

PM32

675-25

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FEB 8 1990

Ms. Ruth Trager
National Laboratories
Lehn & Fink Products Group
225 Summit Avenue
Montvale, NJ 07645

Dear Ms. Trager:

Subject: Amphyl Disinfectant Deodorant Spray
EPA Registration No. 675-25
Your Amendment Dated October 9, 1990

A review of your amendment requesting the addition of virucidal claims has the following comments.

1. The submitted data appear adequate to support efficacy of the product as a virucide against HAV (Hepatitis A) on hard non-porous surfaces in the presence of moderate amount of organic soil (10% blood serum) undiluted with a contact time of 10 minutes at approximately 23 °C.
2. The submitted data appear adequate to support efficacy of the product as a virucide against Cytomegalovirus and Parainfluenza, Type 2 on hard non-porous surfaces in the presence of moderate amount of organic soil (5% blood serum) undiluted with a contact time of 10 minutes at approximately 20 °C.
3. The submitted data appear adequate to support efficacy of the product as a bactericide against Staphylococcus aureus, Methicillin and Gentamicin resistant on hard non-porous surfaces in the presence of moderate amount of organic soil (5% blood serum) undiluted with a contact time of 10 minutes at approximately 20 °C.

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50928:I:Pringle:32-1:KEVRIC:1/30/91:2/28/91:EK:EK:tlc
R:56608:Pringle:L32-9:KEVRIC:02/07/91:03/06/91:CL:wo:DD:aw

CONCURRENCES

SYMBOL	H-75846						
SURNAME	Pringle						
DATE	2-20						

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records. Five copies of the finished labeling must be submitted before you release the product for shipment.

If you have any further questions, please contact Ms. Barbara Pringle at (703) 557-0484.

Sincerely yours,



Walter C. Francis
Acting Product Manager (32)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosure

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Amphyl Spray also kills the following bacteria and fungi on environmental surfaces:

Salmonella choleraesuis

Salmonella paratyphi

Salmonella enteritidis

Proteus mirabilis

Escherichia coli

Staphylococcus aureus

Proteus vulgaris

Enterobacter aerogenes

Klebsiella pneumoniae

Mycobacterium tuberculosis var bovis

Pseudomonas aeruginosa

Pseudomonas cepacia

Pseudomonas putida

Corynebacterium diphtheriae

Candida albicans

Trichophyton mentagrophytes

Shigella dysenteriae

Shigella flexneri

Staphylococcus epidermidis

Staphylococcus aureus (Penicillin resistant)

Staphylococcus aureus (Methicillin & gentamicin resistant)

Neisseria elongata

Listeria monocytogenes

Campylobacter jejuni

Serratia marcescens

Streptococcus faecalis

Streptococcus pyogenes

Salmonella schottmulleri

Aspergillus niger

Acinetobacter calcoaceticus

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.

DIRECTIONS FOR USE

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

TO DISINFECT:

1. Thoroughly clean surface prior to application of Amphyl 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 Spray is effective in 10 minutes at 20°C. (68° F.) on surfaces that have been thoroughly cleaned prior to application of Amphyl Spray.

TO DEODORIZE:

1. Hold can upright, pointing valve in desired direction.
2. Spray into air 3 to 5 seconds, towards center of room.

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 OR RAYON FABRICS

NATIONAL LABORATORIES
LEHN & FINK PRODUCTS GROUP
MONTVALE, N.J. 07645
PLANT: TOLEDO, OHIO 43612

SIDE PANELS

AMPHYL Spray

POWERFUL HOSPITAL SPRAY DISINFECTANT for nonporous environmental surfaces such as:

- | | | |
|-----------------------|----------------------|------------------|
| air duct louvers | door handles | dressing carts |
| bed springs | linen carts, hampers | stretcher wheels |
| toilet seats, urinals | clean-up carts | bassinets |
| garbage cans | blood pressure sets | wheelchairs |

GERMICIDAL: Staphylocidal . Tuberculocidal . Pseudomonacidal .

VIROCIDAL* against Herpes Simplex Types 1 and 2, Influenza A2 (Japan 305/57), Influenza B (Hong Kong 5/72), Rhinovirus Type 39, Respiratory Syncytial Virus, Echovirus Type 12, Rotavirus (Wa), Poliovirus Type 1, Adenovirus Type 2, Hepatitis A Virus, Parainfluenza Type 2, Cytomegalovirus,** Canine Parvovirus and Human Immunodeficiency Virus Type 1 (HIV-1) (AIDS Virus) and Vaccinia.

FUNGICIDAL: Against Trichophyton mentagrophytes (athlete's foot fungus) on environmental surfaces, such as floors, showers, and bathtubs.

*on hard inanimate surfaces.

**Tested in the presence of 50% whole human blood.

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 DECONTAMINATION 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.

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

QUICK ACTION DEODORIZER. Removes offensive odors from dressing rooms, patient rooms, utility areas.

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