

31 733 085

Ayerst Laboratories
685 Third Avenue
New York, New York 10017

Attn: Mr. Justin B. Victoria

Subject: Sonacide
EPA Reg. No. 8991-11
Submission dated December 14, 1984

The amendment referred to above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A), in response to Agency's letter of May 2, 1984 is acceptable, provided that you:

1. Make the labeling changes listed in the attached Technical Support Section Efficacy Review II before you release the product for shipment bearing the amended labeling.
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 label is enclosed for your records.

Sincerely,
JHL
Lee

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

Enclosure

BEST AVAILABLE COPY

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

ADC 0046-1040-89

Sonacide[®]

(potentiated acid glutaraldehyde)

DISINFECTING SOLUTION

- Bactericidal
- Virucidal
- Fungicidal
- Pseudomonacidal

- Ready for use • No premixing
- Use undiluted

Active ingredient:
 Glutaraldehyde 2%
 Inert ingredients 98%

contains nonionic ethoxylates of isomeric linear alcohols [(CH₂)_n(CH₂)₂O(CH₂-CH₂O)_nH • with 11 ≤ n ≤ 15] as synergistic agents with 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.

*See Directions for Use

NET CONTENTS: 5 GALLONS (640 FL OZ)

Ayerst Manufactured by
 AYERST LABORATORIES INC.
 New York, N.Y. 10017

EPA Reg. No. 8001-11 EPA Est. 8001-NY-1 278

ATTENTION NEW LABELING
 Disinfectant claims only

ACCEPTED
 WITH COMMENTS
 by EPA Letter Dated:

FEB 21 1985

Write to:
 Act
 pesticide
 EPA Reg. No.
 8991-11

DIRECTIONS FOR USE

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

FOR DISINFECTION. To destroy vegetative organisms including *Pseudomonas* species, pathogenic fungi and viruses*, immerse objects in SONACIDE for 10 minutes at room temperature.

Remove and rinse with sterile water.

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

Rinse this container thoroughly with water before discarding.

* When used as directed, this product will disinfect against Influenza A₂ (Hong Kong) virus, herpes simplex virus, Newcastle disease virus, and Echo virus Type 25 on inanimate surfaces.

RECOMMENDED FOR USE IN HOSPITALS, VETERINARY HOSPITALS, CLINICS, NURSING HOMES AND MEDICAL OFFICES

FOR DISINFECTING RUBBER AND PLASTIC OBJECTS, STAINLESS STEEL SURGICAL AND MEDICAL INSTRUMENTS, SHARP 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 Disinfecting Solution is fast acting at room temperature (10 minutes for disinfection).

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

Use in covered containers to reduce evaporation.

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.

U.S. PATENTS 3,007,222, 3,012,450 AND 3,068,248

SONACIDE may be effectively re-used as a disinfectant solution for up to 35 days (105 cycles), in automated or manual systems.

BEST COPY AVAILABLE

Revised Draft Label