

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 31 1992

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

Attn: Peter J. Fryatt

Subject: ACTIV VIII 1280
EPA Registration No. 1459-86
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 prdouct 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 1280

DISINFECTANT CLEANER

& ODOR COUNTERACTANT

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

EPA REG. NO. 1459-86 EPA EST. NO. 1459 PA- 01

**KEEP OUT OF REACH OF CHILDREN
 DANGER**

See side panels for additional
 precautionary and first aid statements.

ACTIVE INGREDIENTS

n-Alkyl(60%C14,30%C16,5%C12,5%C18)
 dimethyl benzyl ammonium chlorides4.50%
 n-Alkyl (68% C12, 32% C14) dimethyl
 ethylbenzyl ammonium chlorides4.50%
 INERT INGREDIENTS91.00%
TOTAL 100.00%

MANUFACTURED BY
 THE BULLEN COMPANIES, FOLCROFT, PA 19032

NET. CONTENTS: 1 GALLON

BEST AVAILABLE COPY

This product is a phosphate free concentrated detergent / disinfectant which provides disinfection. This detergent / disinfectant has been designed specifically for hospital processing plants and other institutions where housekeeping is of prime importance.

When diluted at the rate of 1 ounce per gallon of water it is an effective disinfectant against Pseudomonas aeruginosa and meets all requirements for hospital use. When used as directed on inanimate hard surfaces such as walls, floors, sink tops, toilet bowls, tables, chairs, and areas such as operating rooms, patient care facilities and restrooms. It is designed for disinfecting and deodorizes those areas which generally are hard to keep fresh such as empty garbage bins and cans, toilet bowls and any other areas which are prone to odors.

DISINFECTION - At 1 ounce per gallon dilution, this product exhibits effective disinfection against Pseudomonas aeruginosa PRD-10, Escherichia coli, Brevibacterium ammoniagenes, Staphylococcus faecalis, Salmonella schuttmuelleri, Shigella dysenteriae, Salmonella choleraesuis, Staphylococcus aureus. At this level the product is also effective against trichophyton mentagrophytes.

VIRUCIDAL* ACTIVITY: When used on environmental inanimate hard surfaces at 1 ounce per gallon dilution, this product exhibits effective virucidal* activity against Influenza A2 - Asian (representative of influenza simplex), Adeno virus type 12 (causative agent of fever blisters and mononucleosis), and Vaccinia Virus (representative of the pox virus group).

Efficacy tests have demonstrated that this product is an effective bactericide, fungicide, and virucide on organic soil (5% blood serum).

*Kills HIV-1 (AIDS virus) on pre-cleaned environmental surfaces/objects previously used in health care settings (Hospitals, Nursing Homes) or other settings in which there is an exposure to blood or body fluids, and in which the surfaces/objects likely to be contaminated can be associated with the potential for transmission of human immunodeficiency virus (HIV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST BLOOD/BODY FLUIDS.

Personal Protection: When handling items soiled with blood or body fluids use gloves and eye coverings.

Cleaning Procedures: Blood and body fluids must be thoroughly cleaned from surfaces before use 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 or disposed in accordance with local health department regulations for infectious waste disposal.

MOLD AND MILDEWSTAT - Controls mold and mildew and the odors they cause.

ACCEPTED
 with COMMENTS
 by EPA Letter Batch

AUG 31 1992

Under the authority of the Administrator,
 Environmental Protection Agency,
 this document is hereby approved for
 release under the provisions of
 Executive Order 12958, No.
 1459-86

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 1 ounce 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 1 ounce 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 1 ounce 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.

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