

AUG 31 1992

The Bullen Companies  
1640 Delmar Drive  
P.O. Box 37  
Eldersburg, PA 19032

Attn: Peter J. Fryatt

Subject: ACTIV VIII 640  
EPA Registration No. 1459-84  
Amendment dated March 12, 1992

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to include virucidal claims against the HIV-1 (AIDS VIRUS), is acceptable subject to the comments below. A stamped copy of the labeling is enclosed for your records.

Five copies of the finished labeling must be submitted before you release the product for shipment.

1. Under "Special Instructions" for the AIDS Virus, revise the section "Disposal of Infectious Material" to read:

"Disposal of Infectious Material: Blood and other body fluids should be autoclaved and disposed of according to Federal, State and local regulations for infectious waste disposal".

2. In the "Precautionary Section" include the word "Corrosive" after the statement "Keep Out of Reach of Children".

If you have any questions concerning this letter, please contact Martha DeLaney at (703) 305-6982.

Sincerely,



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

Enclosure

CONCURRENCES

SYMBOL	SURNAME	DATE						

# ACTIV VIII 640

## DISINFECTANT CLEANER & ODOR COUNTERACTANT

**GERMICIDE, VIRUCIDE\*, FUNGICIDE & MILDEWSTAT**  
(Vs. Pathogenic Fungi) (on hard inanimate surfaces)

**KEEP OUT OF REACH OF CHILDREN**  
**DANGER**

See side panel for additional  
precautions and first aid statements.

**ACTIVE INGREDIENTS**  
n-Alkyl(60% C14, 30% C16, 5% C12, 5% C18)  
dimethyl benzyl ammonium chlorides .....2.25%  
n-Alkyl (68% C12, 32% C14) dimethyl  
ethylbenzyl ammonium chlorides .....2.25%  
**INERT INGREDIENTS** .....95.50%  
**TOTAL 100.00%**

EPA REG. NO. 1459-84 EPA EST. NO. 1459 PA- 01

**NET CONTENTS: 5 U.S. GAL**

### PRECAUTIONARY STATEMENTS • Hazard to Humans and Domestic Animals

**DANGER:** Keep out of reach of children. Causes severe eye and skin damage. Do not get in eyes, on skin or clothing. Harmful if swallowed. Wear goggles or face shield and rubber gloves when handling. Avoid contamination of food. Remove and wash contaminated clothing.

**STATEMENT OF PRACTICAL TREATMENT** - In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash all contaminated clothing before reuse. If swallowed, drink milk, egg whites, gelatin solution or if these are not available, drink large quantities of water. Call a physician.

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

### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Store only in original container. Do not reuse empty container. Keep this product under locked storage sufficient to make it inaccessible to children or persons unfamiliar with its proper use.

**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 use 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** - (Larger than 1 gal.)- Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. In addition, plastic containers may be disposed of by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. (1 gal. and smaller)- Do not reuse empty container. Wrap container and put in trash.

### DIRECTIONS FOR USE

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

This detergent/ disinfectant has been designed specifically for hospitals, nursing homes, schools, food processing plants, food service establishments and other institutions where housekeeping is of prime importance.

**DISINFECTION** - To disinfect hard inanimate surfaces (such as walls, floors, table tops) add 2 ounces detergent/ disinfectant per gallon of water. Apply solution with mop, cloth sponge or mechanical sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes and then let air dry.

To disinfect toilet bowls, flush toilet, add 2 ounces detergent/ disinfectant directly to the bowl water. Swab the bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand for 10 minutes and flush.

For heavily soiled areas, a pre-cleaning step is required and recommended. Prepare a fresh solution for each use.

**MILDEWSTAT** - To control mold and mildew on pre-cleaned, hard non-porous surfaces (such as floors, walls, table tops) add 2 ounces of this product per gallon of water. Apply solution with a cloth, mop or sponge making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application at weekly intervals or when mildew growth reappears.

**BEST AVAILABLE COPY**

This product is a phosphate free concentrated detergent / disinfectant which provides effective cleaning, deodorizing and disinfection. This detergent / disinfectant has been designed specifically for hospitals, nursing homes, schools, food processing plants and other institutions where housekeeping is of prime importance in controlling the hazard of cross contamination.

When diluted at the rate of 2 ounces per gallon of water it is an effective disinfectant against the organism *Pseudomonas aeruginosa* and meets all requirements for hospital use. When used as directed, this product is formulated to disinfect inanimate hard surfaces such as walls, floors, sink tops, toilet bowls, tables, chairs, telephones and bed frames. For larger areas such as operating rooms, patient care facilities and restrooms. It is designed to provide both general cleaning and disinfecting and deodorizes those areas which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, toilet bowls and any other areas which are prone to odors caused by microorganisms.

**DISINFECTANT** - At 2 ounces per gallon dilution, this product exhibits effective disinfectant activity against the following: *Pseudomonas aeruginosa* PRD-10, *Escherichia coli*, *Brevibacterium ammoniagenes*, *Klebsiella pneumoniae*, *Streptococcus faecalis*, *Salmonella schultzei*, *Shigella dysenteriae*, *Salmonella choleraesuis*, *Enterobacter aerogenes*, *Streptococcus salivarius*, *Staphylococcus aureus*. At this level the product is also fungicidal against the pathogenic fungi *Trichophyton mentagrophytes*.

**MOLD AND MILDEWSTAT** - Controls mold and mildew and the odors they cause on hard non-porous inanimate surfaces.

**VIROCIDAL\* ACTIVITY**: When used on environmental inanimate hard surfaces at 2 ounces per gallon of water this product exhibits effective virucidal\* activity against influenza A2 - Asian (representative of the common flu virus) and Herpes Simplex (causative agent of fever blisters and mononucleosis), Adeno virus type 5 (causative agent of upper respiratory infections), and Vaccinia Virus (representative of the pox virus group).

Efficacy tests have demonstrated that this product is an effective bactericide, fungicide and virucide\* in the presence of organic soil (5% blood serum).

\*Kills HIV-1 (AIDS virus) on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (Hospitals, Nursing Homes) 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).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OF SURFACES/ OBJECTS SOILED WITH BLOOD/BODY FLUIDS.**

**Personal Protection**: When handling items soiled with blood or body fluids use disposable latex gloves, gowns, masks, or eye coverings.

**Cleaning Procedures**: Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant.

**Contact Time**: Allow surface to remain wet for 10 minutes.

**Disposal Of Infectious Material**: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

ACCEPTED  
with COMMENTS  
in EPA Letter Docket

AUG 31 1992

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

1459-84

BEST AVAILABLE COPY