

July 8, 2003

Mr. Sean McNear  
Senior Regulatory Affairs Specialist  
Reckitt Benckiser Inc.  
1655 Valley Road  
Wayne, NJ 07474-0943

Subject: **Lysol® Brand Disinfectant S.A. Cleaner**  
EPA Registration Number 675-55  
Letter Dated May 2, 2003

Dear Mr. McNear:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended is acceptable with the following comments:

**Proposed Amendment**

- revised labeling per EPA letter dated 10/29/2002.

**General Comments:**

Since this product is being used in hospital and other health own facilities, the statement must be included on the label:

"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 for 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 percle ~~sterilize~~ **sterilize** contaminate critical or semi-critical

SYMBOL	medical	devices prior	to sterilization	or high level disinfection."				
SURNAME								
DATE								

Refer to PR Notice 94-4 for detailed information.

- 2. With respect to precautionary statement heading, the heading letters must be in the same type size, large bold letters.

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Drusilla Copeland at (703) 308-6224.

Sincerely,

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

enclosure:

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

Country Scent®/Fresh Scent™/Original Scent™/Lemon Scent/Pacific  
Fresh/Summer Breeze Scent, Green Apple

Tuberculocidal	Antibacterial Action
Mildewstatic	Deodorizes
Virucidal*	Disinfects
	Hospital Disinfectant

DISINFECTS AS IT CLEANS  
TOUGH ON SOAP SCUM  
TOUGH ON LIMESCALE  
TOUGH ON HARD WATER STAIN

GOODHOUSE KEEPING  
SEAL

Contains No Abrasives or Bleach  
(Deodorizes), 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.  
Cleans and Prevent Mold and Mildew  
Removes Soap Scum  
Cleans, deodorizes & (and) disinfects

**Active Ingredient**

Citric Acid .....	2.50%
<b>Inert ingredients **</b> .....	<u>97.50%</u>
<b>Total</b> .....	100.00%

\*\* (Includes detergents and other grease cutting agents)

KEEP OUT OF REACH OF CHILDREN

**WARNING:** SEE BACK PANEL FOR ADDITIIONAL PRECAUTIONARY  
STATEMENTS

Net Contents	17 FL. OZ. (1PT. 1 FL. OZ.)	502 mL
<b>ACCEPTED</b>	24 FL OZ. (1PT. 8 FL. OZ.)	709 mL
<b>with COMMENTS</b>	29.3FL. OZ. (1PT. 13.3 FL. OZ.)	866.5 mL
<b>EPA Letter Dated:</b>	32 FL. OZ. (1 QTS.)	946 mL
	64 FL. OZ. (2 QTS.)	1.89 L
<b>JUL 8 2003</b>	128 FL. OZ. (4 QTS.)	3.78 L
	144 FL. OZ. (1.125 gallons)	4.25 L

Product of ...  
EPA Reg. No. 675-55

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

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

- Cleans  
Tough on soap scum, limescale and hard water stains. No scrubbing or rinsing required.
- Deodorizes  
Eliminates odors [caused by bacteria and germs]. Leaves your bathroom smelling clean and fresh.
- Disinfects  
Kills germs, bacteria, viruses and fungi while it cleans tough bathroom messes.
- Does not harm most bathroom surfaces  
Contains no abrasives or bleach. Great on surfaces such as porcelain, stainless steel fixtures, glazed tile, laminated plastic and vinyl. For other surfaces, spot test in an inconspicuous area.

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 hard nonporous inanimate environmental bathroom surfaces made from: glazed porcelain, glazed ceramic, stainless steel (Non-medical), chrome (Non-medical), glass, synthetic marble and laminated plastic surfaces.

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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 glazed porcelain, stainless steel sinks, synthetic marble, tile, plastic and vinyl. For other surfaces, test in an inconspicuous area.*

*Effectively cleans hard nonporous inanimate environmental surfaces made from: glazed porcelain, glazed ceramic, stainless steel (Non-medical), chrome (Non-medical), glass, synthetic marble and 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.

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

On hard nonporous inanimate environmental surfaces, this product kills the following bacteria, fungi and viruses such as:

**Bacteria:**

Mycobacterium tuberculosis var bovis BCG  
Stapylococcus 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 WA (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 10% fetal bovine serum

**Sanitization Claims:**

(Kills the following organisms in 30 seconds on hard, non-porous surfaces)

Escherichia coli (E. coli) (E. coli 0157:H7)  
Staphylococcus aureus (staphylococcus)  
Staphylococcus aureus (MRSA)  
Enterococcus aerogenes  
Enterococcus faecalis (VRE)  
Rhinovirus Type 39  
Rotavirus Wa

Lysol ® Brand Disinfectant S.A. Cleaner (effectively) cleans, shines and disinfects washable bathroom (restroom) hard nonporous inanimate environmental 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 hard nonporous inanimate environmental bathroom surfaces made from: glazed porcelain, glazed ceramic, stainless steel (Non-medical), chrome (Non-medical), glass, synthetic marble and 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.

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Great on washable surfaces such as porcelain, stainless steel (Non-medical), 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. Will not harm 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 ("ON") (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:** (Apply on) (Spray on) surface until thoroughly (covered with foam) (wet). 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

<p style="text-align: center;"><b>REMOVE</b></p>	<p style="text-align: center;"><b>POUR</b></p>	<p style="text-align: center;"><b>USE</b></p>
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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  
Removes Soap Scum  
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  
Not recommended for Natural Marble  
Meets the requirements of the OSHA Bloodborne Pathogen Standard for Decontamination

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**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 nonporous inanimate environmental surfaces that can be found in home, houses, apartments, boats, schools, hospitals, health care facilities, public places, RVs, trailers, public restrooms, planes, trains, including:

Tile, tubs, sinks, shower doors, fixtures, toilets and other nonporous bathroom surfaces made from: glazed porcelain, glazed ceramic, stainless steel sinks, chrome (Non-medical), glass, synthetic marble and laminated plastic surfaces.

**Alternate Language for Sanitization Claims**

- 1a) Kills [Eliminates] 99.9% of [Bacteria] [viruses] [germs] on hard, non-porous surfaces in seconds.\*
- 1b) Eliminates [kills] 99.9% of [Bacteria] [viruses] [germs] on hard, non-porous surfaces in 30 seconds.\*
- 1c) Kills [Eliminates] [Bacteria] [Viruses] [Germs] on hard, non-porous surfaces in seconds.\*
- 1d) Kills [Eliminates] [Bacteria] [Viruses] [Germs].

**Additions to Back Label**

- 1a) Kills [Eliminates] 99.9% of [Bacteria] [Viruses] [Germs] on hard, non-porous surfaces in 30 seconds.\*
- 1b) Eliminates [Kills] 99.9% of [the] [Bacteria] [Viruses] [Germs] on hard, non-porous surfaces in 30 seconds.\*
- 1c) Kills [Eliminates] [Bacteria] [Viruses] [Germs] on hard, non-porous surfaces in seconds.\*
- 1d) Kills [Eliminates] [Bacteria] [Viruses] [Germs] on hard, non-porous surfaces.

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2a) Sanitize/Deodorize: For hard, non-porous bathroom [restroom] surfaces such as tile, tubs, sinks, shower doors, fixtures, toilets, and other hard, nonporous environmental bathroom surfaces made from: glazed porcelain, glazed ceramic, stainless steel, chrome, glass, synthetic marble, and laminated plastic. Spray surface until thoroughly wet. Let stand 30 seconds before wiping. For heavily (visibly) soiled surfaces, clean first according to GENERAL BATHROOM CLEANING directions.

2b) For hard, non-porous bathroom [restroom] surfaces such as glazed tile, tubs, sinks, shower doors, fixtures, toilets, and other hard, non-porous environmental bathroom surfaces made from: glazed porcelain, glazed ceramic, stainless steel, chrome, glass, synthetic marble, laminated plastic.

Spray until thoroughly wet.

To Sanitize/deodorize: Let stand for 30 seconds before wiping.

To Disinfect/deodorize: Let stand for 10 minutes before wiping.

For heavily (visibly) soiled areas, a pre-cleaning is required.

3) Fast Acting Sanitizer

4) \*Kills [Eliminates] 99.9% of Escherichia coli (E. coli) (E. coli 0157:H7), Staphylococcus aureus (staphylococcus), Staphylococcus aureus (MRSA) Enterococcus aerogenes, Enterococcus faecalis (VRE), Rhinovirus Type 39 and Rotavirus Wa on hard, non-porous surfaces in 30 seconds.

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**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.

<b>FIRST AID</b>	
<b>If in eyes</b>	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>Contact Information</b>	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-228-4722	

**STORAGE/DISPOSAL**

(For sizes 1 gallon or less):

Store in areas inaccessible to small children. Rinse empty container thoroughly and discard.

**STORAGE/DISPOSAL**

(For sizes over one gallon):

Do not contaminate water, food, or feed by storage and disposal.

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

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional office for guidance.

**CONTAINER DISPOSAL:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(For sizes 5 gallons or more)

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

**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.

Visit us at [www.reckittprofessional.com](http://www.reckittprofessional.com)

Reckitt Benckiser Professional (Logo)

Questions? Comments? Call 1-800-228-4722

Or visit us at [www.lysol.com/info](http://www.lysol.com/info) or ([www.lysol.com](http://www.lysol.com))

Reckitt Benckiser Inc. Wayne, NJ 07474-0977

EPA REG. NO. 675-55

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