

675-54

06-05-2009

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

6.5.2009

Ms. Mary Pisculli
Reckitt Benckiser
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NJ 07054-0225

Subject: Lysol Brand Heavy Duty Cleaner Disinfectant Concentrate
EPA Registration No.: 675-54
Amendment Date: March 5, 2009
EPA Receipt Date: March 9, 2009

Dear Ms. Pisculli,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with conditions listed below.

Proposed Amendment

- Add label claims, ATCC Numbers, Terminal Sterilant Statement
- Updated directions and microorganisms' nomenclature
- Update Container Disposal Statements for PR Notice 2007-4

Conditions

Revise the label as follows:

- 1) Qualify the surface, porcelain, as hard nonporous by stating "glazed" porcelain.
- 2) Revise the 12th and 14th claims on page 2 deleting the term, "recommended," to bring the statement in compliance with PR Notice 2000-5, Mandatory Labeling.
- 3) Revise the "Tough Soil Build-Up" statement on page 3 by deleting the term, recommended, to bring the statement in compliance with PR Notice 2000-5, Mandatory Labeling.
- 4) Revise the "Personal Protection" statement under the HIV directions on page 3 by deleting the term, or, and state "and" The items listed under personal protection are not optional when

cleaning blood and body fluids

CONCURRENCES

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5) Revise the "Precautionary Statements" on page 4 to be in agreement with Label Manual, 3rd Edition by stating:

Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eye wear (goggles, face shield, or safety glasses), protective clothing, and rubber gloves. May be harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash before reuse.

6) The container rule no longer separates "Storage and Disposal" by container size; it is distinguished by use pattern such as residential, industrial, institutional, or commercial. Delete the container disposal statements for containers 1 gallon or less for institutional use sites.

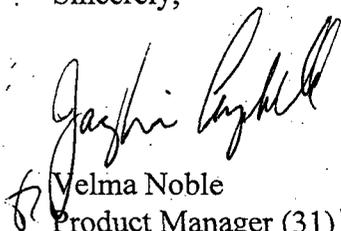
7) Add an "Environmental Hazards" section to page 4 with the statement, "This pesticide is toxic to fish, aquatic invertebrates, oysters, and shrimp."

General Comments

A stamped copy of the accepted 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 concerning this letter, please contact Jacqueline Campbell at (703) 308-6415 and Velma Noble (703) 308-6233.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

CONCURRENCES

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DATE							



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 675-54	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) LYSOL Brand Heavy Duty Cleaner Disinfectant Concentrate	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Reckitt Benckiser Morris Corporate Center IV 399 Interpace Parkway Parsippany, NJ 07054 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of (optional text additions in regards to Influenza A virus and Pandemic 2009 H1N1) per PR Notice 95-2. This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Metal Plastic Glass Paper Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Sally Hayes	Title Agent for Reckitt Benckiser, Inc.	Telephone No. (Include Area Code) (260) 244-6270
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent for Reckitt Benckiser, Inc.	
4. Typed Name Sally Hayes	5. Date 	

<< Front Panel >>

ACTIVE INGREDIENT:

Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₅) dimethyl benzyl ammonium chloride	3.44%
OTHER INGREDIENTS:	96.56%
TOTAL:	100.00%

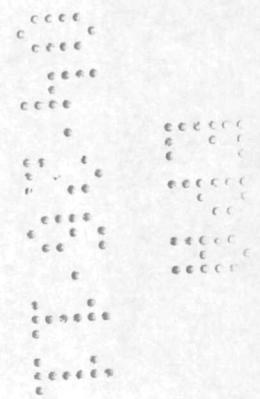
KEEP OUT OF REACH OF CHILDREN

DANGER: See back (side) panel for additional precautionary statements and first aid.

NET CONTENTS: 128 FL. OZ. (1 GAL.) 3.79 L

<< Front or Back Panel >>

EPA Reg. No.: 675-54
 EPA Est. No.: 09019-OH-001
 09019-OH-002
See bottom or side (for Lot/Date code)



<< Back Panel >>

Questions? Comments? Call: 1-800-677-9218
 (or) Visit us at www.reckittprofessional.com
 Made in U.S.A. © RBI (year)
 Distributed by: Reckitt Benckiser Inc., Parsippany, NJ 07054(-xxxx)
 Contains no phosphates
This (bottle) (container) is made of x% post-consumer recycled plastic.

<< Back Panel – Optional text >>

Company Logo (Reckitt Benckiser Professional)
Recycle Symbol
(This product) meets the requirements of the OSHA Bloodborne Pathogen Standard for Decontamination
(This product) meets AOAC Gaseous efficacy standards for hospital disinfectants
NSF certification symbol



ACCEPTED
 with COMMENTS
 in LFP Letter Dated:
 JUN 5 2009
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide is,
 registered under LFP No. No
 675-54

NOTE: Bracketed information is denoted as: << directive >>, [insert as noted], (optional text), { required qualifier }.
 The term "this product" used throughout this document may be replaced with the marketed product brand name.
 To use the term "germ" the product must be efficacious against 2 of the 3 major classes of organisms.
 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 >>

For Hospital and Institutional Use
Disinfects & Deodorizes
Cuts through Tough Soils
Non-Abrasive
Fresh Citrus Lime Scent
(Deodorizer) (Fungicide) (Virucide*)
Kills odor-causing bacteria and fungi
Controls the growth of mold and mildew
Deodorizes with a fresh citrus lime fragrance

(This product) is a one-step disinfectant cleaner that kills *Staphylococcus aureus* and *Streptococcus pyogenes*, *Trichophyton mentagrophytes* (Athlete's Foot Fungus) and controls (inhibits) the growth of mold and mildew and the odors they cause on hard, non-porous environmental surfaces. Its deep cleaning action penetrates tough soils including body oils and soap scum, yet it contains no harsh abrasives. The non-acid formula removes even stubborn bathtub rings and leaves a clean, fresh scent.

(This product) has been formulated to thoroughly clean, disinfect and deodorize tub and shower areas and other hard, non-porous surfaces in hotels, motels, hospitals, nursing homes, health clubs, day care centers, dental offices and other health care facilities; including: glazed ceramic bathroom tile, sinks, toilet bowls and surfaces, garbage cans, bathtubs, shower stalls, chrome and clear acrylic plastic fixtures, porcelain, glazed ceramic tile floors.

(This product) is recommended for use as a Bathroom Disinfectant on hard, non-porous (environmental) surfaces in:

- Day Care Centers
- Hospitals
- Physician's Office
- Dental Offices
- Hotels / Motels
- Restaurants
- Doctor's Office
- Nursing Homes
- Restrooms
- Health Care Facility
- Office Buildings
- School (College)

(This product) disinfects hard, non-porous (environmental) surfaces such as:

- Acrylic Plastic Fixtures
- Glazed Ceramic (Tile)
- Bathtub / Shower (Area)
- Glazed Porcelain (Tile)
- Chrome / Stainless Steel Fixtures
- Sink
- Counters
- Toilet Bowl

(This product) is not recommended for use on polished marble. For other hard, inanimate surfaces, spot test in an inconspicuous area.

BACTERICIDAL – FUNGICIDAL – VIRUCIDAL*

(Test culture with 5% blood serum. Use-dilution in 400 ppm hard water.)

Kills the following (germs) (microorganisms):

Bacteria

- *Acinetobacter calcoaceticus*
- *Pseudomonas aeruginosa*
- *Brevibacterium ammoniagenes*
- *Salmonella enterica*
- *Burkholderia cepacia*
- *Salmonella paratyphi*
- *Corynebacterium diphtheriae*
- *Salmonella schottmuelleri*
- *Enterobacter aerogenes*
- *Salmonella typhi*
- *Enterococcus faecalis*
- *Serratia marcescens*
- *Escherichia coli O157:H7*
- *Shigella dysenteriae*
- *Klebsiella pneumoniae*
- *Staphylococcus aureus*
- *Neisseria elongata*
- *Staphylococcus aureus (MRSA)*
- *Proteus mirabilis*
- *Streptococcus pyogenes*
- *Proteus vulgaris*
- *Streptococcus salivarius*

Viruses*

- Herpes Simplex Virus Type 1 & 2
- Human Immunodeficiency Virus Type 1 (AIDS Virus)
- Influenza A₂ Virus (Japan 305/57)
- Respiratory Syncytial Virus (RSV)
- Rotavirus WA

Fungi

- *Aspergillus niger*
- *Candida albicans*
- *Trichophyton mentagrophytes*

<< Terminal Sterilant Statement – qualified metal surfaces >>

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

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

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

(This product) is a concentrate. Always dilute in accordance with label instructions.

For General Cleaning:

Light Soil: Use a 1:32 solution for routine maintenance when heavy soil build-up is not a problem.

Medium Soil: Use solution of 1:8 to 1:16 for areas of moderate soil.

Tough Soil Build-Up: For stubborn soil or heavy build-up, such as soap scum and body oils on bathtubs / shower walls, a solution of 1:4 is recommended.

For General Disinfection: Remove heavy soil and gross filth prior to disinfection as per General Cleaning instructions.

For broad spectrum disinfection, dilute 1:32 in water [1/2 cup per gallon], apply with cloth or sponge and thoroughly wet surface for 10 minutes, then remove excess. ** For Pseudomonacidal activity in Hospitals and other Health Care facilities dilute 1:8.

To Control Mold & Mildew: Clean surfaces first. Using a 1:32 dilution wet surfaces, let stand 10 minutes, then remove excess. Repeat application weekly or when needed.

For Cleaning and Disinfecting Toilet Bowls: Prior to disinfection, remove all heavy soil and flush toilet. Add 4 oz. of (this product) full strength into the bowl water [1:25 dilution]. Thoroughly brush all bowl surfaces and under the rim. Let stand 10 minutes and then flush.

DILUTION CHART		
To prepare proper dilutions, add (this product) full strength to water as below.		
Dilution Ratio	(This product)	Water
1:32	1 oz.	1 Quart (32 oz.)
	4 oz.	1 Gallon (128 oz.)
1:16	2 oz.	1 Quart (32 oz.)
	8 oz.	1 Gallon (128 oz.)
1:8 **	4 oz.	1 Quart (32 oz.)
	16 oz.	1 Gallon (128 oz.)
1:4	8 oz.	1 Quart (32 oz.)
	32 oz.	1 Gallon (128 oz.)

** For Pseudomonacidal activity (in Hospitals and other Health Care Facilities) dilute 1:8.

Prepare a fresh solution daily and change solution frequently if heavily soiled or diluted. (This product) is proven effective in hard water (up to 400 ppm) in the presence of 5% blood serum contamination.

Proper dilution provides maximum cleaning benefits and product economy.

KILLS HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 [HIV-1 AIDS Virus] ON PRE-CLEANED 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 / body fluids; and in which the surfaces / objects likely to be soiled with blood / 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 [AIDS Virus] ON SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS:

PERSONAL PROTECTION: When handling items soiled with blood / body fluids, use disposable latex gloves, gowns, masks & eye protection.

CLEANING PROCEDURES: Blood / body fluids must be thoroughly cleaned from surfaces / objects before application of (this product).

CONTACT TIME: Allow surfaces / objects to remain wet for 10 minutes.

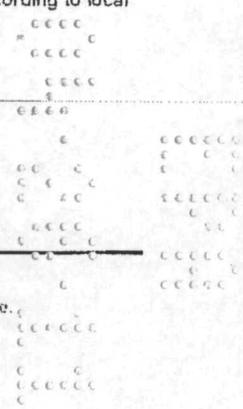
DISPOSAL OF INFECTIOUS MATERIALS: Blood / body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

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PRECAUTIONARY STATEMENT: Hazards to Humans and Domestic Animals.
DANGER: Corrosive. Causes eye damage and skin irritation. Do not get in eyes, on skin or on clothing. Wear appropriate eye protection and rubber gloves. May be harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

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.
If Swallowed	<ul style="list-style-type: none">Call a Poison Control Center or doctor immediately for treatment advice.Have person sip a glass of water if able to swallow.Do not induce vomiting unless told to do so by the Poison Control Center or doctor.Do not give anything by mouth to an unconscious person.
CONTACT NUMBER	
Questions? Comments or in case of an emergency call toll free 1-800-677-9218. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

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: Non-refillable container. Do not reuse or refill this container. Discard in trash or offer for recycle, if available.

<< Professional containers greater than 1 gallon and less than 5 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: Non-refillable container. Do not reuse or refill this container. 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.

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<< This page is for information purposes only. >>

Disinfection - Hard non-porous surfaces

Bacteria:	Acinetobacter calcoaceticus †	<u>ATCC # 15473</u>
	Brevibacterium ammoniagenes †	<u>ATCC # 6871</u>
	Burkholderia (Pseudomonas) cepacia †	<u>ATCC # 35254</u>
	Corynebacterium diphtheriae †	<u>ATCC # 11913</u>
	Enterobacter aerogenes †	<u>ATCC # 13048</u>
	Enterococcus faecalis †	<u>ATCC # 828</u>
	Escherichia coli O157:H7	<u>ATCC # 43698</u>
	Klebsiella pneumoniae	<u>ATCC # 9927</u>
	Neisseria elongata †	<u>ATCC # 25295</u>
	Proteus mirabilis †	
	Proteus vulgaris †	<u>ATCC # 9920</u>
	Pseudomonas aeruginosa †	<u>ATCC # 15442</u>
	Salmonella (choleraesuis) enterica	<u>ATCC # 10708</u>
	Salmonella paratyphi	<u>ATCC # 9281</u>
	Salmonella schottmuelleri	<u>ATCC # 10719</u>
	Salmonella typhi	<u>ATCC # 6539</u>
	Serratia marcescens	<u>ATCC # 8195</u>
	Shigella dysenteriae	<u>ATCC # 11835</u>
	Staphylococcus aureus	<u>ATCC # 6538</u>
	Staphylococcus aureus [MRSA] (Methicillin Resistant)	<u>ATCC # 33592</u>
Streptococcus pyogenes	<u>ATCC # 12384</u>	
Streptococcus salivarius	<u>ATCC # 9222</u>	
Viruses:	Herpes Simplex Virus Type 1	<u>ATCC # VR-733</u>
	Herpes Simplex Virus Type 2	<u>ATCC # VR-734</u>
	Human Immunodeficiency Virus Type 1	
	Influenza A ₂ Virus [Japan 305/57]	<u>ATCC # VR-109</u>
	Respiratory Syncytial Virus [RSV]	<u>ATCC # VR-26</u>
Rotavirus WA	<u>ATCC # VR-2018</u>	
Fungi:	Aspergillus niger	<u>ATCC # 6275</u>
	Candida albicans	<u>ATCC # 10231</u>
	Trichophyton mentagrophytes	<u>ATCC # 9533</u>

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