

MAY 19 1995

Pettibone Laboratories  
136 Central Avenue  
Clark, NJ 07066

Attention: Joseph M. Kelley,

Subject: CRYOCIDE 20  
EPA Registration Number 10589-4  
Your Amendment Dated November 15, 1994

This is in response to your amendment to update your label, and include a claim that the product is tuberculocidal with efficacy data.

The submitted efficacy data developed by the AOAC Tuberculocidal Test Method appear adequate to support effectiveness of the product as a tuberculocide against Mycobacterium bovis ATCC 35743 on hard, non-porous surfaces in the presence of 5% organic load for a contact time of 10 minutes at 20 degrees Celsius.

The labeling 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 revisions indicated below before you release the product for shipment bearing the amended labeling.

1. Under the subheading, "Disposal of Infectious Materials", change disposed of according to local regulations..." to read "...disposed of according to federal, state, and local regulations...".

A stamped copy of the labeling is enclosed for your records. Submit five copies of the final printed label including these revisions before you release the product for shipment bearing the amended label.

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

5-1-3

If you have any questions concerning this letter, please  
contact me at (703)-305-7964.

Sincerely,



Ruth G. Douglas  
Product Manager (32)  
Antimicrobial Program Branch  
Registration Division (7505C)

# CRYOCIDE-20

Broad-Spectrum

## HOSPITAL DISINFECTANT

• BACTERICIDAL • FUNGICIDAL (Pathogenic) • PSEUDOMONICIDAL • VIRUCIDAL\*  
ODOR COUNTERACTANT

• TUBERCULOCIDAL

\*• Human Immunodeficiency Virus Type 1 (HIV-1) (AIDS Virus)

\*• Herpes Simplex Virus Type 1 and 2 • Influenza A<sub>2</sub> (Hong Kong - 68) Virus  
On Inanimate Environmental Surfaces

### ACTIVE INGREDIENTS:

Chlorine Dioxide .....0.72%

Didecyl Dimethyl

Ammonium Chloride .....0.40%

INERT INGREDIENTS: 98.88%

### KEEP OUT OF REACH OF CHILDREN

### CAUTION

See additional precautionary statements on back..

EPA Reg. No.10589-4

EPA Est. 9150-RI-1

U.S. and Foreign Patents Issued and Pending.

### NET CONTENTS

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

MAY 19 1995

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended for the pesticide  
registered under EPA Reg. No.  
10589-4

## CRYOCIDE-20

Broad-Spectrum

## HOSPITAL DISINFECTANT

Bactericidal • Fungicidal (Pathogenic)

• Pseudomonocidal • Virucidal\*

\*• Human Immunodeficiency Virus Type 1 (HIV-1) (AIDS Virus)

\*• Herpes Simplex Virus Type 1 and 2 • Influenza A<sub>2</sub>  
(Hong Kong - 68) Virus • Odor Counteractant  
On Inanimate Environmental Surfaces

**CRYOCIDE-20** provides broad-spectrum efficiency and economy for commercial, institutional, industrial and agricultural disinfection. CRYOCIDE-20'S ability to OXIDIZE MALODORS offers a definite plus to its disinfecting activity.

**DIRECTIONS FOR USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling. CRYOCIDE-20 is effective for disinfection of hard non-porous surfaces, at room temperature (20° - 25°) in the presence of moderate amounts of organic soil. Remove gross filth and heavy soil prior to application. For general disinfection, apply CRYOCIDE-20 full strength to surface, wetting thoroughly with sponge, mop, spray, or by immersion in solution, and allow to remain wet for 10 minutes, and wipe dry. Although CRYOCIDE-20 destroys HSV-1 and 2 (Herpes virus) and HIV-1 (AIDS virus) within 30 seconds of contact (see Special Instructions below) this contact time will not control other common types of viruses and bacteria.

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS** that involve healthcare 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 soiled with blood or body fluids can be associated with the transmission of HIV-1: CRYOCIDE-20 destroys HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood or other body fluids in 30 seconds contact. **PERSONAL PROTECTION:** The worker should wear disposable latex gloves, gown, mask and eye protection to prevent contamination from soiled items. **CLEANING PROCEDURE:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of CRYOCIDE-20. **CONTACT TIME:** Allow CRYOCIDE-20 to contact treated items for 30 seconds. This contact time will not control other common types of viruses and bacteria. **DISPOSAL OF INFECTIOUS MATERIALS:** Any blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

**SUGGESTED USES:** For use on non-food, hard surfaces such as glass, plastic, chrome, floors, examining tables and toilets in - • Hospitals • Nursing Homes • Institutions & Public Places • Meat Packing Plants • Fish Processing Plants • Poultry Processing Plants • Poultry Hatcheries • Industrial Processing Plants • Dairies • Food Processing Plants

**STORAGE & DISPOSAL:** Store in original closed container in a cool, dry place away from heat and open flame. **DISPOSAL:** Do not contaminate water, food or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. For container disposal, triple rinse (or equivalent), then place in trash receptacle. **PRECAUTIONARY STATEMENTS** Hazards to Human & Domestic Animals - **CAUTION:** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Avoid contamination of food.

**STATEMENT OF PRACTICAL TREATMENT - If in Eyes:** Flush with plenty of water. Get medical attention if irritation persists. If Swallowed: Drink large quantities of water. Avoid alcohol. Call a physician immediately. **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. In On Skin: Flush skin with plenty of soap and water.

Distributed by

PETTIBONE LABORATORIES, INC., 136 Central Ave., Clark, N.J. 07066

(INSERT)

FOR DISINFECTION AGAINST TUBERCULOSIS BACTERIA - ACTIVATE FULL STRENGTH CRYOCIDE 20 BY REDUCING ITS pH TO 3.0 ± 0.05 WITH 1.0 NORMAL HCl OR H<sub>2</sub>SO<sub>4</sub> AND ALLOWING TO STAND FOR AT LEAST 15 MINUTES. THEN USING THIS RESULTING SOLUTION, PROCEED AS DIRECTED UNDER "GENERAL DISINFECTION".

## BEST COPY AVAILABLE