

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV - 1 2000

Mr. Michael Rekhelman  
VP Technical Services  
ABC Compounding Co., Inc.  
P.O. Box 16247  
Atlanta, GA. 30321

Dear Mr. Rekhelman:

Subject: Additional Efficacy Claims for Influenza A2/Hong Efficacy and  
Product Chemistry Review Hospital Surface Disinfectant Room Deodorizer  
EPA Registration Number 3862-104  
Your Application Dated May 18, 2000

We have completed a review of the efficacy data titled, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces "(MRID #451299-01), and conclude that the data is acceptable to support the additional label claim for the effectiveness of the subject product against influenza Virus A (H3N2).

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable provided that you make the labeling changes indicated below prior to release for shipment of product bearing the amended labeling. All listed organisms must list complete no nomenclature. Revise "Staph, Herpes II and TB germs" to read "Staphylococcus aureus, Herpes simplex virus, Type II, and Maycobacterium tuberculosis, var bovis."

The product Chemistry data submitted in support of the two new alternate inert ingredient fragrances in the subject product formulation are acceptable. The following comments apply to the Confidential Statement of Formula (CSF).

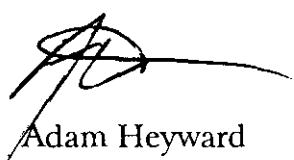
CONCURRENCES							
SYMBOL							
SURNAME							
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- a. The names and addresses of the ingredient suppliers must be provided in item 11 for the following: sodium benzoate, triethanolamine and water. The source of the water must be identified, e.g. municipal water, well deionized water etc.
- b. The full street address of the producer must be provided in item 2 of the CSF. Use of a P.O. Box in completing item 2 is not acceptable.
- c. The revise the CSF product name under EPA Reg. No. 49403-17 is Pentaphen 67 not Napacide PTAP as given on the CSF.

Submit three (3) copies of your final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for your records.

If you have question concerning this letter please contact Drusilla Copeland at (703) 308-6224.

Sincerely,



Adam Heyward  
 Product Manager  
 Regulatory Management Branch II  
 Antimicrobials Division (7510C)

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
NOV - 1 2000

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
ABC Compounding Co., Inc.  
3862-104

quark/aeroaeroart/kelly/newEPAerosol.cdr  
(proof back to Kellie 5-17-00) (5-17-00 made changes... back to Kellie)  
(5-18-00 made changes... back to Kellie)

**CLAIMS AND USES: "VIRUCIDAL"** - Inactivates these agents: Human Immunodeficiency Virus Type I (HIV-1: A retro virus that causes "AIDS" (Acquired Immune Deficiency Syndrome)); Herpes Simplex Type II; Influenza A2/Hong Kong on hard, non-porous, inanimate surfaces. Kills most dangerous Staph, Herpes II, and TB germs on environmental surfaces. Disinfects and controls mold and mildew on hard, nonporous surfaces such as bathroom fixtures, empty garbage cans and diaper pails, furniture in sick rooms and nurseries, fishing equipment and sports equipment such as skate shoes and bowling shoes. Aids in the control of athletes foot fungi (Trichophyton mentagrophytes) on environmental surfaces. Controls Staphylococcus aureus and Salmonella choleraesuis. Spray in the shower stalls, shoes, and walking areas.

**USED IN: HOSPITALS AND OTHER MEDICAL, INDUSTRIAL, INSTITUTIONAL, COMMERCIAL AND RESIDENTIAL FACILITIES.**

**DIRECTIONS FOR USE:** It is a violation of federal law to use this product in a manner inconsistent with its labeling.

**GENERAL: HOLD CONTAINER UPRIGHT. SHAKE OCCASIONALLY DURING USE.**

**SPECIAL INSTRUCTIONS for cleaning and decontaminating against HIV-1 (Aids Virus) on surfaces/objects soiled with blood/body fluids:** wear disposable gloves, gowns, masks, or eye coverings when handling items soiled with blood/body fluids. Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. Blood and other body fluids, and cleaning materials removed from surface/objects should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

**FOR TUBERCULOCIDAL USE:** Remove heavy soil and thoroughly clean surfaces prior to application of this product. Spray from 6-8" until thoroughly wet. Allow surface to remain undisturbed for at least 10 minutes at 20° C before wiping.

**FOR DISINFECTING, mildew control, and deodorizing of clean surfaces:** spray from 6-8" until thoroughly wet. For disinfection, allow surface to remain undisturbed for at least 10 minutes before wiping. Repeat treatment weekly to maintain effective control of mildew.

**FOR DEODORIZING MOPS:** Shake well before using. Rinse wet mops thoroughly with clean water and wring out prior to treatment. Shake dust and debris from dust mops prior to application. Hold can upright 6 to 8 inches from mop and spray until yarn surfaces are wet. Turn mop over and also inside out to allow spray to contact all yarn surfaces. Hang mop in well ventilated area. Allow dust mops to dry before use (at least ten minutes).

# Hospital Surface Disinfectant

## ROOM DEODORIZER

**SAVES MOP FROM ODOR AND DECAY  
KILLS HIV-1 (AIDS VIRUS) AND HERPES SIMPLEX TYPE II VIRUSES  
ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS  
PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS.**

**BACTERICIDAL PSEUDOMONICIDAL  
STAPHYLOCIDAL TUBERCULOCIDAL**

**FUNGICIDAL VIRUCIDAL\***

**A BROAD-SPECTRUM ANTIMICROBIAL AGENT FOR ENVIRONMENTAL SURFACES.**

**CONTROLS MOLD/MILDEW**

**ELIMINATES ODORS BY ATTACKING THEM AT THEIR SOURCE.**

## Desinfectante

**Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand this label, find someone to explain it to you in detail.)**

**ACTIVE INGREDIENTS:**  
Orthophenyphenol..... 0.08%  
Paratertiary amyphenol..... 0.02%  
**INERT INGREDIENTS:..... 99.90%**

EPA REG. NO. 3862-104  
SDA - TEX- 822  
EPA EST. NO. 9143-TX-1

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

**CONTENTS UNDER PRESSURE.  
See additional precautionary statements on side panel.**

**Net Wt.: 17 oz. (482g) Volume 20 FL. OZ.**

Manufactured By:  
**ABC COMPOUNDING CO., INC.**  
P. O. BOX 16247  
ATLANTA, GEORGIA 30321

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

### CAUTION

Causes temporary eye irritation; do not get on or toward eyes or face. Avoid breathing spray mist or vapors. Do not contaminate food or feed, nor surfaces that they may contact.

FIRST AID:	
If Inhaled	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
If on skin or clothing	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
If in eyes	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue eye.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
If swallowed	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor for further treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

**PHYSICAL AND CHEMICAL HAZARDS**  
Flammable. Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

#### STORAGE AND DISPOSAL

**GENERAL:** Do not contaminate other materials, including water, food or feed during transport, use, storage, or disposal. If damaged or leaking, soak up and wrap waste, then dispose of as below. **Storage:** Keep in a cool, dry, locked area inaccessible to children and away from flames, sparks, sunlight, or other sources of heat or ignition. Containers heated above 130° F (54°C) may burst. **Disposal:** Relasten protective cap on container, securely wrap in several layers of newspaper, and discard in trash. Do not incinerate or puncture.

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