

NOV 08 1985

Ayerst Laboratories
685 Third Avenue
New York, NY 10017

Attention: Justin R. Victoria

Gentlemen:

Subject: SONACIDE®
EPA Registration No. 8991-11
Your Submission Dated July 23, 1985

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:

The claim "virucidal" must be qualified by annotating the claim with a reference mark that is keyed to the specific viruses specified on the label.

2. Submit five (5) copies of your one gallon jug 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. Only the one gallon jug labels have been stamped. This is the basic label. The other size labels are enclosed unstamped.

Sincerely yours,

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

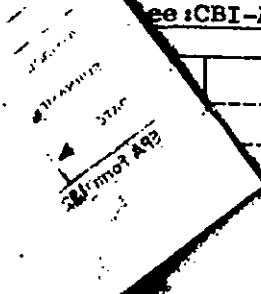
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CONCURRENCES

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NDC 0046-1040-86

RECOMMENDED USES: Hospitals, Veterinary Hospitals, Clinics, Nursing Homes, and Medical Offices.

For Sterilizing and Disinfecting Rubber and Plastic Objects, Stainless Steel Surgical and Medical Instruments, Lenses, Thermometers, Anesthesia and Inhalation Therapy Equipment, such as Face Masks and Corrugated Rubber and Plastic Tubing. (Not recommended for carbon steel. When used at room temperature, SONACIDE is not recommended for nickel plated instruments.)

SONACIDE Sterilizing and Disinfecting Solution is fast-acting at room temperature (10 minutes for disinfection, 20 minutes to destroy tubercle bacilli).

SONACIDE is *activated* by heat (60 minutes at 60° C (140° F) for complete sterilization).

SONACIDE may be used in pails or trays, in any standard thermostatically controlled heating bath, or in automated machines.

Note: Fresh SONACIDE solutions are translucent. With age, SONACIDE may turn slightly yellow, but this coloration does not affect the potency.

CONTAINER DISPOSAL: Rinse this container thoroughly with water before discarding.

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.

Use in covered containers to reduce evaporation.

U.S. PATENTS 3,697,222; 3,912,450 and 3,968,248

Sonacide®

(potentiated acid glutaraldehyde)

STERILIZING AND DISINFECTING SOLUTION

ACCEPTED
with COMMENTS
EPA Letter Dated:

NOV 08 1985

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 8991-11

- Sporicidal*
- Bactericidal
- Virucidal
- Fungicidal
- Pseudomonacidal
- Tuberculocidal**

- Ready for use
- No premixing
- Use undiluted

See Directions for Use

Active ingredient:
Glutaraldehyde
Inert ingredients
contains nonionic ethoxylates of isomeric alcohols [(CH₃)₂(CH₂)_nO(CH₂-CH₂O)₁₂H 11 ≤ n ≤ 15] as synergistic agents when necessary, orthophosphoric acid is used to adjust the pH to between 2.7 and 3.7

WARNING: HARMFUL IF SWALLOWED.
SEE OTHER WARNINGS ON RIGHT SIDE OF CONTAINER.
NET CONTENTS: 1 GALLON (128 FL OZ)

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Ayerst® Manufactured by
AYERST LABORATORIES
New York, NY 10017

EPA Reg. No. 8991-11 EPA Est. 8991-NY-1

DIRECTIONS FOR USE

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

PREPARATION: Clean, rinse, and drain instruments before immersing in undiluted SONACIDE. The lumen of hollow instruments should be flushed and filled with SONACIDE solution.

DISINFECTION: SONACIDE may be effectively reused as a disinfectant solution in automated or manual systems. SONACIDE has been demonstrated effective for 35 days, based upon a usage of 3 cycles/day. (With a 5-cycle maximum daily usage, 21 days' reuse is recommended.)

Manual: Immerse objects in a pail or tray of SONACIDE for 10 minutes at room temperature.

Automatic: Follow manufacturer's directions for use.

When used as directed, this product will disinfect against Influenza A₂ (England) virus, Herpes Simplex virus Type 1, Rhinovirus Type 17, Adenovirus Type 5, Poliovirus Type 1, as well as *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa* and *Trichophyton mentagrophytes* on inanimate surfaces.

** To destroy tubercle bacilli, immerse objects in a pail or tray of SONACIDE for 20 minutes at room temperature. Remove and rinse with sterile water. When used as a tuberculocide, the solution should be discarded after one day's use.

STERILIZATION: *For complete sterilization, to destroy viruses, tubercle bacilli, and resistant spores, including *Clostridium sporogenes* and *Bacillus subtilis*, immerse objects in SONACIDE maintained at 60° C (140° F) for 60 minutes. Remove and rinse with sterile water. When used for sterilization, the solution should be discarded after one day's use.

NDC 0046-1040-86

Sonacide®

(potentiated acid glutaraldehyde)

STERILIZING AND DISINFECTING SOLUTION

Sporicidal*
Bactericidal
Virucidal
Fungicidal
Pseudomonacidal
Tuberculocidal**

- Ready for use
- No premixing
- Use undiluted

See Directions for Use

Active ingredient:

Glutaraldehyde 2%
Inert ingredients 98%

contains nonionic ethoxylates of isomeric linear alcohols [(CH₃)₂(CH₂)_nO(CH₂-CH₂O)₁₂H with 11 ≤ n ≤ 15] as synergistic agents when necessary, orthophosphoric acid is added to adjust the pH to between 2.7 and 3.7.

WARNING: HARMFUL IF SWALLOWED.

SEE OTHER WARNINGS ON RIGHT SIDE PANEL.

NET CONTENTS: 1 GALLON (128 FL. OZ.)

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AYERST LABORATORIES INC.
New York, NY 10017

EPA Reg. No. 8991-11 EPA Est. 8991-NY-1 GP1