

PM 32

675-25

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 12 1995

National Laboratories Division  
Reckitt & Colman, Inc.  
225 Summit Avenue  
Montvale, NJ 07645

Attention: Ruth Trager  
Sr. Regulatory Affairs Associate

Subject: Amphyl Disinfectant Deodorant Spray  
Registration No. 675-25  
MOU Compliance Amendment dated July 11, 1995

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, will be acceptable provided that you make the labeling change listed below before you release the product for shipping bearing the amended label.

1. Remove the term "POWERFUL", such claims imply heightened efficacy and are not allowed on the label.

A stamped copy of your labeling is enclosed for your records. Submit five (5) copies of the final label prior to releasing the product for marketing.

If you have any questions concerning this letter, please contact Wanda Mitchell at (703) 305-6141.

Sincerely,



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

CONCURRENCES

| SYMBOL  |  |  |  |  |  |  |  |
|---------|--|--|--|--|--|--|--|
| SURNAME |  |  |  |  |  |  |  |
| DATE    |  |  |  |  |  |  |  |

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Front Panel

**PART OF YOUR INFECTION CONTROL PROGRAM**

**AMPHYL®**

**DISINFECTANT-DEODORANT  
SPRAY**

**FOR USE IN INSTITUTIONAL AND INDUSTRIAL FACILITIES**

**Germicidal  
Tuberculocidal  
Fungicidal  
Virucidal\***

ACCEPTED  
with COMMENTS  
to EPA Letter Dated:

\*see back panel

SEP 12 1995

Symbol: Contains NO CFC's or other ozone depleting substances.

Use as an insecticide,  
fungicide, or disinfectant. Act as  
a disinfectant and insecticide  
under EPA Reg. No.  
675-25

Federal regulations prohibit CFC propellants in aerosols.

**ACTIVE INGREDIENTS:**

|                                 |                |
|---------------------------------|----------------|
| o-Phenylphenol.....             | 0.136%         |
| Ethanol.....                    | 78.500%        |
| <b>INERT INGREDIENTS:</b> ..... | <b>21.364%</b> |

EPA Reg. No. 675-25  
EPA Est. No. 777-IL-1, NJ-2 (See Bottom)

**KEEP OUT OF REACH OF CHILDREN  
WARNING:**

See back panel for additional precautions.

Net Contents: 13 Oz. (368.55 g)

NL Logo  
National Laboratories Division  
Reckitt & Colman Inc., Montvale, NJ 07645

95013-000

Back Panel (Part 1)

**AMPHYL® DISINFECTANT-DEODORANT SPRAY**

**POWERFUL HOSPITAL SPRAY DISINFECTANT** for nonporous environmental surfaces such as counters, louvers, bed springs, toilet seats, urinals, showers, sinks, garbage cans, door handles, telephones, linen carts, hampers, clean-up carts, blood pressure sets, dressing carts, stretchers, and wheelchairs. Removes offensive odors from dressing rooms, patient rooms, utility areas.

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

**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 preclean or decontaminate critical or semi-critical devices prior to sterilization or high level disinfection.**

**TO DISINFECT:**

1. Thoroughly clean surface prior to application of AMPHYL® Disinfectant-Deodorant Spray.
2. Hold can upright, 6" to 8" from surface.
3. Spray surface 2 to 3 seconds until thoroughly wet.
4. Allow to stand ten minutes for effectiveness.
5. Wipe dry with cloth.

For tuberculocidal activity, AMPHYL® Disinfectant-Deodorant Spray is effective in 10 minutes at 20°C (68°F) on surfaces that have been thoroughly cleaned prior to application of AMPHYL® Disinfectant-Deodorant Spray.

**ELIMINATES ODORS:** AMPHYL® Disinfectant-Deodorant Spray deodorizes by killing the microorganisms that cause odors. To eliminate odors retained in fabrics, spray on draperies, curtains and upholstered furniture. Spray on surfaces to eliminate damp musty odors in areas where air does not circulate.

**TO PREVENT MILDEW:**

Spray surface until moist. Allow to dry on surface and repeat when mildew growth appears. **DO NOT USE ON POLISHED WOOD FURNITURE, ACRYLIC PLASTICS, OR RAYON FABRICS**

**GERMICIDAL:** Staphylocidal • Pseudomonacidal • Tuberculocidal

**VIRUCIDAL\*:** Against HIV-1 (AIDS Virus)\*\*, Adenovirus Type 2, Canine Parvovirus, Cytomegalovirus, Echovirus Type 12, Hepatitis A, Herpes Simplex Types 1 and 2, Influenza A<sub>2</sub> (Japan 305/57), Influenza B (Hong Kong 5/72), Parainfluenza Type 2, Poliovirus Type 1, Respiratory Syncytial Virus, Rhinovirus Type 39, Rotavirus (Wa), and Vaccinia.

**FUNGICIDAL:** Against *Aspergillus niger*, *Candida albicans*, and Trichophyton mentagrophytes on environmental surfaces such as floors, showers, and bathtubs.

\* on hard inanimate surfaces.      \*\* Tested in the presence of 50% whole human blood.

Back Panel (Part 2)

**KILLS HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) (AIDS VIRUS) ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS**, in health care 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 HIV-1 (associated with AIDS):

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATING AGAINST HIV-1 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 other body fluids must be thoroughly cleaned from surfaces and objects before application of AMPHYL® Disinfectant-Deodorant Spray.

**CONTACT TIME:** Allow surface to remain wet for 10 minutes.

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

**AMPHYL® Disinfectant-Deodorant Spray also kills the following bacteria on environmental surfaces:** Mycobacterium tuberculosis var bovis, Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, Acinetobacter calcoaceticus, Campylobacter jejuni, Enterobacter aerogenes, Enterococcus faecalis, Escherichia coli, Klebsiella pneumoniae, Listeria monocytogenes, Proteus mirabilis, Proteus vulgaris, Pseudomonas cepacia, Pseudomonas putida, Salmonella enteritidis, Salmonella paratyphi, Serratia marcescens, Shigella dysenteriae, Shigella flexneri, Staphylococcus aureus (methicillin & gentamicin resistant), Staphylococcus aureus (penicillin resistant), Staphylococcus epidermis, Streptococcus pyogenes.

**KILLS MOLD AND MILDEW.** Dries instantly, leaves no oily film. Repeat application when new mildew growth appears.

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

**WARNING:** Avoid spraying in eyes. Avoid contact with food.

**FIRST AID:** In case of eye contact, immediately flush eyes thoroughly with water, remove any contact lenses and continue to flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation persists.

**PHYSICAL OR 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.

**STORAGE AND DISPOSAL:**

**STORAGE:** Store in original container in areas inaccessible to small children.

**DISPOSAL:** Replace cap. Wrap and discard in trash. Do not puncture or incinerate.

This can is made from an average of 25% recycled steel (10% post-consumer).