

JUN 09 1987

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

Attention: R.M.G. Boucher, Ph.D.

Gentlemen:

Subject: WAVICIDE-01 Concentrate
EPA Registration No. 15136-2
Your Submission Dated November 14, 1986

The amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable provided that you:

1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:
 - a. Under "STERILIZATION" include the statement "DO NOT REUSE FOR STERILIZATION."
 - b. Under "DISINFECTON OF DENTAL INSTRUMENTS" change "MIX ON PART BY WEIGHT" to read "MIX ONE PART BY WEIGHT."
 - c. Change "Poliovirus Types II" to read "Poliovirus Type II."
 - d. Under the paragraph "To destroy Mycobacterium tuberculosis . . ." revise "For single use of fresh solution at 20° immerse 15 minutes" to read "For single use of fresh 2% or 0.5% active active ingredient solution at 20°C immerse 15 minutes."
 - e. Under "FEATURES":
 - (1) Delete the statement "Effective in presence of proteins."

94759:I/C:Lee:L-9:KENCO:06/05/87:06/18/87:de:vo:sjh:lisa:ek:bjp

CONCURRENCES

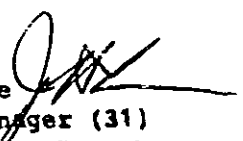
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- (2) Revise "42 day reuse for disinfection . . ." to read "42 day reuse for disinfection with 2% bovine serum and 2% active ingredient."
- (3) Revise "21 day reuse for disinfection . . ." to read "21 day reuse for disinfection with 2% bovine serum and 0.5% active ingredient."
- f. Change "42 and 21 day repeated reuse in manual (bucket and tray) system" to read "42 and 21 day repeated reuse in manual (bucket and tray) system for disinfection."
- g. The statement "The shelf life of diluted solutions is the same as the expiration date on the bottom of the concentrate bottle" must be supported by the data or delete the claim. Explain what is meant by "shelf life."
- 3. 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 section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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

Sincerely yours,

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

Enclosure

WAVICIDE-01

SPORICIDAL, VIRUCIDAL,
BACTERICIDAL, FUNGICIDAL,
TUBERCULOCIDAL,
PSEUDOMONACIDAL

CONCENTRATE
A STABLE, RAPID ACTING, STERILIZING AND DISINFECTING
SOLUTION FOR DENTAL OFFICES

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 dried before immersion in WAVICIDE-01. Metal objects should be washed in hot water.

STERILIZATION

MIX ONE PART BY WEIGHT OR VOLUME OF THIS CONCENTRATE TO NINE PARTS OF DISTILLED WATER FOR A 1:10 DILUTION (2% SOLUTION) TO BE USED FOR STERILIZATION.

Immerse objects to be sterilized in a 1:10 dilution of WAVICIDE-01 (2% active ingredient) solution maintained for 10 hours at 25° C (77° F). Remove instruments from the solution using a sterile technique and rinse thoroughly with sterile water if available. If it is not, use 70% isopropyl alcohol or hot tap water for rinsing. This is a complete sterilization procedure including the destruction of viruses, tubercle bacilli and pathogenic spores.

DISINFECTION OF HOSPITAL INSTRUMENTS

Contact equipment, wares or objects by spray or immersion with 1:10 dilution of WAVICIDE-01 (2% active ingredient) for 10 minutes at room temperature. After processing instruments should be rinsed with water that meets federal drinking water standards.

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

Wavicide 01 diluted 1:10 (2% active ingredient) can be used and reused as a disinfectant for up to 42 days (six weeks).

DISINFECTION OF DENTAL INSTRUMENTS

MIX ONE PART BY WEIGHT OR VOLUME OF THIS SOLUTION TO THIRTY-NINE PARTS OF POTABLE WATER FOR A 1:40 DILUTION (0.5% SOLUTION) TO BE USED FOR DISINFECTION.

Contact equipment, wares or objects by mist, spray or immersion with 1:40 dilution of WAVICIDE-01 (0.5% active ingredient) for 10 minutes at room temperature. After processing instruments should be rinsed with water that meets federal drinking water standards.

This procedure will destroy the vegetative organisms listed above.

Wavicide 01 diluted 1:40 (0.5% active ingredient) can be used and reused for up to 21 days (3 weeks).

42 and 21 day repeated reuse in manual (bucket and tray) system.

RECOMMENDED FOR
Rubber, aluminum, and plastic objects
Lenses and stainless steel instruments
Burs, mirrors, and dental feet
and Endoscopes

ACTIVE INGREDIENT
Gutaraldehyde (1.5 Povidone) 29.5%
HEAVY METALS 79.5%
Inert ingredients contain non-ionic ethoxylates of isomeric linear alcohols as synergistic agent
[CH₂(CH₂)_n-CH(CH₂)₂-CH₃]
O-(CH₂CH₂O)_nH with n = 8-12



Net contents 400cc (13.53 oz.)

*For virucidal action at room temperature use the 1:40 dilution (0.5% Active Ingredients) to destroy Herpes Simplex Types I and II, Rotavirus Type WA, and Poliovirus Types II on inanimate surfaces.

**To destroy *Mycobacterium tuberculosis* at 20° C on inanimate surfaces use either the 1:10 diluted (2% active ingredient) solution for 42 days or the 1:40 diluted (0.5% active ingredient) solution for 21 days by immersing completely for 30 minutes for single use of fresh solution at 20° immerse 15 minutes. Remove equipment from the solution and rinse thoroughly.

DILUTE FOR
STERILIZATION &
DISINFECTION

KEEP OUT OF REACH OF CHILDREN
DANGER: MAY BE FATAL
OR HARMFUL IF
SWALLOWED
EPA Registration No. 15136-2

See label and other precautions on
vial panel.
ACCEPTED
with COMMENTS
In EPA Letter Dated: 1/21/80

JUN 09 1987

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
15136-2

Wave Energy Systems Inc.
200 East 64th St.
New York, NY 10021

EPA Establishment No. 15136 PA-01

STORAGE AND DISPOSAL

DO NOT reuse empty container. Rinse thoroughly with water and dispose in trash. This product should be stored at room temperature, preferably in a cool place.

DANGER

Causes eye damage or skin irritation. May be absorbed through the skin. Do not get in eyes, on skin or clothing. Protect eyes and skin when handling. A possibility of absorbing vapors. Avoid contamination of food.

Use in covered containers to avoid evaporation and to minimize odor.

FIRST AID

In case of contact, immediately flush eyes or skin with plenty of water. For eyes, call physician if swallowed. Use a tablespoon of corn oil or glass of warm water. Repeat until vision is clear. Get milk or egg white beaten in water. Call a physician immediately. Rinse empty container thoroughly with water and discard it.

corrected
14 November 1986

R. Brindley

The shelf life of diluted solutions is the same as the expiration date on the bottom of the concentrate bottle.

BEST AVAILABLE COPY

WAVICIDE-01

Corrosion Inhibitor

Sodium Nitrite Solution

This solution will help protect metal instruments against corrosion when used as directed.

Contents: 60 cc (2 oz)

Wave Energy Systems, Inc.
200 East 64th Street,
New York, NY 10021

DIRECTIONS FOR USE

SEE MIXING DIRECTIONS

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 09 1987

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

15136-2

corrected
14 November 1986

R. Boncher

5/5

U.S. Patent 3,067,271 3,173,450 3,068,264

WAVICIDE-01[®]

CONCENTRATE

SPOROICIDAL, VIRUCIDAL,
BACTERICIDAL, FUNGICIDAL,
TUBERCULOCIDAL,
PSEUDOMONACIDAL

STERILIZING AND DISINFECTING SOLUTION

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 dried before immersion in WAVICIDE-01. Non-metallic objects should be flushed and dried.

STERILIZATION

See ONE PART BY WEIGHT OR VOLUME OF THIS CONCENTRATE TO NINE PARTS OF DISTILLED WATER FOR A 1:10 DILUTION (2% SOLUTION) TO BE USED FOR STERILIZATION.

Immense objects to be sterilized in a 1:10 solution of WAVICIDE-01 (2% active ingredient) solution should be immersed for 10 hours at 20°C (68°F). Immerse instruments from the solution using a sterile technique and rinse thoroughly with sterile water if available. If it is not, use 70% alcohol to remove water before use. This is a complete sterilization procedure including the destruction of viruses, tubercle bacilli and pathogenic spores.

DISINFECTION OF HOSPITAL INSTRUMENTS

Contact equipment, wares or objects by spray or immersion with 1:10 solution of WAVICIDE-01 (2% active ingredient) for 10 minutes at room temperature. After processing, instruments should be rinsed with water that meets Federal drinking water standards.

This procedure will destroy vegetative organisms including *Staphylococcus aureus*, *Salmonella choleraesuis*, *Escherichia coli*, *Pseudomonas* species, *Shigella dysenteriae* and pathogenic fungi: *Trichophyton mentagrophytes* and *Candida albicans*.

Wavicide-01 diluted 1:10 (2% active ingredient) can be used and reused as a disinfectant for up to 42 days (3 weeks).

DISINFECTION OF DENTAL INSTRUMENTS

See ONE PART BY WEIGHT OR VOLUME OF THIS SOLUTION TO TWENTY-NINE PARTS OF POTABLE WATER FOR A 1:30 DILUTION (0.5% SOLUTION) TO BE USED FOR DISINFECTION.

Contact equipment, wares or objects by mist spray or immersion with 1:30 solution of WAVICIDE-01 (0.5% active ingredient) for 10 minutes at room temperature. After processing, instruments should be rinsed with water that is free of drinking water standards.

This procedure will destroy the vegetative organisms listed above.

Wavicide-01 diluted 1:30 (0.5% active ingredient) can be used and reused for up to 21 days (3 weeks).

*For virucidal action at room temperature use the 1:40 dilution (0.5% active ingredient) to destroy Herpes Simplex Types I and II, Poliovirus Type WA and Poliovirus Types II on inanimate surfaces.

**To destroy Mycobacterium tuberculosis at 20°C on inanimate surfaces use either the 1:10 diluted (2% active ingredient) solution for 42 days or the 1:40 diluted (0.5% active ingredient) solution for 21 days by immersion completely for 30 minutes. For simple use of fresh solution at 20°C immerse 15 minutes. Do not re-immerse from the solution and reuse thoroughly.

STORAGE AND DISPOSAL

DO NOT reuse empty containers. Avoid thoroughly with water and dispose in trash. This product should be stored at room temperature and safely in a cool place.

WARNING

Carries five degree of skin irritation. May be absorbed through the skin. Avoid contact with eyes. Avoid contact with mucous membranes. Avoid contact with food.

Use in covered containers to avoid eye irritation and to minimize odor.

FIRST AID

In case of contact, immediately flush eyes or skin with plenty of water. In eyes, call physician if available. Get a tablespoon of salt in a glass of warm water. Repeat until vision is clear. Get milk or egg white beaten in water. Get a physician immediately. Rinse empty container thoroughly with water and discard it.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 09 1987

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

Wave Energy Systems Inc.
200 East 64th St.
New York, NY 10021

PRINTED IN U.S.A.

WAVICIDE-01

Potentiated Glutaraldehyde for Sterilization/Disinfection

FEATURES :

- 2-year shelf life.
- 42 day reuse for disinfection with 2% active ingredient.
- 21 day reuse for disinfection with 0.5% active ingredient.
- Herpes types I and II and Polioviruses killed in ten minutes.
- Single use fresh 0.5% active ingredient solution tuberculocidal in 15 minutes at 20°C.
- Effective in presence of proteins.
- Contains corrosion inhibitor.
- Pleasant lemon scent.

WAVICIDE-01 CONCENTRATE

STERILIZATION

42 and 21 days

A STABILIZED
AND DISINFECTANT

RECOMMENDED FOR:
Rubber, aluminum
Lenses and stainless
steel, mirrors
and Fiberglass

ACTIVE INGREDIENTS:
Glutaraldehyde
INERT INGREDIENTS:
ethoxylates of
synergistic agents
(CH₂)₂(C₂H₅)₂O

E.P.A. REGISTRATION NO.
15136-2



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