

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 05 1997

Household Products Division  
Reckitt & Colman, Inc.  
225 Summit Avenue  
Montvale, NJ 07645

SUBJECT: Lysol Brand Foaming Disinfectant Basin, Tub &  
Tile Cleaner II  
EPA Registration No. 777-71  
Amendment Dated June 5, 1997

ATTN: Bruce Paolella

Dear Sir:

The submitted data package (MRID # 442940-01) supports the product's effectiveness as a household/hospital disinfectant cleaner with an additional claim against Escherichia coli 0157:H7, when used undiluted as a pressurized spray, in the presence of moderate amounts of organic soil, on hard, non-porous, inanimate, environmental surfaces for a contact time of ten minutes at an ambient testing temperature between 21.4 -23.7° C.

Labeling

The proposed label must be revised in the following manner:

- A. On the back panel, under the heading "Tuberculocidal" revise "...on inanimate surfaces." to read, "...on precleaned, hard, nonporous, inanimate surfaces."
- B. On the back panel, revise "Mycobacterium tuberculosis var. bovis" to read "Mycobacterium bovis (BCG)".
- C. Revise the term "nonporous surface" to read, "hard, nonporous surface" everywhere it appears on the label.

A stamped label is enclosed for your records.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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If you have any further questions, please contact Ms. Barbara Pringle at (703)308-6236.

Sincerely,



Velma Noble  
Acting Team Leader  
Regulatory Management Branch I  
Antimicrobial Division (7510W)

FRONT PANEL

LYSOL® BRAND FOAMING DISINFECTANT  
BASIN TUB & TILE CLEANER II

Cleans and Shines  
Fresh Clean Scent  
Deep Down Clean!  
Tough on Soap Scum  
Disinfects as it Cleans  
Part of Your Infection Control Program  
24 Oz. Economy Size

Contains no CFC's or other ozone depleting substances.  
Federal regulations prohibit CFC propellants in aerosols.

Active Ingredients: Octyl Decyl Dimethyl Ammonium Chloride...0.050%  
Dioctyl Dimethyl Ammonium Chloride.....0.025%  
Didecyl Dimethyl Ammonium Chloride.....0.025%

Inert  
Ingredients: \*.....99  
\*Includes detergents and other grease cutting agents

KEEP OUT OF REACH OF CHILDREN  
CAUTION  
See back panel for additional precautionary statements

Net Wt. 17 oz. (1 lb. 1 oz.) 482 g.  
Net Wt. 24 oz. (1 lb. 8 oz.) 680 g.  
Net Wt. 21.25 oz. (1 lb. 5.25 oz.) 602 g.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
DEC 5 1997  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.  
777-71

RECEIVED

**BACK PANEL**

Lysol® Brand Foaming Disinfectant Basin Tub & Tile Cleaner II

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

**Tuberculocidal.** Kills Mycobacterium tuberculosis var bovis after 40 minutes at 20°C (68°F) on inanimate surfaces.

**Effective.** Cleans, shines and disinfects washable bathroom (restroom) surfaces and fixtures around the home, in schools and other public places.

**ALTERNATE LANGUAGE FOR SIZES MAKING MEDICAL DEVICE CLAIMS:**

Cleans, shines and disinfects nonporous washable bathroom (rest room) surfaces and fixtures around the home, in schools, hospitals, and other public places, in the dental office, and in other health care facilities, for example, medical lamps, stands, patient bed frames, bedside tables, wheelchairs and other similar equipment. Use this product to both clean and disinfect noncritical 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 to clean and wipe off. No scrubbing or rinsing. Even sprays upside down.

**Does not harm most bathroom (rest room) 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.

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- 3 -



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 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 medical devices prior to sterilization or high-level disinfection.

**BACK PANEL CONTINUED**

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 (effective against) Trichophyton mentagrophytes (athlete's foot fungus), dangerous Staphylococcus aureus, Escherichia coli, and Streptococcus faecalis germs, Pseudomonas aeruginosa, Influenza A<sub>2</sub> (Japan), Poliovirus Type 1, Rhinovirus Type 39, Respiratory Syncytial Virus, 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. Wipe with damp cloth or sponge.

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To kill Mycobacterium tuberculosis var bovis, spray on precleaned surface until thoroughly covered with foam. Leave for 40 minutes. Wipe with damp cloth or sponge.

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.

**BACK PANEL CONTINUED**

**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 **ACCEPTED with COMMENTS** discarding can in fire or incinerator may cause bursting. **in EPA Letter Dated:**

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**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 Reckitt & Colman Inc. 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, 8:45 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.

**IMPORTANT FACTS:**

Contains no phosphates.

Encourage your local authorities to establish a program to recycle this can.

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

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Reckitt & Colman Inc.  
Montvale, NJ 07645

EPA Reg. No. 777-71

EPA Est. No. 777-NJ-2; 11525-IL-1, RI-1; 8791-MO-1 (See bottom)

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