

JAN 6 1995

Gulfstream Medical Inc.
 550 Pleasant Street
 Winthrop, MA 02152

Attention: Adolph E. D'Amico
 Vice President

Subject: Diacide HD Disinfecting Solution
 EPA Registration No. 63720-1
 MOU Compliance Amendment dated October 4, 1994

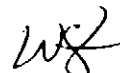
The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you make the labeling changes listed below before you release the product for shipping bearing the amended label.

1. Revise the following statement found on the right panel: "Diacide HD Solution may not totally eliminate all vegetable microorganisms..." to read, "Diacide HD Solution may not totally eliminate all vegetative microorganisms..."
2. Delete the phrase "Restricted use Pesticide" from the center panel.

A stamped copy of the labeling is enclosed for your records. Submit 5 copies of the final label prior to releasing the product for marketing.

If you have any questions concerning this letter, please contact Wanda Mitchell at (703) 305-6141.

Sincerely yours,



Walter C. Francis
 Acting Product Manager (31)
 Antimicrobial Program Branch
 Registration Division (7505C)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

2 7 4
*** CENTER PANEL ***

Restricted use Pesticide

Concentrate Formula for Decontaminating

Hemodialysate Delivery Systems

Rapid-Acting/Nonrusting/Nonstaining

Pseudomonacidal Bactericidal

Virucidal* Fungicidal

Recorder No. E.P.A. Reg.No. 63720-1-MA-001

3500 E.P.A. Est.No. 63720

CONCENTRATE

Diacide HD

disinfecting solution

Active Ingredient
Glutaraldehyde 26%
Inert Ingredients 74%
Total 100.00%

NOTE: This product is a concentrate and must be activated and diluted immediately prior to use. Activator must be added to fluid before this product is effective. See Directions for Activation and Dilution.

Keep out of reach of children.

DANGER: See right side panel for precautions.
*See directions for disinfection.

Control No. 2657

Revision A 02/09/93

GULFSTREAM

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 6 1995

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

63720-1

BEST AVAILABLE COPY

*** LEFT PANEL ***

Follow specific equipment manufacturer's recommendation for cleansing and disinfecting the hemodialysate delivery system. DIACIDE HD Disinfecting Solution Concentrate is formulated to be diluted 34:1 for disinfection of hemodialysate delivery systems in 15 minutes.

DIRECTIONS FOR ACTIVATION AND DILUTION:

Add contents of enclosed vial to this container of DIACIDE HD Concentrate. Mix, activated DIACIDE HD Concentrate is ready to use. When activated, solution changes color to blue. Dilute activate DIACIDE HD Concentrate *immediately* after activation with 34 equivalent parts of softened water. For proportioning type hemodialysate delivery systems, place activated DIACIDE HD Concentrate into the hemodialysate delivery system and dilute activated DIACIDE HD Concentrate with 34 equivalent parts of softened water.

NOTE: Use of an insufficient quantity of activated DIACIDE HD Concentrate will result in inadequate treatment of the hemodialysate delivery system. Some systems will require a larger quantity of activated DIACIDE HD Concentrate than provided in this container. Additional quantities of activated DIACIDE HD Concentrate are prepared by mixing at 50:1 volume ratio, 50 parts of DIACIDE HD Concentrate with 1 part of activator. Use activated DIACIDE HD Concentrate as described in the Directions for Activation and Dilution.

DIRECTIONS FOR DISINFECTION:

It is a violation of federal law to use this product in a manner inconsistent with its labeling. For use in hospitals, dialysis centers and health care institutions It is recommended that disinfection be carried out *immediately* after and just prior to use of the hemodialysate delivery system.

Flush equipment *thoroughly* with water prior to filling the delivery system with DIACIDE HD Solution. After filling the delivery system, hold DIACIDE HD Solution in the system for a minimum of 15 minutes. Within 15 minutes contact time at 20°C, DIACIDE HD Solution will destroy A Typical Water Mycobacteria (*Mycobacterium Fortuitum* and *Mycobacterium Chelonqi*) vegetative pathogens including *Pseudomonas aeruginosa* and hydrophilic and lipophilic viruses (Poliovirus Type 1; Coxsackievirus B-1, Influenza Type A2 (Hong Kong), Herpes simplex Type 1) on inanimate surfaces. Prior to machines use, drain DIACIDE HD Solution and *thoroughly rinse* with water. TO assure complete rinsing, test final rinse water using a glutaraldehyde residual test ampule. This is a single use product.

NOTE: DIACIDE HD Concentrate should not remain in hemodialysate delivery systems for more than 12 hours.

This product is not to be used as a terminal sterilant/high level disinfectant or on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

MANUFACTURED BY:

GULFSTREAM MEDICAL INC.
550 Pleasant St.
Winthrop, MA 02152

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*** RIGHT PANEL ***

DIACIDE HD Solution is recommended for decontaminating single patient and multi-patient hemodialysate delivery systems. DIACIDE HD Solution has been shown to be an effective disinfectant (virucide, fungicide, bactericide, pseudomonacide) when tested by AOAC and EPA test methods. DIACIDE HD Solution may not totally eliminate all vegetable microorganisms in hemodialysate delivery systems due to their construction and/or assembly, but can be relied upon to reduce the number of microorganisms to acceptable levels when used as directed. This product should be used in a disinfection program which includes bacteriological monitoring of the hemodialysate delivery system. DIACIDE HD Solution is not recommended for use in hemodialyzers or reverse osmosis (RO) membranes.

Consult the guidelines for hemodialysis systems which are available from the Hepatitis Laboratories, CDC, Atlanta, Georgia 30301

PRECAUTIONARY STATEMENTS:

(DANGER: HAZARD TO HUMANS

FOLLOW ALL LABEL DIRECTIONS

Prevent contact with skin or eyes by using eye protection and rubber gloves with handling or pouring.

Eyes - Corrosive, causes eye damage. Do not get in eyes. In case of contact, flush with water immediately and get medical attention.

Ingestion - Harmful if swallowed. Avoid contamination of food.

Inhalation - Avoid spillage. Use in a well ventilated area.

Skin - Avoid skin contact as possibility of sensitization exists. Can cause skin irritation. For skin contact, flush thoroughly with water. Get medical attention if irritation occurs.

STORAGE AND DISPOSAL:

Keep in a cool place. Triple rinse empty container with water and dispose in an incinerator or landfill approved for pesticide containers.

CONTENTS 32 FL OZ (0.95 LITERS)
MADE IN U.S.A.
CONTROL NUMBER ON BOTTOM

NOTE DATES HERE
MIXING DATE _____
EXPIRATION DATE _____

GULFSTREAM

BEST AVAILABLE COPY