

675-55

2/23/2005

Page 1 of 12

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

February 23, 2005

Mary C. Pisculli
Regulatory and Registration Compliance Associate
Reckitt Benckiser Inc.
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NJ 07054-0225

Subject: Lysol Disinfectant S.A: Cleaner
EPA Registration Number 675-55
Application Date: November 22, 2004
EPA Received Date: November 26, 2004

Dear Ms. Pisculli:

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

Proposed Amendment

- Revised labeling

Conditions

Revise the label as follows:

- The following terms must not be used in connection with FIFRA claims:
 - Advanced
 - Outdoor
 - Unique
 - Unbeatable
 - Quick & Easy

CONCURRENCES

SYMBOL	273-05							
URNAME	Shay							
DATE	7/10/05							

0712

-Super, Mega
-Eradicates

2. On Page 2, delete the phrase “(and other)(public places).” Use sites must be specific and this phrase is too broad.
3. On Page 5, delete the phrase “...(illness causing)...” from the label. The claim is considered FDA related and therefore must be deleted from the label.

General Comments

A stamped copy of the labeling accepted with conditions 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.

Sincerely,



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

3 7 12

<< Front Panel >>

ACTIVE INGREDIENT:

Citric Acid 2.50%

OTHER INGREDIENTS: 97.50%

TOTAL: 100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING: See back (side) panel for additional precautionary statements

NET CONTENTS:	17 FL. OZ.	(1 PT. 1 OZ.)	(502 mL)
	24 FL. OZ.	(1 PT. 8 OZ.)	(709 mL)
	29.3 FL. OZ.	(1 PT. 13.3 OZ.)	(866 mL)
	32 FL. OZ.	(1 QT.)	(946 mL)
	64 FL. OZ.	(2 QT.)	(1.89 L)
	128 FL. OZ.	(1 GAL.)	(3.79 L)
	144 FL. OZ.	(1.125 GAL.)	(4.25 L)

<< Front or Back Panel >>

EPA Reg. No.: 675-55

EPA Est. No.: 8791-MO-1

09019-OH-2

777-NJ-2

See bottom or side (for Lot/Date code)

<< Back Panel >>

Questions? Comments? Call: (1-800-228-4722) (1-800-677-9218)

(or) Visit us at (www.lysol.com) (www.reckittprofessional.com)

Made in U.S.A. © RBI (year)

Distributed by: Reckitt Benckiser Inc., Parsippany, NJ 07054(-xxxx)

<< Back Panel – Optional text >>

Monday – Friday, 8:45 am – 4:30 p.m. [Eastern time]

Company Logo (Reckitt Benckiser Professional)

Graphic Symbol (Hospital Disinfectant – Meets AOAC Standards)

Recycle Symbol

ACCEPTED
with COMMENTS
EPA Letter Dated:

FEB 23 2005

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

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The product label must identify the specific bacteria, virus, fungus & mold.

<< Front or Back Panel - Marketing / Product Performance claims – use as bullet point or in paragraph format >>

(Country) (Fresh) (Green Apple) (Lemon) (Original) (Pacific Fresh) (Summer) (Summer Fresh)
(Breeze) (Scent) (Fragrance) (Unfragranced) (Unscented) (New & Improved Fragrance)
(New & Improved Scent) (Good Housekeeping seal)

(Advanced) (Antibacterial Action) (Best) (Complete) (Improved) (New) (Unbeatable) (Unique) Formula

An effective disinfectant cleaner on (non-food contact surfaces) and deodorant (for use in the)
(bathroom) (restroom).

An effective disinfectant cleaner (on non-food contact surfaces) and deodorant for use on {insert use sites}.

Contains no abrasives (or bleach) (or harsh acids) (so it won't scratch surfaces)

Contains no phosphates

Convenient Trigger Spray

Easy to use

Economy size

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

For a cleaner, fresher household

(Still) Great for (bathrooms) (restrooms)

Great on {insert surfaces}

Important facts (about this product):

Leaves no sticky residue

Leaves your (bathroom) (restroom) smelling clean and fresh.

Meets AOAC Germicidal Spray Test Standards

No scrubbing (or streaking) (or filming)

Non-abrasive formula (will not scratch surfaces)

Part of your infection control program

Pleasant fragrance

Protect your family from germs with LYSOL® Brand Disinfectant products.

Quick & Easy

Ready to use

Starts to work before you do

(Super) (Mega) (Great) Value

This (bottle) (container) is made of x% post-consumer recycled plastic.

Use this product on all washable hard non-porous inanimate environmental surfaces that can
be found in {insert use sites}.

Versatile

Wipes away dirt and grime with little or no scrubbing.

Works on a wide range of (bathroom) (restroom) surfaces.

(This product) cleans, shines and disinfects most non-porous (bathroom) (restroom) surfaces (and leaves
your (bathroom) (restroom) with a fresh and clean scent).

(This product) effectively cleans, shines and disinfects washable (bathroom) (restroom) hard
non-porous inanimate environmental surfaces and fixtures (around the home), (in schools),
(hospitals) (health care facilities) (and other) (public places). (Also effective on tough
(bathroom) (restroom) dirt and grime).

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<< Front or Back Panel - Cleaning claims – use as bullet point or in paragraph format >>

An efficient way to clean

Antibacterial cleaning power (on hard, non-porous surfaces) (for) (bathrooms) (restrooms).

Brilliant (streak-free) (glistening) (sparkling) shine

Cleans and prevents mold and mildew

Cleans everyday (bathroom) (restroom) messes.

Cleans (shines) (deodorizes) (disinfects)

Cleans the toughest (soap scum) (grease) (and grime) (mold and mildew stains)

Cleans to a brilliant shine

Cleans tough (soap scum) (grease) (and grime) (mold and mildew stains)

Cleans tough messes fast

Cleans without bleaching

Cuts cleaning time

Cuts (Cleans) greasy dirt (and) (soap scum) (bathroom soils)

Cuts grease and grime

Deep Down Clean!

Destroys (Eradicates) (tough) (soap scum) (mold and mildew)

Foams and clings on tough soap scum

Fresh Clean Scent!

Good for (everyday cleaning) (your toughest (bathroom) stains)

Great for everyday use (in) (bathrooms) (restrooms)

Good for most indoor and outdoor cleaning tasks

Makes your cleaning job easier (in the) (bathroom) (restroom).

No scrubbing or rinsing required

(The) One-step cleaner

Penetrates deep beneath the surface

Powers (Cuts) through tough soap scum (mold) and (mildew)

Powers through your toughest cleaning jobs.

Removes and cleans: {insert soils}

Removes mold and mildew at the root

Removes (tough) soap scum

The most powerful (bathroom) (restroom) cleaner you can buy.

Tough on hard water stains (limescale) (soap scum) (mold and mildew)

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<< Front or Back Panel – Sanitizing non-food contact surface claims – >>

(Sanitizer) (Sanitizes)

Fast Acting Sanitizer

Kills (Eliminates) 99.9% of germs***

Kills (Eliminates) 99.9% of (bacteria) (viruses) (germs) on hard, non-porous surfaces in seconds.***

Kills (Eliminates) 99.9% of (bacteria) (viruses) (germs) on hard, non-porous surfaces in 30 seconds.***

Kills (Eliminates) 99.9% of germs in 30 seconds.***

Kills (Eliminates) (bacteria) (viruses) (germs) on hard, non-porous surfaces in seconds.***

Leaves (household) (bathroom) (restroom) surfaces sanitary.

One step cleaning and sanitizing

Sanitizes (household) (bathroom) (restroom) surfaces in 30 seconds.***

<< Back Panel – Sanitizing claim qualifier >>

***Kills (Eliminates) 99.9% of {insert 'E & F' organisms} on hard, non-porous surfaces in 30 seconds.

***Kills 99.9% of the following germs in 30 seconds: {insert 'E & F' organisms}

<< Front or Back Panel – Disinfecting & Deodorizing claims – use as bullet point or in paragraph format >>

(Antibacterial Action) (Deodorizer) (Deodorizes) (Disinfects) (Hospital Disinfectant) (Mildewstatic)
(Tuberculocidal) (Virucidal[†])

Disinfects as it cleans.

Effective: Cleans, shines, deodorizes and disinfects washable (bathroom) (restroom) surfaces
and fixtures.

Effectively cleans, shines and disinfects (washable non-porous surfaces in) {insert use sites}

Eliminates (Removes) odors

Eliminates odors caused by (bacteria*) (germs**) (mildew).

Kills Athlete's Foot Fungus in the (bathroom) (restroom)

Kills (Disinfects) common (household) (germs**) (bacteria*) (viruses[†]) (fungi*) without bleaching.

Kills (Eliminates) (bacteria*) (viruses[†]) (germs**)

Kills Germs**

Kills germs** that ordinary cleaners don't.

Kills germs** while it cleans.

Kills (germs**) (bacteria*) (viruses[†]) (and) (fungi*) while it cleans tough (bathroom) (restroom) messes.

Kills germs** and controls the (spread) (growth) of fungi and mold.

Kills (household) bacteria* (and sanitizes without bleaching).

Kills odor-causing bacteria* (in the) (bathroom) (restroom).

Kills Echovirus Type 12, Hepatitis A, Herpes Simplex Virus Type 1 & 2, Influenza A₂ [Japan 305/57],
Poliovirus Type 1 and Rotavirus WA in 5 minutes.

Kills Rhinovirus Type 39 and Rotavirus WA in 30 seconds.

On hard, non-porous, inanimate environmental surfaces this product kills the following (germs**)
(bacteria*) (fungi*) (viruses[†]): {insert 'A – B – C' organisms}

Prevents (Controls) mold and mildew growth.

Prevents the spread of harmful (illness-causing) (household) germs**.

(The one step cleaner) (The two-job cleaner) that kills (common household) germs** (bacteria*) (viruses[†])
(fungi*) while it cleans (tough) (everyday) (bathroom) (household) messes.

(This product) meets the requirements of the OSHA Bloodborne Pathogen Standard for Decontamination.

(This product) meets AOAC Germicidal Spray efficacy standards for hospital disinfectants.

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The product label must identify the specific bacteria, virus, fungus & mold.

<< Back Panel - Use directions – IMPORTANT: Advisory statements must be included were appropriate >>

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

General (Bathroom) (Restroom) Cleaning: Apply (this product) straight from the bottle onto a damp sponge or pour directly onto surfaces, then wipe clean.

To Clean: Turn nozzle to ("ON") (desired) position. Spray surface until thoroughly wet. Wipe off with clean cloth or sponge. For stubborn stains, allow 15-20 seconds before wiping.

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

For Mold & Mildew Control on Non-porous Surfaces: (Apply on) (Spray) surface until thoroughly (covered with foam) (wet). Let stand for 3 minutes. Wipe with damp cloth or sponge. Reapply as necessary.

To Sanitize / Deodorize: For hard, non-porous (bathroom) (restroom) surfaces, spray surface until thoroughly wet. Let stand 30 seconds before wiping. For heavily (visibly) soiled surfaces, clean first according to cleaning directions.

To Sanitize / Deodorize / Disinfect: For hard, non-porous (bathroom) (restroom) surfaces, spray until thoroughly wet. **To Sanitize:** Let stand for 30 seconds before wiping. **To Disinfect:** Let stand for 10 minutes before wiping. For heavily (visibly) soiled areas, (a) pre-cleaning is required.

To Refill Bottle: Remove trigger sprayer from empty (bottle) (container). Unscrew cap on refill and pour contents into empty (bottle) (container). Replace trigger sprayer and use as you normally would. Refill container only with (this product).

To Refill:

1. REMOVE: Remove trigger sprayer from empty (bottle) (container).
2. POUR: Unscrew cap on refill and pour contents into empty (bottle) (container).
3. USE: Replace trigger sprayer and use as you normally would.

(This product) can also be used straight from this refill.

<< Advisory Statements >>

Does not harm most (bathroom) (restroom) surfaces

Will not harm septic tanks.

On painted surfaces, test a small area.

Not recommended for use on acrylic plastics.

For other surfaces, spot test in an inconspicuous area.

For all other surfaces, test on a small hidden area before use.

May etch some older sinks and tubs.

Should not be used on marble surfaces.

May discolor painted surfaces, including decorative tile and colored grout.

Not recommended for natural marble.

If the last portion of cleaner is difficult to dispense, turn trigger 180° (degrees) to face opposite direction.

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<< Back Panel >>

<< IMPORTANT: All organisms must be identified by genus & species.
Abbreviations may be included but must appear in (parens). >>

<< Hard non-porous surfaces >>

<< A. Disinfection against Bacteria >>

Campylobacter jejuni
Enterococcus faecalis
Enterococcus faecium
Escherichia coli 0157:H7 (E.coli 0157:H7)
Mycobacterium tuberculosis var bovis [BCG]
Pseudomonas aeruginosa (Pseudomonas)
Salmonella choleraesuis (Salmonella)
Staphylococcus aureus (Staph)
Streptococcus pyogenes (Strep)

<< B. Disinfection against Virus >>

Adenovirus Type 2
Echovirus Type 12
Hepatitis A
Herpes Simplex Virus Type 1 & 2
Human Immunodeficiency Virus Type 1 [HIV-1] [AIDS Virus]
(HIV-1 was tested in the presence of 10% Fetal bovine serum)
Influenza A₂ [Japan 305/57]
Parainfluenza Type 2
Poliovirus Type 1
Respiratory Syncytial Virus (RSV)
(- an important cause of ear infections in children)
(- the leading cause of lower respiratory infection in children)
Rhinovirus Type 39
(- the leading cause of the common cold)
Rotavirus WA
(- the leading cause of infectious diarrhea in children)

<< C. Disinfection against Fungi >>

Trichophyton mentagrophytes (Athlete's Foot Fungus)

<< D. Fungistatic against Fungi >>

Aspergillus niger (mold & mildew)

<< E. *** Sanitization against Bacteria >>

Enterobacter aerogenes
Enterococcus faecalis [VRE]
Escherichia coli 0157:H7 (E. coli 0157:H7)
Staphylococcus aureus (Staphylococcus)
Staphylococcus aureus [MRSA] (Staphylococcus MRSA)

<< F. *** Sanitization against Virus >>

Rhinovirus Type 39
Rotavirus WA

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<< Back Panel >>

<< Soil / Surface / Use Site - May be listed on product label in plural form >>

Soils: (Graphic – depicting soil)

Bathtub Rings	Grime	Mud	Smudges
Dirt	Hard Water Stain	Outdoor Grime	Tough Soil
Fingerprint	Limescale	Pet Stain	
Grease	Mildew Stain	Soap Scum	

Surface Types:

Chrome [^]	Glass	Laminated Plastic	Synthetic Marble
Crystal	Glazed Ceramic	Linoleum	Stainless Steel [^]
Enamel	Glazed Porcelain	Metal	Vinyl
Fiberglas			

[^]Non-Medical or Fixture

Surfaces: (Graphic – depicting use site)

Appliance Exterior	Floor (Linoleum)	Plastic Laundry Basket (Hamper)
Bathtub (Tub)	Floor (No-wax)	Shelves (Drawers)
Cabinet	Floor (Vinyl)	Shower Door
Changing Table	Garbage Can (Pail)	Shower Stall (Area)
Counter (Countertop)	Glazed Ceramic Tile	Sink (Basin)
Crib	Glazed Porcelain Tile	Stove (Stovetop)
Diaper Pail	Highchair (non-food contact area)	Table (Tabletop)
Door Knob (Handle)	Light Fixture	Toilet Bowl Exterior / Urinal
Exhaust Fan (Hood)	Metal Blinds	Vanity Top
Fixture (Chrome)	Non-medical (Chrome)	Washable Wall
Fixture (Stainless Steel)	Non-medical (Stainless Steel)	Window (Windowsill)
Floor (Glazed Ceramic Tile)	Painted Woodwork	Other hard, non-porous surfaces

Household Use Sites: (Graphic – depicting use site)

Basement	Den / Study	Home / House	Playroom
Bathroom	Family Room	Kitchen	Other Household Areas
Bedroom	Garage	Living Room	

Professional Use Sites: (Graphic – depicting use site)

Cafeteria	Health Care Facility	Nursing Home	Restroom
Day Care Center	Hospital	Office Building	School
Dental Office	Hotel / Motel	Physicians Office	Other Public Places
Doctors Office	Infirmary	Restaurant	

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<< Back Panel - IMPORTANT: The following is required for professional products making claims against: >>

<< Human Immunodeficiency Virus Type 1 [HIV-1] [AIDS Virus] >>

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 this product.

CONTACT TIME: Allow surface / object 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.

<< Terminal Sterilant Statement – qualified metal surfaces >>

This product is not for use on critical & semi-critical medical devices or medical equipment surfaces.

<< Terminal Sterilant Statement – unqualified metal surfaces >>

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 enters normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

<< Back Panel >>

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	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a Poison Control Center or doctor for treatment advice.
CONTACT NUMBER	
Questions? Comments or In case of an emergency, call toll free (1-800-228-4722) (1-800-677-9218). Have the product container or label with you when calling a Poison Control Center, or doctor, or going for treatment.	

<< Storage and Disposal language – Household containers >>

STORAGE AND DISPOSAL: Store in areas inaccessible to small children. Rinse empty container thoroughly and discard in trash or recycle.

<< Storage and Disposal language – Professional containers 1 gallon or less >>

STORAGE AND DISPOSAL

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

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

DISPOSAL: Rinse empty container thoroughly and discard in trash or recycle.

<< Storage and Disposal language – Professional containers greater than 1 gallon >>

STORAGE AND DISPOSAL

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.

<< Environmental Hazard language – Professional (container sizes 5 gallon or larger) >>

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

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