

Nipa Laboratories, Inc.  
3411 Silverside Road  
Wilmington, DE 19810

15 SEP 1994

Attn: George Pazianos,  
Authorized Agent for Nipa Laboratories, Inc.

Subject: Ocide Hospital Cleaner-Disinfectant  
EPA Registration No. 49403-23  
Your Amendment of July 20, 1994

Your application to amend the subject product registration by changing the label directions for the HIV-1 use dilution rate form 1:128 to 1:256 has completed review. The following is a result of our review.

1. The confirmatory efficacy data submitted in support of this amendment is acceptable. The data supports the effectiveness of the product formulation as a virucide against HIV-1 (AIDS Virus) when diluted in a 1:256 ratio with AOAC hard water for a contact time of 10 minutes at 23°C.

2. The revised product labeling, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable subject to the comments listed below. A stamped copy is enclosed for your records. Five copies of the finished labeling must be submitted before releasing the product for shipment.

- In the HIV-1 (AIDS Virus) use directions, revise the use dilution rate form 1:128 to 1:256.

If you should have any questions concerning this letter, you may call Robert Travaglini on (703) 305-6909.

Sincerely,



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

CONCURRENCES							
SYMBOL	1505C						
SURNAME	Travaglini						
DATE	15 SEP 1994						

2042

## DIRECTIONS FOR USE

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

This is an extremely effective cleaner and disinfectant, recommended for general hospital use on hard, non-porous surfaces such as floors, walls, woodwork, and equipment in all departments.

For disinfection, use 1/2 oz. to each gallon of water. This product is effective in controlling *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Salmonella choleraesuis*, *Mycobacterium tuberculosis* var *hominis* (BCG), *Trichophyton mentagrophytes*.

Before disinfecting, remove heavy soil and thoroughly pre-clean surfaces. Apply solution; allow to remain wet for at least ten minutes. Mop or wipe up. For heavy duty cleaning, first remove loose soil. Use 2 oz. per gallon of water, mop or wipe on; allow to soak several minutes, remove.

For rapid cleaning, use 4 oz. per gallon of water in automatic scrubbing machines. Always rinse floors before applying polish or wax.

For daily maintenance of waxed floors, damp mop with solution of 1-1/2 oz. per gallon of water to remove most soils.

Recommended for use in hospitals, clinics, veterinary hospitals, rest homes, athletic departments, industrial plants - where a need exists to clean and disinfectant thoroughly.

## DIRECTIONS FOR USE AGAINST

### \* HIV-1 (AIDS VIRUS)

Kills HIV-1 (AIDS Virus) on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in 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 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:** Disposable latex or vinyl gloves, gowns, face masks, or eye coverings as appropriate, must be worn during all cleaning of body fluids, blood and decontamination procedures.

**CLEANING PROCEDURES:** Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant.

**CONTACT TIME:** Effective against HIV-1 (AIDS Virus) on hard, nonporous surfaces in the presence of a moderate amount of organic soil (5% blood serum) when diluted at 1:128 dilution in 400 ppm CaCO<sub>3</sub> hard water for a contact time of 10 (ten) minutes at room temperature (20-25 degrees C).

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

## OCIDE HOSPITAL CLEANER-DISINFECTANT

VIRUCIDAL • FUNGICIDAL • TUBERCULOCIDAL • PSEUDOMONACIDAL

### ACTIVE INGREDIENTS:

Ortho-Benzyl-Para-Chlorophenol.....	10.10%
Ortho-Phenylphenol.....	4.90%
Para-Tertiary-Amylphenol.....	2.50%

INERT INGREDIENTS..... 82.50%

TOTAL: 100.00%

## KEEP OUT OF REACH OF CHILDREN DANGER

## PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

Danger. Corrosive. Causes eye and skin damage or skin irritation. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Remove and wash contaminated clothing before reuse.

## STATEMENT OF PRACTICAL TREATMENT

If on skin: Wash with plenty of soap and water. Get medical attention. If in eyes: Hold eyelids open and flush with a steady gentle stream of water for 15 minutes. Call a physician. If swallowed: Drink promptly, large quantities of water. Call a physician. Do not give anything by mouth to an unconscious person. Avoid alcohol.

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

EPA REG NO. 49403-23

EPA EST. NO. 49403-EN-01

1 U.S. GALLON/3.8 LITERS

Manufactured By: Nipa Laboratories, Inc.  
3411 Silverside Road  
Wilmington, DE 19810

Proposed Label  
Punch 1

## DIRECTIONS FOR USE HOUSE AND FARM PR

Do not use in milking stalls, milking parlors.

1. Remove all poultry, animals, and feed.  
2. Remove all trucks, coops, crates, water troughs, etc.  
3. Remove all gross soil, litter, manure, etc. from floors, walls and surfaces of hatches and other facilities and fixtures of house and poultry.

4. Empty all troughs, racks and other feed containers.  
5. Thoroughly clean and saturate all surfaces with product disinfectant per gallon of water.

Use high pressure sprayer or other suitable equipment.

6. Allow disinfectant to remain in contact with surfaces for 10 minutes.

7. Immerse halters, ropes and other types of equipment and restraining animals, as well as for removing litter and manure, in a solution of disinfectant per gallon water. Allow to remain for 10 minutes.

8. Thoroughly scrub treated feed racks, troughs, waterers, and mangers with a solution of 1/2 oz. per gallon of water.

Rinse with potable water before reuse.

9. Ventilate buildings, coops and other structures containing poultry or livestock or employ equipment to absorb, set or dried.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed. Dumping is prohibited. Store only in original container. Keep this product inaccessible to children or persons.

**PESTICIDE DISPOSAL** - Pesticide disposal is prohibited. Improper disposal of excess pesticide, spray material, or empty container, is a violation of federal law. If these waste materials are not disposed of properly, they may be hazardous to the environment. Contact your local Environmental Control Agency, or the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL** - (Large containers only). Then offer for recycling or disposal in a sanitary landfill, or by other means approved by state and local authorities. In addition, plastic containers should be incinerated, or if allowed by state and local authorities, burned, stay out of smoke. (1 gal. and less containers). Wrap container and put in trash. **DO NOT USE OR STORE NEAR HE**