

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 28 2000

Mr. Bruce Paolella  
Reckitt & Colman Inc.  
1655 Valley Road  
Wayne, New Jersey 07474

Dear Paolella:

Subject: Label Amendment-Add Additional Efficacy Claims and  
Appropriate Label Language for Lysol Brand Disinfectant  
EPA Registration Number 675-55  
Your Application Dated July 21, 1999

The amendment referred to above, submitted in connection with registration under FIFRA is acceptable provided that you.

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) and sec. 4 when the Agency requires all registrants of similar products to submit such data.
2. All of the efficacy data submitted is accepted for the additional efficacy claims except for the product's effectiveness as a fungicide against *Aspergillus Niger* (ATCC 16404) when tested ready to use after 7 days. Therefore, you must delete this use from the label.
3. The following comments are applicable to the submitted label "Lysol® Brand Disinfectant S.A. Cleaner". The label and alternate language for Pro-Brand Product must be revised to reflect the following:
  - a. Product should be used on hard, non-porous inanimate environmental surfaces such as glazed porcelain, glazed ceramic tile...
  - b. On page 4, revise safe for septic tanks to "will not harm septic tanks".
  - c. On pages 1 and 6, the term "new" can only be used for 6 months.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6 (e). Your release for shipment of the product constitutes acceptance to these conditions.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

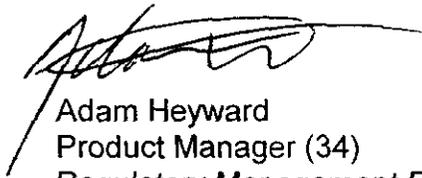
Submit five (5) copies of your final printed labeling before you release the product for shipment.

A stamped copy of the label is enclosed for your records.

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

Enclosed for you information, a copy of EPA/AD efficacy review dated January 18, 2000.

Sincerely,



Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division ( 7510C)

Enclosure

3 9 10

**LYSOL® BRAND DISINFECTANT S.A. CLEANER**

Country Scent®/Fresh Scent™/Original Scent™/Lemon Scent/Pacific Fresh

Tuberculocidal  
Mildewstatic  
Virucidal\*

Antibacterial Action  
Deodorizes  
Disinfects  
Hospital Disinfectant

DISINFECTS AS IT CLEANS  
TOUGH ON SOAP SCUM  
TOUGH ON LIMESCALE  
TOUGH ON HARD WATER STAIN  
NEW and/or IMPROVED FORMULA  
Cleans, shines [deodorizes] and disinfects  
Fresh Clean Scent!  
Deep Down Clean!  
29.3oz. Economy Size  
Meets AOAC Germicidal Spray Test Standards  
Convenient Trigger Spray. No scrubbing or rinsing required.

GOODHOUSE KEEPING  
SEAL

ACCEPTED  
with COMMENTS  
In EPA Letter Dated:  
JAN 28 2000

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
extended for the pesticide  
registered under EPA Reg. No. 675-55

**Active Ingredient**

Citric Acid .....2.50%

**Inert ingredients**

(Includes detergents and other grease cutting agents).97.50%

**Total** .....100.00%

**WARNING:**

KEEP OUT OF REACH OF CHILDREN

SEE BACK PANEL FOR  
ADDITIONAL PRECAUTIONARY  
STATEMENT

Net Wt. 17 FL. OZ. (1PT. 1 OZ.) 502 mL  
24 FL. OZ. (1PT. 8 OZ.) 709 mL  
29.3FL. OZ. (1PT. 13.3 OZ.) 866.5 mL  
32 FL. OZ. (1 QTS.) 946 mL  
64 FL. OZ. (2 QTS.) 1.89 mL  
128 FL. OZ. (4 QTS.) 3.78 mL

Note: Bracketed[] information is optional text. Text separated by a comma(,) denotes-and/or options.

4 7 10

**Optional Disinfectant related bullets/bursts/sentences-Front or Back Label**

An effective disinfectant cleaner on [non-food contact surfaces] and deodorant for use in the bathroom.

Disinfects -or- Kills [common household] germs and/or bacterial and/or viruses and/or fungi without bleaching.

[The two-job cleaner] or [The one step cleaner] that kills [common household] germs and/or bacteria and/or viruses and/or fungi while it cleans [tough] [everyday] [bathroom] [household] messes.

**Statements which can be used on all products**

An effective disinfectant cleaner [on non-food contact surfaces] and deodorant for use on tile, tubs, sinks, shower doors, fixtures, toilets and other nonporous bathroom surfaces made from: porcelain, ceramic, stainless steel, chrome, glass, synthetic marble and Formica® laminated plastic surfaces.

Alternate Language for Pro-Brand Product

*Effectively cleans, shines and disinfects washable non-porous surfaces in health care facilities. Great on washable surfaces such as porcelain, stainless steel sinks, synthetic marble, tile, plastic and vinyl. For other surfaces, test in an inconspicuous area.*

*Effectively cleans nonporous surfaces made from: porcelain, ceramic, stainless steel, chrome, glass, synthetic marble and Formica ® laminated plastic surfaces. May etch some older sinks and tubs. Should not be used on marble surfaces. Contains no abrasives or bleach.*

This product is mildewstatic and will effectively inhibit the growth of mildew and the odors caused by them when applied to hard non-porous surfaces.

This product meets AOAC Germicidal Spray efficacy standards for hospital disinfects and/or is a broad-spectrum disinfectant.

Kills Athlete's Foot Fungus in the bathroom.  
Protects your family from illness causing germs.

Eliminates odors caused by [bacteria] [germs] [mildew].  
Cleans, shines and disinfects.

5 8 10

On hard non-porous surfaces, this product kills the following bacteria, fungi and viruses (hydrophilic and lipophilic) and fungi such as:

**Bacteria:**

Mycobacterium tuberculosis var bovis BCG  
Staphylococcus aureus  
Streptococcus pyogenes  
Pseudomonas aeruginosa  
Salmonella choleraesuis  
Enterococcus faecium  
Enterococcus (streptococcus) faecalis  
Escherichia coli (E.coli)  
) Campylobacter jejuni

**Fungi:**

Trichophyton mentagrophytes (Athletes foot fungus)

**\*Viruses:**

Human Immunodeficiency Virus Type 1 (HIV-1)\*\* (AIDS Virus)  
Rhinovirus Type 39 (the leading cause of the common cold)  
Poliovirus Type 1  
Echovirus 12  
Rotavirus (the leading cause of infectious diarrhea in children)  
Adenovirus Type 2  
Herpes Simplex Type 1 and 2  
Hepatitis A virus  
Respiratory Syncytical Virus (RSV) (the leading cause of lower respiratory infection in children and/or an important cause of ear infections in children)  
Parainfluenza  
Influenza A2.

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

Lysol ® Brand Disinfectant S.A. Cleaner (effectively) cleans, shines and disinfects washable bathroom (restroom) surfaces and fixtures around the home, in schools, hospitals and other health care facilities and other public places. Also effective on tough bathroom dirt and grime. Wipes away tough dirt and grime with little or no scrubbing.

Effectively cleans, shines and disinfects tile, tubs, sinks, shower doors, fixtures, toilets and other nonporous bathroom surfaces made from: porcelain, ceramic, stainless steel, chrome, glass, synthetic marble and Formica® laminated plastic surfaces. For all other surfaces, test on a small hidden area before use. May discolor painted surfaces, including decorative tile and colored grout. Does not harm most bathroom surfaces. Great on washable surfaces such as porcelain, stainless steel, synthetic marble, tile, plastic and vinyl. For other surfaces, spot test in an inconspicuous area. May etch some older sinks and tubs. Contains no abrasives or bleach. Safe for septic tanks.

Shower Doors or Curtains	Tubs and Tile	Vanity Tops, Sinks & Chrome
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Lysol® Brand Disinfectant S.A. Cleaner meets AOAC Germicidal Spray standards for hospital disinfectants.

Lysol® Brand Disinfectant S. A. Cleaner is a convenient disinfectant cleaner that you can use straight from the bottle.

Lysol® Brand Disinfectant S.A. Cleaner, cleans, shines and disinfects most nonporous bathroom surfaces and leaves your bathroom with a fresh and clean scent.

**DIRECTIONS FOR USE**

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

**GENERAL BATHROOM CLEANING:** Apply LYSOL® Brand Disinfectant S.A. Cleaner straight from the bottle onto a damp sponge or pour directly onto surfaces, then wipe clean. On painted surfaces, test a small area. Not recommended for use on acrylic plastics.

**TO CLEAN:** Turn nozzle to desired position. Spray 6-8 inches from (Apply on) surface to be cleaned until thoroughly wet. Wipe off with clean cloth or sponge. For stubborn stains, allow 15-20 seconds before wiping.

**TO DISINFECT:** If surface are visibly dirty, follow cleaning directions first; then spray on (apply on) surface until thoroughly wet. Leave for 10 minutes. Wipe with a damp cloth or sponge.

**FOR MOLD AND MILDEW CONTROL ON NONPOROUS SURFACES:** Spray on surface until thoroughly covered with foam. Let stand for 3 minutes. Wipe with damp cloth or sponge. Reapply as necessary.

**KILLS HIV-1 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 LYSOL® Brand Disinfectant S.A. Cleaner.

**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.

**DIRECTIONS FOR REFILL BOTTLE:** remove trigger sprayer from empty LYSOL® BRAND DISINFECTANT S.A. CLEANER. Unscrew cap on refill and pour contents into empty bottle. Replace trigger sprayer and use as you normally would.

Refill container only with LYSOL ® BRAND DISINFECTANT S.A. CLEANER

Alternate for refill bottle  
TO REFILL LYSOL ® BRAND DISINFECTANT S.A. CLEANER

REMOVE	POUR	USE
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- 1. REMOVE:** Remove trigger sprayer from empty LYSOL® Brand Disinfectant S.A. Cleaner.
- 2. POUR:** Unscrew cap on refill and pour contents into empty bottle
- 3. USE:** Replace trigger sprayer and use as you normally would

LYSOL® Brand Disinfectant S.A. Cleaner can also be used straight from this refill.

**Optional Non-disinfectant related bullets/bursts/sentences:**

- New [improved]
- No scrubbing
- Cleans without bleaching
- Contains no bleach
- Ready to use
- Bath time is no time for germs

Note: Bracketed[] information is optional text. Text separated by a comma(,) denotes and/or options.

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**Optional Non-disinfectant related bullets/bursts/sentences  
Continued:**

One step cleaner  
Cleans with a shine  
An efficient way to clean  
Eliminate [Remove] odors  
Cleans and shines  
Pleasant fragrance  
Leaves your bathroom smelling clean and fresh  
Prevents mold and mildew growth

**Removes and Cleans:**

Dirt  
Soap Scum  
Bathtub ring  
Cleans limescale  
Cleans Hard Water stains

**Surfaces for Disinfecting, Cleaning and Shinning:**

Use this product on all [washable] hard non-porous surfaces that can be found in home, houses, apartments, boats, schools, hospitals, health care facilities, public places, RVs, trallers, public restrooms, planes, trains, including:

Tile, tubs, sinks, shower doors, fixtures, toilets and other nonporous bathroom surfaces made form: porcelain, ceramic, stainless steel sinks, chrome, glass, synthetic marble and Formica® laminated plastic surfaces

10 710

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

**WARNING:** CAUSES EYE IRRITATION. DO NOT GET IN EYES ON SKIN OR ON CLOTHING. WASH THOROUGHLY WITH SOAP AND WATER AFTER HANDLING.

**FIRST AID:** If in eyes, 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 occurs.

**STORAGE/DISPOSAL:** Store in areas inaccessible to small children. Rinse empty container thoroughly and discard.

**Important Facts:**

Contains no phosphates

This bottle is made of 25% post-consumer recycled plastic.

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

If the last portion of cleaner is difficult to dispense, turn trigger 180° to face opposite directions.

Questions? Comments? Call 1-800-228-4722  
Reckitt & Colman Inc. Wayne, NJ 07474-0977

EPA REG. NO. 675-55

EPA EST. NO. 8791-MO-1; 09019-OH-002; 777-NJ-2