

15 NOV 1993

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

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

Subject: Ocide Hospital-Cleaner Disinfectant
EPA Registration No. 49403-23
Your Labeling Amendment of June 23, 1993

The proposed amendment to the subject registration, the addition of an HIV-1 (AIDS Virus) claim to the product label, has completed review. The submitted efficacy data supports the product effectiveness against the HIV-1 virus at a 1:128 dilution rate in hard water with a contact time of 10 minutes on hard non-porous surfaces. Please note the following.

The labeling referred to above, 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 you release the product for shipment.

1. The labeling text of on page one of the draft label under in the "Directions For Use" section is barely legible and must be printed more clearly in subsequent printings and/or submissions of the label.

2. Add the word "Virucidal*" on the front panel of the label under the product name.

3. Add an asterisk (*) next to "HIV-1" in the "Directions For Use Against *HIV-1 (AIDS Virus)" heading on page two of the label.

CONCURRENCES							
SYMBOL	7505C						
SURNAME	George Pazianos						
DATE	15 NOV 1993						

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 (7504C)

5
362
Ocide

HOSPITAL CLEANER-DISINFECTANT

FUNGICIDAL TUBERCULOCIDAL PSEUDOMONACIDAL
ACTIVE INGREDIENTS

Ortho-Benzyl-Para-Chlorophenate	10.10%
Ortho-Phenylphenate	4.90%
Para-Tertiary-Amylphenate	2.50%
INERT INGREDIENTS	82.50%

TOTAL: 100.00%

KEEP OUT OF THE 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.

BEST AVAILABLE COPY

See other precautionary and first aid statements on right panel.

1 U.S. GALLON/3.8 LITERS

ACCEPTED
with COMMENTS
in EPA Letter Dated:
7 5 NOV 1993

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.
79403-23

STATEMENT OF FIRST AID

If on skin: Wash with water.
Get medical attention.
If in eyes: Open and flush with water for 15 minutes.
If swallowed: Drink promptly.
Call a physician. Do not
to an unconscious person.

NOTE TO PHYSICIAN: Probable
contraindicate the use
of diuretics against circulatory
depression and convulsions.

DIRECTIONS

It is a violation of Federal
law to use this product in a manner inconsistent with the label.

This is an extremely strong
disinfectant. Recommend
use on hard, non-porous
surfaces, walls, woodwork, and
equipment.

For disinfection, use 1
part product to 10 parts
water. This product is
effective against Staphylococcus aureus,
Pseudomonas aeruginosa,
Salmonella choleraesuis,
tuberculosis var bovis,
and mentagrophytes.

Before disinfecting,
surfaces should be
thoroughly pre-cleaned.
Allow to remain wet for 10
minutes. Mop or wipe up. For
spill removal, remove solid
material, mop or wipe up
water, mop or wipe up
for 10 minutes, remove.

For rapid cleaning, use
1 part product to 10 parts
water in automatic scrubbers.
Clean floors before applying.

For daily maintenance,
mop with solution of 1
part product to 100 parts
water to remove most
soiling.

Recommended for use in
veterinary hospitals,
laboratories, industrial
plants to clean and disinfect.

POULTRY HOUSE AND FARM PREMISE:

5
4
Do not use in milking stalls, milking parlors, or milk houses.

1. Remove all poultry, animals, and feed from the premises.

2. Remove all trucks, coops, crates, water troughs and feed racks.

3. Remove all gross soil, litter, manure, droppings from animals and poultry from floors, walls and surfaces of barns, pens, stalls, chutes, hatches and other facilities and fixtures occupied or traversed by animals and poultry.

4. Empty all troughs, racks and other feeding and watering appliances.

5. Thoroughly clean and saturate all surfaces with a solution of 1/2 oz. of product disinfectant per gallon of water.

Use high pressure sprayer or other suitable sprayer.

6. Allow disinfectant to remain in contact for at least ten minutes.

BEST AVAILABLE COPY

7. Immerse halters, ropes and other types of equipment used in handling and restraining animals, as well as forks, shovels, scrapers used for removing litter and manure, in a solution of 1/2 oz. of product disinfectant per gallon of water. Allow to remain in contact for 10 minutes.

8. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers, and mangers with a solution of product disinfectant at 1/2 oz. per gallon of water.

Rinse with potable water before reuse.

9. Ventilate buildings, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.

**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).

**ING AND DECONTAMINATION:
HIV-1 (AIDS VIRUS) OF
OBJECTS SOILED WITH
FLUIDS.**

PERSONAL PROTECTION: latex or vinyl gloves, face masks, or eye coverings, 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 non-porous surfaces in the presence of a moderate amount of soil (5% blood serum) when used at a 1:128 dilution in ppm CaCO₃ hard water for a contact time of 10 (ten) minutes at room temperature (20 to 25 degrees C).

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

ACCEPTED
with COMMENTS
in EPA Letter Dated

12 5 NOV 1993

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

49403-23

STORAGE AND DISPL

5
5
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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

75 NOV 1993
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, this pesticide
registered under No.

49403-23

NIPA LABORATORIES, INC.
104 Hagley Building
3411 Silverside Road
Wilmington, DE 19810
Tel. (302) 478-1522

BEST AVAILABLE COPY