

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 20 1989

Pettibone Laboratories
136 Central Avenue
Clark, NJ 07066

Attention: Bruce S. Galbraith
President

Gentlemen:

Subject: Cryocide-20
EPA Registration No. 10589-4
Your Application Dated June 22, 1989
Your Submission Dated March 16, 1989

This is in regard to your request to amend the registration of the subject product to include additional virucidal claims.

Efficacy Supported By The Data

The submitted data meet the requirements to support effectiveness of the product as a virucide against HIV-1 (AIDS virus) on hard, non-porous surfaces in the presence of a moderate amount of organic soil (10% blood serum) when used at a 1:10 dilution in deionized water for a contact time of 30 seconds at room temperature (20 to 25 °C).

The submitted data also meet the requirements to support effectiveness of the product as a virucide against Herpes Simplex Type 1 and Herpes Simplex Type 2 viruses on hard, nonporous surfaces in the presence of a moderate amount of organic soil (5 percent blood serum) when used at 20 percent in 400 parts per million AOAC hard water (1:5) for a contact time of 30 seconds at room temperature (20 to 25 °C).

The amendment referred to above is acceptable provided that you:

1. Make the labeling changes indicated below before you release the product for shipment bearing the amended labeling.
 - a. Include the method(s) of application (e.g., "by sponge, mop, spray," or "by immersion in the solution," followed by a statement such as "to wet all surfaces thoroughly").

57216:I:Dutch:K-5:KENCO:7/19/89:7/28/89:AS:gj:VO:DE:EK:KA

CONCURRENCES

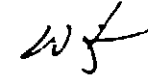
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- b. Change "Viroban" to "Cryocide-20" wherever it appears throughout the labeling.
2. Submit five (5) copies of your final printed labeling for inclusion in your product file.

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 yours,



 Jeff Kempter
Product Manager (32)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosure

CRYOCIDE—20

Broad-Spectrum HOSPITAL DISINFECTANT

Bactericidal • Fungicidal (Pathogenic)

• Pseudomonicidal • Virucidal*

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

* Herpes Simplex Virus Type 1 and 2 • Influenza A₂

(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'S** 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, with good wetting action, and allow to remain wet for 10 minutes. 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 **Viroban**. **CONTACT TIME:** Allow **Viroban** 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 promptly a large quantity of milk, egg whites, gelatin solution, or, if these are not available, drink large quantities of water. Avoid alcohol. **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. **If On Skin:** Flush skin with plenty of soap and water.

Distributed by

PETTIBONE LABORATORIES, INC., 136 Central Ave., Clark, NJ 07066

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUL 20 1989

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

CRYOCIDE-20

Broad-Spectrum

HOSPITAL DISINFECTANT

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

*• Human Immunodeficiency Virus Type 1 (HIV-1) (AIDS Virus)
*• Herpes Simplex Virus Type 1 and 2 *• Influenza A₂ (Hong Kong - 68) Virus
On Inanimate Environmental Surfaces

ACTIVE INGREDIENTS:

Chlorine Dioxide0.72%
Didecyl Dimethyl
Ammonium Chloride0.40%
Isopropanol1.00%

INERT INGREDIENTS: 97.88%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See additional precautionary statements on back..

EPA Reg. No. 10589-4-59292

EPA Est. 41260-NY-1

U.S. and Foreign Patents Issued and Pending.

NET CONTENTS ONE GALLON - (128 Fl. oz.) (3.78 LITERS)