DEC 06 1990

Medical-Surgical Division
3M Health Care Group
3M Center
St. Paul, MN 55144-1000

Attention: Marvin L. Hart
Regulatory Affairs Specialist

Gentlemen:

Subject: Glutarex Brand Disinfecting & Sterilizing Solution
EPA Registration No. 7182-4
Your Letter Dated June 18, 1990

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

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

   a. On the left panel, outline your special instructions for the HIV claims in accordance with the enclosed "example format."

   b. On the front panel, we prefer the active ingredient to follow the product name.

   c. Change "See back panel for precautions" to read "See back panel for additional precautionary statements."

   d. Include the subheading:

      - Pesticide Disposal

   e. Delete the word "Can" in the precautionary statement.

56348:I:DeLaney:L31-20:KENCO:11/9/90:12/8/90:EK:JH:DD

	CONCURRENCES							
SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1 (12-70) OFFICIAL FILE COPY

f. Delete the word "May" in the precautionary statements, wherever it appears.

g. Include a "Note to Physician" statement to read:

Note To Physician

Probable mucosal damage may contraindicate the use of gastric lavage.

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 section 6(e). 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.

If you have any questions concerning this letter, please contact Martha DeLaney at (703) 557-6982.

Sincerely yours,

John H. Lee
Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosures

Glutarex™ 3M

Disinfecting and Sterilizing Solution

Activator Solution

For use with Glutarex Disinfecting and Sterilizing Solution 0500.

Keep out of reach of children.

DANGER

See back panel for precautions.

Net Contents 5.4 fl oz • 159 ml

7182-4

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animal

DANGER — Causes severe eye and skin irr
May cause allergic skin reactions. Har
swallowed.

Precautions — Prevent eye contact. Wear
cal safety glasses or goggles.
Wear gloves and protective clothing, as nee
prevent skin contact.
Do not eat or smoke in area when handl
material. Wash hands thoroughly before
or smoking.

STATEMENT OF PRACTICAL TREATMENT

Eye Contact — Flush eyes with large amo
water for at least 15 minutes. Call a phys

Skin Contact — Wash with soap and w
irritation occurs, get medical attention.

Ingestion — If swallowed, drink 2 glasses
or water. Do not induce vomiting. Call a ph

DIRECTIONS: Add the contents of this co
to one gallon of solution. Mix well. Do no
Glutarex disinfecting and sterilizing sol
now green in color and ready for use.

Contains: Potassium Nitrite, Potassium
phate Dibasic, FD and C Blue No. 1.

Made in U.S.A. for

Medical-Surgical Division
3M Health Care

St. Paul, MN 55144-1000
34-7017-2931-0

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Glutarex™ 3M

0515

Corrosion Inhibited

Disinfecting And Sterilizing Solution

Catalyzed GLUTARALDEHYDE

Broad Spectrum Antimicrobial

Sporicidal	Pseudomonacidal
Virucidal*	Bactericidal
Tuberculocidal	Fungicidal

Keep out of reach of children.

DANGER

See back panel for precautions.

Active Ingredient:	
Glutaraldehyde	2.0%
Inert Ingredients:	98.0%
Total	100.0%

Note: Contents of attached bottle **must** be added to solution before this product is effective. **See directions for activating.**

Net Contents 32 fl oz • 943 ml When Activated

*See "Recommendations for Use"

EPA Reg. No. 7182-4 / EPA Est. No. 42705-MN 01

DIRECTIONS FOR ACTIVATING

Add contents of the attached activator solution container to one quart of the solution provided. *Mix Well.* Do not *dilute.* Glutarex disinfecting and sterilizing solution is now green in color and ready for use. The shelf life of the activated unused stock solution is 28 days.

DIRECTIONS FOR USE

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

For Use in Hospitals, Dental Offices, Nursing Homes and Health Care Institutions.

For disinfection or sterilization of medical instruments and equipment, the items should be thoroughly cleaned, rinsed and rough dried before immersing in *activated* solution. Flush and fill cleansed lumen of any hollow instrument. Avoid entrapment of air bubbles. Surfactant action will facilitate penetration of hinged and hard-to-reach areas.

METAL ITEMS

Glutarex disinfecting and sterilizing solution will not prevent or remove oxidation caused by poor or improper plating, cleaning or care of instruments. Caution should be used to avoid the immersion of and contact between dissimilar metals.

DISINFECTION

Manual: Immerse item completely for a minimum of *10 minutes* at room temperature (>20°C [68°F]). Automatic: Follow manufacturers directions for use in your decontamination machine.

STERILIZATION

Immerse item completely for a minimum of *10 hours* at room temperature (>20°C [68°F]).

Using aseptic technique, remove item from the solution and *rinse thoroughly* with sterile water.

RECOMMENDATIONS FOR USE - SEE LEFT SIDE PANEL

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PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals.

DANGER. Corrosive. Causes eye damage. Can cause severe eye and respiratory irritation. May cause asthma-like respiratory system reaction and temporary nervous system impairment. May cause skin sensitization. May be absorbed through the skin in harmful amounts. Harmful if swallowed. May cause severe digestive system irritation.

Precautions: Prevent eye contact. Wear chemical safety glasses or goggles. Wear gloves and protective clothing, as needed, to prevent skin contact. Avoid breathing vapors. Keep all containers closed or covered. Use with local exhaust ventilation for all open containers. Per OSHA, a worker's exposure must not exceed a ceiling limit of 0.2 ppm during any time of the workday. If vapors are not well controlled, a full face piece respirator with organic vapor cartridge will be needed to prevent irritation of the eyes and respiratory tract. Do not eat or smoke in area when handling this material. Wash hands thoroughly before eating or smoking.

STATEMENT OF PRACTICAL TREATMENT

Eye Contact—Flush eyes with large amounts of water for at least 15 minutes. Call a physician.

Skin Contact—Wash with soap and water. If irritation occurs, get medical attention.

Inhalation—In case of vapor overexposure, remove individual to fresh air. Call a physician.

Ingestion—If swallowed, drink 2 glasses of milk or water. Do not induce vomiting. Call a physician.

STORAGE AND DISPOSAL

Store this container and any of its unused contents in a *cool* safe area reserved for disinfecting and sterilizing products. Do not store in the presence of pharmaceuticals or food. Do not contaminate water, food or feed by storage or disposal.

This product must be kept in secured storage sufficient to make it inaccessible to children or persons unfamiliar with its proper use.

Do not re-use empty container.

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. Bleed spent solutions and small product quantities, < 5 gal., to a wastewater treatment system. Mix with flammable material and incinerate in an industrial or commerical facility. Disposal alternative: Dispose of completely absorbed waste product in a facility permitted to accept chemical wastes. Since regulations vary, contact your State Pesticide or ENVIRONMENTAL Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL INSTRUCTIONS

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

RECOMMENDATIONS FOR USE

When used as directed for DISINFECTION, Glutarex disinfecting and sterilizing solution will kill pathogenic bacteria (including *P. aeruginosa, S. aureus* and *S. choleraesuis*) and pathogenic fungi (*T. mentagrophytes*).

*This product has also been shown to irreversibly inactivate lipophilic viruses (*Adenovirus Type 5, Influenza* A_2 (England) and *Herpes simplex Type 1*) and hydrophilic virus (*Poliovirus Type 1*) on environmental surfaces. *Glutarex disinfecting and sterilizing solution can be reused for disinfection up to the earlier of 28 days or 140 cycles after activation.*

Note: If tuberculosis contamination is suspected, use unused activated Glutarex disinfecting and sterilizing solution. It is effective in 10 minutes at 20°C. Thoroughly clean the surfaces/items prior to application of product.

When used as directed for STERILIZATION, Glutarex disinfecting and sterilizing solution will kill the hepatitis—B virus, human immunodeficiency virus Type 1 (HIV-1) (AIDS virus), and the desiccated resistant spores of *C. sporogenes & B. subtilis. Use the solution only once when used for sterilization.*

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

PRECLEANING SOAK TREATMENT

This solution does NOT coagulate blood. Items from septic cases should be placed directly into fresh solution until final cleaning and terminal disinfection or sterilization of contaminated objects.

3M makes no warranty, expressed or implied, concerning the use of this product other than as indicated on the label. Buyer assumes all risk of use or handling of this material, when such use or handling is contrary to label instructions.

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34-7018-3305-3

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Activation Date

7182-4

Made in U.S.A. for

Medical-Surgical Division
3M Health Care
St. Paul, MN 55144-1000

Expiration Date