Glutaraldehyde) can be used and re-used for up to 21 days (three weeks) or 63 cycle-loads, whichever comes first.

**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 at 20°C immerse during 15 minutes. Remove equipment from the solution and rinse thoroughly.

STORAGE AND DISPOSAL: Do not reuse empty containers. 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. Avoid contamination of food.

See Bottom for lot no. and exp. date.

WAVICIDE-01

A RAPID ACTING STERILIZING AND DISINFECTANT

SPORICIDAL

VIRUCIDAL*

BACTERICIDAL

TUBERCULOCIDAL**

PSEUDOMONACIDAL

FUNGICIDAL

KEEP OUT OF REACH OF CHILDREN

WARNING: HARMFUL IF SWALLOWED

See Left Panel For Additional Precautionary Statements.

ACCEPTED

SEP 11 1986

SEP 11 1986

Under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, this product is registered under EPA Reg. No. 15136-1

15136-1