

APR 25 1994

Michele F. Herrity  
 Lehn Fink Products  
 225 Summit Avenue  
 Montvale, N.J. 07645

Subject: Lysol Brand Foaming Disinfectant Basin Tub  
 and Tile Cleaner II  
 EPA Registration No. 777-71  
 MOU Compliance Amendment Dated March 31, 1994

Dear Ms. Herrity:

This letter responds to your amendment request to add the disclaimer statement required by the EPA/FDA June 4, 1993 Memorandum of Understanding (MOU) regarding medical devices to the Lysol Brand Disinfectant Spray product label.

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 following comment. A stamped copy is enclosed for your records.

Under the recommendations for use of this product, delete "dental units". The term is vague and may be misunderstood by users.

Submit (5) copies of the final printed labeling before the product is released for shipment.

Sincerely,



Marshall Swindwell, (Acting PM 31)  
 Antimicrobial Program Branch  
 Registration Division (7505C)

CONCURRENCES							
SYMBOL	7505C						
SURNAME	D. Arvids						
DATE	4/25/94						

2074

FRONT PANEL

Part of Your Infection Control Program

**LYSOL® BRAND FOAMING DISINFECTANT  
BASIN TUB & TILE CLEANER II**

**Cleans and Shines  
Fresh Clean Scent**

Active Ingredients: Octyl Decyl Dimethyl Ammonium Chloride...0.050%  
 Dioctyl Dimethyl Ammonium Chloride.....0.025%  
 Didecyl Dimethyl Ammonium Chloride.....0.025%  
 Inert Ingredients:\*.....99.900%  
 \*Includes detergents and other grease cutting agents

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

See back panel for additional precautionary statements

EPA Reg. No. 777-71  
EPA Est. No. 777-IL-1, NJ-2, 11525-IL-1, RI-1 (See bottom)

Net Wt. 17 oz. (1 lb. 1 oz.) 482 g.  
Net Wt. 24 oz. (1 lb. 8 oz.) 680 g.

L & F Products  
Montvale, NJ 07645

**ACCEPTED  
with COMMENTS  
in EPA Letter Dated:**

**APR 25 1994**

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

**777-71**

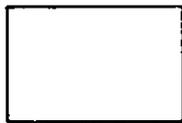
BACK PANEL

LYSOL® Brand Foaming Disinfectant Basin Tub & Tile Cleaner II meets AOAC efficacy standards for hospital aerosol disinfectants. Effective against Salmonella choleraesuis, Staphylococcus aureus and Pseudomonas aeruginosa in 10 minutes.

Effective. Cleans, shines and disinfects nonporous washable bathroom (rest room) surfaces and fixtures around the home and in schools, and other public places, in hospitals, dental offices, and in other health care facilities for example, medical lamps, stands, patient bedframes, bedside tables, wheelchairs, dental units and other similar equipment. Use this product to both clean and disinfect nonporous surfaces in all health care facilities including dental and physician offices. Satisfies infection control practices for removing blood and other potentially infectious material and decontaminating hard, environmental surfaces.

Convenient. Just spray on and wipe off. No scrubbing or rinsing. Even sprays upside down.

Does not harm most bathroom (rest room) nonporous hard surfaces. Contains no abrasives, harsh acids, or bleach. Great/Use on modern washable surfaces such as fiberglass, porcelain, stainless steel, synthetic marble, tile, plastic and vinyl. For other surfaces, spot test in an inconspicuous area.



Shower Doors  
or Curtains



Tubs and Tile



Vanity Tops,  
Sinks & Chrome

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 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.

For cleaning: Shake well before using. Point button to mark on rim. Hold can 6 to 8 inches from surface to be cleaned. Press button and cover area lightly with white foam. After a few seconds, wipe off with clean cloth or sponge. For stubborn stains or heavily soiled areas, allow foam to remain longer on surface before wiping.

GERMICIDAL - VIRUCIDAL\* - FUNGICIDAL - TUBERCULOCIDAL

\*For disinfecting, killing Trichophyton mentagrophytes (athlete's foot fungus), dangerous Staphylococcus aureus and Streptococcus faecalis germs, Pseudomonas aeruginosa, Influenza A<sub>2</sub> (Japan), Mycobacterium tuberculosis var bovis, Poliovirus Type 1, Rhinovirus Type 39, Rotavirus, Herpes simplex Type 1 and Type 2, and Human Immunodeficiency Virus Type 1 (HIV-1) (AIDS Virus) on hard nonporous surfaces: If surfaces are extremely dirty, follow cleaning directions first, then spray on surface until thoroughly covered with foam. Leave for 10 minutes. For 100% tuberculocidal activity, leave on surfaces for 40 minutes. Wipe with damp cloth or sponge.

Effective against:  
Trichophyton mentagrophytes (athlete's foot fungus)  
Staphylococcus aureus  
Pseudomonas aeruginosa  
Streptococcus faecalis germs

ACCEPTED  
with COMMENTS  
in EPA Letter Date:

APR 25 1994

Under the Federal Insecticide,  
Fungicide and Rodenticide Act,  
amended by the FIFRA Act of 1990,  
registered under EPA Reg. No.

777-71

4044

ACCEPTED  
with COMMENT  
in EPA Letter I...

APR 25 1994

Under the Federal  
Pesticide Control Act  
EPA Reg. No. 777-71

Back Panel Page 2

- Herpes simplex Type 1 and Type 2
- Human Immunodeficiency Virus Type 1 (HIV-1) (AIDS Virus)
- Influenza A<sub>2</sub> (Japan)
- Mycobacterium tuberculosis var bovis
- Poliovirus Type 1
- Rhinovirus Type 39
- Rotavirus

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 Human Immunodeficiency Virus (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 LYSOL® Brand Foaming Disinfectant Basin Tub & Tile Cleaner II.

**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.

**For mold and mildew control on nonporous surfaces:** To control mold and mildew, spray on surface until thoroughly covered with foam. Let stand 3 minutes. Wipe with damp cloth or sponge. Reapply as necessary.

**Precautionary Statements: Hazards to Humans and Domestic Animals**  
Caution: May cause eye irritation. Avoid contact with eyes or skin. Keep out of reach of children.

**Statement of Practical Treatment:** 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. Consult a physician if irritation persists.

**Physical or Chemical Hazards:** Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperature above 120°F or in sun or discarding can in fire or incinerator may cause bursting.

**Storage/Disposal:** Store in original container in areas inaccessible to small children. Do not reuse empty container. Replace cap and discard in trash. Do not incinerate or puncture.

LYSOL® Brand Foaming Disinfectant Basin Tub & Tile Cleaner II is part of a system of infection control products provided by National Laboratories. People respect the LYSOL Brand name for providing high quality and trusted surface disinfection, and gain the added benefit of a clean sanitary environment. We invite you to call us at 1-800-677-9218, Monday through Friday, 8:30 a.m. to 4:30 p.m. (Eastern time), if you have any questions or comments on our products.

LYSOL® Brand Foaming Disinfectant Basin Tub & Tile Cleaner II contains no phosphates and is germicidal when used as directed for disinfecting, but differs in composition from other LYSOL® Brand products.

This can is made from an average of 25% recycled steel (10% post-consumer). Contains no CFC's or other ozone depleting substances. Federal regulations prohibit CFC propellants in aerosols.