

777-71

6-8-2005

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN - 8 2005

Ms. Liane Stocky
Regulatory & Registration Compliance Associate
Reckitt Benckier, Inc.
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NY 07054-0225

Subject: **Lysol Brand Forming Disinfectant Basin, Tub & Tile Cleaner**
EPA Registration Number 777-71
Application Dated December 20, 2004

Dear: Ms. Stocky:

The following label revisions submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, are acceptable with comments.

Proposed Amendment:

- label amendment

Efficacy Review:

1. The efficacy data (MRID 464313-01) to support the use of the product, Lysol Basin Tub & Tile Cleaner, as a disinfectant with virucidal activity against Rhinovirus Typ 39, strain 209 on hard, non-porous surfaces in the presence of a 10% fetal bovine serum for a contact time of 30 seconds. Complete inactivation (no growth) was indicated in the 10⁻² through 10⁻⁷ dilutions. The Agency acknowledges that only one batch of test product was performed as allowed in case of modified testing based on Agency policy for supplemental efficacy claims (i.e. virucides) using a reduced number of batches.
2. The Agency acknowledges that AppTec has provided the antibiotic resistance profile and notes that based on the information provided, the Staphylococcus aureus (ATCC 33592) used for testing had maintained its resistance over a seven year period (1993-2000).

CONCURRENCES

MBOL							
SURNAME							
DATE							

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Chemistry Review:

The study, MRID #464313-03, is partially acceptable. You must comply with the requirement, recommendations, as follows:

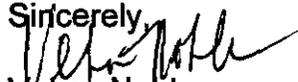
1. You must show the data that support the average calculation per batch
2. You must submit the attachments that the study reference.
3. You must meet the 40-CFR § 160.105 (a), (b), (c), (d), & (e) guidelines.

General Comments:

A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy 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 Drusilla Copeland at (703) 308-6224.

Sincerely,



Velma Noble

Product Manager (31)

Regulatory Management Branch I

Antimicrobials Division (7510C)

Enclosure: Chemistry Review dated May 5, 2005

Efficacy Review dated May 10, 2005

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<< Front Panel >>

ACTIVE INGREDIENTS:

Octyl Decyl Dimethyl Ammonium Chloride	0.050%
Diocetyl Dimethyl Ammonium Chloride	0.025%
Didecyl Dimethyl Ammonium Chloride	0.025%
OTHER INGREDIENTS:	99.900%
TOTAL:	100.000%

KEEP OUT OF REACH OF CHILDREN

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

NET WT.: 24 OZ. (1 LB. 8 OZ.) (680 g)

<< Front or Back Panel >>

EPA Reg. No.: 777-71

EPA Est. No.: 777-NJ-2

11525-IL-1; RI-1

See bottom or side (for Lot/Date code)

Federal regulations prohibit CFC propellants in aerosols.

Graphic Symbol (Contains no CFCs or other ozone depleting substances)

<< 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)

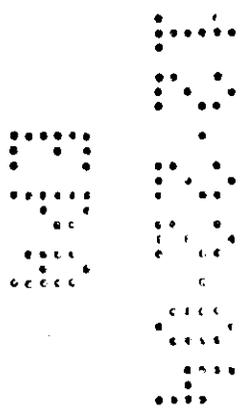
Distributed by: Reckitt Benckiser Inc., Parsippany, NJ 07054(-xxxx)

<< Back Panel – Optional text >>

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

Company Logo (Reckitt Benckiser Professional)

Recycle Symbol



ACCEPTED
with COMMENTS
EPA Letter Dated:

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
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The product label must identify the specific bacteria, virus, fungus & mold.

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

(Country) (Floral) (Fresh) (Green Apple) (Lavender) (Original) (Pacific Fresh) (Summer)
(Summer Fresh) (Breeze) (Scent) (Fragrance) (Unfragranced) (Unscented) (New) (Improved)
(New & Improved Fragrance) (New & Improved Scent)

(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)).

Clings to vertical surfaces

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

Contains no phosphates

Easy to use

Economy size

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

For a cleaner, fresher household

(Great) For use on ({insert surfaces}) (hard non-porous surfaces located in: {insert use sites}).

(Great) For use on (the following) (modern) washable surfaces ({insert surfaces}).

For any surface where germs are a concern.

For use on (medical) (lamps) (stands) (patient) (bed frames) (bedside tables) (wheelchairs) (and other
similar equipment).

Formulated for medical institution's (infection control program) needs.

(Still) Great for (bathrooms) (restrooms)

Great on {insert surfaces}

Important facts (about this product):

Leaves no (sticky) residue

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

Meets AOAC efficacy standards for hospital aerosol disinfectants.

Meets AOAC Germicidal Spray Test standards.

No scrubbing (or streaking) (or filming)

Non-abrasive formula (will not scratch surfaces)

People respect the LYSOL® brand name for providing surface disinfection (and gain the added benefit
of a clean, sanitary environment).

Pleasant fragrance

Protect your (family) (work place) from germs with (Professional) LYSOL® Brand Disinfectant products.

Quick & Easy

Ready to use

Starts to work before you do

(Super) (Mega) (Great) Value

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

(This product) is germicidal when used as directed for disinfecting.

Use this product to clean, shine and disinfect hard, non-porous washable (bathroom) (restroom)
surfaces and fixtures (around the home) (in) {insert use sites}.

Use this product to (both,) clean and disinfect non-critical hard, non-porous environmental surfaces
in all health care facilities (including dental and physician offices).

Versatile

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

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

A clean that cares.
An efficient way to clean.
Antibacterial cleaning power (on hard non-porous surfaces) for (bathrooms) (restrooms).
Brilliant (streak-free) (bright) (glistening) shine.
Cleans (Shines) (Deodorizes) (and) (Disinfects)
Cleans and disinfects (all over the house) (bathrooms) (restrooms).
Cleans (and prevents mold and mildew).
Cleans as it disinfects
Cleans everyday (bathroom) (restroom) messes.
Cleans everyday dirt and grime
Cleans the toughest (soap scum) (and grime) (mold and mildew stains).
Cleans to a brilliant shine.
Cleans tough (soap scum) (mold and mildew) (and grime).
Cleans tough messes fast.
Cleans without bleaching.
Convenient: Just spray foam onto hard, non-porous surface. Even sprays upside down.
Convenient: Just spray on to clean and wipe off. (No scrubbing or rinsing.) (Even sprays upside down.)
Cuts cleaning time
Cuts (Cleans) greasy dirt (and) (soap scum) (bathroom soils) (restroom soils)
Cuts through tough (soap scum) (and) (mold and mildew)
Deep Down Clean!
Destroys (Eradicates) (tough) (soap scum) (and grime) (mold and mildew).
Foaming Action
Foaming & Deodorizing Action
Foams and clings on tough soap scum.
Fresh Clean Scent
Good for (everyday cleaning) (your toughest bathroom stains) (your toughest restroom 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) (household) (all over the house).
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 (tough) soap scum
Removes (tough) mold and mildew (stains) (at the root).
Removes tough dirt (and grime).
The most powerful (bathroom) (restroom) cleaner you can buy.
The ultimate clean
Tough on (hard water stains) (limescale) (soap scum) (mold and mildew).
Use daily to help maintain a clean, fresh and shiny surface.

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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) (viruses) (bacteria)***

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

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

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

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

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

A disinfecting, effective (non-food contact surface) cleaner (for use in the) (bathroom) (bedroom) (and other household areas).

A disinfecting, effective (non-food contact surface) cleaner (on hard, non-porous surfaces). Controls mold and mildew growth (from its root)

Deodorizer

Disinfects as it cleans.

Effective against {insert organisms} (in 10 minutes).

Effective: Cleans, shines and disinfects.

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

Eliminates (Removes) odors

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

For disinfecting against {insert organisms} on hard non-porous surfaces.

For killing {insert organisms} on hard non-porous surfaces.

For use as a (disinfectant) (or) (sanitizer) in: {insert use sites}

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

Kills Germs**

Kills germs** that ordinary cleaners don't.

Kills germs** while it cleans.

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

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

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

Kills odor-causing germs**.

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

Removes odors from the following surfaces: {insert surfaces}.

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

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

(This product) is an effective fungicide against Trichophyton mentagrophytes (Athlete's Foot Fungus) in (locker rooms) (dressing rooms) (showers and bath areas) (and) (exercise facilities). Follow disinfection directions.

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<< 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.

Shake well before using.

(For) General (Bathroom) Cleaning: Shake well before using. Point button to mark on rim. Hold can 6-8 inches from surface to be cleaned and spray the entire surface. Press button and cover area lightly with white foam. After a few seconds, wipe off with a clean cloth or sponge. For (heavily) (visibly) soiled surfaces allow foam to remain longer on surface before wiping.

General Disinfection: Hold can 6-8 inches from surface and thoroughly saturate surface with foam. Let stand for 10 minutes. Remove excess liquid with cloth or sponge. For (heavily) (visibly) soiled surfaces, clean first according to (General) Cleaning directions.

Tuberculocidal: To kill Mycobacterium bovis BCG: Spray on pre-cleaned surface until thoroughly covered with foam. Leave on for 40 minutes. Wipe with damp cloth or sponge.

For Mold & Mildew Control on Hard, Non-porous Surfaces: Spray on surface until thoroughly covered with foam. Let stand 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 (General) 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.

<< Advisory Statements >>

Does not harm most (bathroom) (restroom) surfaces.

For other surfaces, spot test in an inconspicuous area.

Rinse all surfaces that come in contact with food with potable water before reuse.

Do not use on utensils, glasses and dishes.

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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 >>

Enterococcus faecalis
Escherichia coli 0157:H7 (E.coli 0157:H7)
Mycobacterium bovis [BCG]
Pseudomonas aeruginosa (Pseudomonas)
Salmonella choleraesuis (Salmonella)
Staphylococcus aureus (Staph)

<< B. Disinfection against Virus >>

Herpes Simplex Virus Type 1 & 2
Human Immunodeficiency Virus Type 1 [HIV-1] [AIDS Virus]
Influenza A₂ [Japan 305/57]
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 >>

Aspergillus niger (mold & mildew)
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 Viruses >>

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

Surface Types:

Chrome [^]	Glass	Hard 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)
Bed Frame	Floor (Vinyl)	Shower (Door) (Curtain)
Cabinet	Garbage Can (Pail)	Shower (Stall) (Area)
Chair	Glazed Ceramic Tile	Sink (Basin)
Changing Table	Glazed Porcelain Tile	Stove (Stovetop)
Counter (Countertop)	Highchair (non-food contact area)	Table (Tabletop)
Crib	Light Fixture	Telephone
Diaper Pail	Metal Blinds	Toilet Bowl Exterior / Urinal
Door Knob (Handle)	Microwave Exterior	Vanity Top
Exhaust Fan (Hood)	Non-medical (Chrome)	Washable Wall
Fixture (Chrome)	Non-medical (Stainless Steel)	Window (Windowsill)
Fixture (Stainless Steel)	Painted Woodwork	Other hard, non-porous surfaces
Floor (Glazed Ceramic Tile)		

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	Infirmery	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 (, for Mycobacterium bovis BCG surfaces must remain wet for 40 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.

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PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals.
CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or 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.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• 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.	

<< Physical / Chemical Hazards >>

PHYSICAL AND 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 and Disposal language – Household containers >>

STORAGE AND 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.

<< Storage and Disposal language – Professional containers >>

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.

DISPOSAL: Do not reuse empty container. Replace cap and discard in trash.
Do not incinerate or puncture.

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