

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 19 1989

Chemical Laboratories, Inc.  
1000 North Street  
P.O. Box 100  
Baltimore, MD 21201

Attention: Robert Macdonald

Reference:

Subject: Hi-Tor Germicidal Detergent  
EPA registration no. 305-91  
Your Application dated March 14, 1989  
EPA received date March 21, 1989

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

- 1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:
  - a. Immediately above the heading, "SPECIAL INSTRUCTIONS FOR CLEANING . . ." include the statement "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)."
  - b. Change "SPECIAL INSTRUCTIONS FOR . . . SOLIDS . . ." to "SPECIAL INSTRUCTIONS FOR . . . SOILED . . ."
  - c. Change "PERSONAL PROTECTION: Intact latex or intact vinyl gloves . . ." to read "PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable latex or vinyl gloves, gowns, masks, or eye coverings."

56891: I: DeLaney: L-7: XENCO: 9/13/89: 10/26/89: AS: vo: ek: dg

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

- d. Delete the words "General Classification."
- e. Delete the word "concentrate" from the Precautionary Statements.
2. The submitted information completes and clarifies the data report.

Your release for shipment of the product bearing the amended label 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)

Enclosure

# Huntington.

# HITOR

## GERMICIDAL DETERGENT

Product Number 102720

- Disinfects, Cleans, Deodorizes
  - Pleasant fragrance
  - Economical to use

ACTIVE INGREDIENTS: Octadecyl dimethyl ammonium chloride . . . . . 9.22  
 n-Alkyl (C14 50%, C12 40%, C10 10%) dimethyl benzyl ammonium chloride . . . . . 6.14  
 INERT INGREDIENTS . . . . . 81.64

### KEEP OUT OF REACH OF CHILDREN DANGER

See side panel for additional precautionary and practical treatment statements

### CONTENTS ONE GALLON (3.785 Liters)

BEST AVAILABLE COPY

- ANTIBIOTIC RESISTANT BACTERICIDAL, FUNGICIDAL, VIRUCIDAL**
- HITOR is a broad spectrum disinfectant and detergent which is effective against a wide range of microorganisms. It is effective against the following organisms:
- \* *Staphylococcus aureus*
  - \* *Staphylococcus aureus* phage 80
  - \* *Staphylococcus aureus* phage 81
  - \* *Staphylococcus epidermidis*
  - \* *Streptococcus pyogenes*
  - \* *Trichophyton mentagrophytes*
  - \* *Candida albicans*
  - \* *Rubella*
  - \* *Avian Infectious Bronchitis*
  - \* *Avian Influenza A/Mict*
  - \* *Bovine Parvovirus*
  - \* *Infectious Bovine Rhinotracheitis*
  - \* *HIV-1 (AIDS Virus)*
  - \* *Adenovirus Type 2*
  - \* *Herpes Simplex Type 1*
  - \* *Influenza Type A/Mich*
  - \* *Measles*
  - \* *Adenovirus Type 4*
  - \* *Herpes Simplex Type 2*

\*\* Tested against antibiotic resistant strain only  
 † Tested against standard ATCC strains and antibiotic resistant strains  
 ‡ Classified by Underwriters Laboratories Inc. as to electrical conductivity when used on conductive floors and spontaneous heating. HITOR for use with tested electrically conductive flooring of the vinyl type - 378Y

Huntington Laboratories, Inc., Huntington, IN 46730  
 Lanedale, PA 19446 • Dallas, TX 75227  
 Oakland, CA 94621 • Bramalea, Ontario, Canada, L6T 1E3

**SOLUTIONS:** 1 to 200 . . . . . ONE-HALF OUNCE PER GALLON  
**DIRECTIONS FOR USE:** GENERAL CLASSIFICATION

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

#### GENERAL USE DIRECTIONS

**USES:** Floors, walls, metal surfaces, painted surfaces, exterior bowl surfaces, empty basins, showers, conductive flooring, and lavatory fixtures. For institutional use only such as in hospitals and nursing homes, schools and colleges, medical and dental offices, and veterinary clinics.

**APPLICATION:** Use one-half ounce of HITOR per gallon of water for a minimum contact time of 10 minutes in a single application. For disinfecting, remove gross dirt and heavy soil deposits, then thoroughly wet surfaces. HITOR is extremely versatile and can be applied with a mop, sponge, or cloth as well as soaking. The recommended use solution is used once and discarded. Rinsing is not necessary on floor surfaces unless floors are to be waxed or polished.

#### SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS Virus) OF SURFACES/OBJECTS SOLIDS WITH BLOOD/BODY FLUIDS

**PERSONAL PROTECTION:** Intact latex or intact vinyl gloves must be worn during all cleaning of body fluids and decontamination procedures.

**CLEANING PROCEDURE:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of HITOR. This cleaning may be accomplished with any cleaning solution including this product.

**CONTACT TIME:** HIV-1 is inactivated after one (1) minute of contact at 25°C. Testing on other common types of viruses and bacteria were conducted using a 10 minute contact time at 20°C.

**DISPOSAL OF INFECTIOUS MATERIALS:** Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

EPA Reg No 303-91 EPA Est No 303-IN 1

(See shoulder or bottom of container for plant identification number, HL-10140-5-021688-FL-3)

#### STATEMENT OF PRACTICAL TREATMENT

In case of skin contact, wash thoroughly with soap and water. In case of eye contact, immediately flush eyes with water for 15 minutes and get prompt medical attention. If swallowed, drink promptly a large quantity of egg whites, gelatin solution or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

#### PRECAUTIONARY STATEMENTS

##### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER**  
 Corrosive. Concentrate causes eye and skin damage. May be absorbed through the skin. Do not get in eyes, on skin or clothing. Wear goggles or face shield and rubber gloves when handling. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse. Harmful if swallowed. Avoid contamination of food, water or feed.

#### STORAGE AND DISPOSAL

##### PRECAUTIONS

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

##### PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by site according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

##### CONTAINER DISPOSAL

**PLASTIC CONTAINERS**  
 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.

**GENERAL**  
 Consult federal, state, or local disposal authorities for approved alternative procedures such as limited open burning.

ACCEPTED  
 with COMMENTS  
 in EPA Letter Dated:  
 SEP 19 1989

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, this pesticide is registered under EPA Reg. No. 303-91