

777-44

01/25/2008

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JAN 25 2008

Ms. Mary C. Pisculli
Reckitt Benckier, Inc.
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NY 07054-0225

Subject: **Lysol Brand Disinfectant Deodorizing Cleaner**
EPA Registration Number 777-44
Application Dated September 12, 2007
EPA Received Date September 17, 2007

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 following conditions:

Proposed Amendments:

Label amendment.

Conditions

Revise the label as follows:

- 1) Under Disinfecting – Hard, nonporous surface claims on page 2, revise the 3rd claim by deleting the term, "dangerous."
- 2) Under "Disinfection/Mold & Mildew Prevention" on page 3, add the statement, "For Mold/Mildew Prevention: Repeat application every seven day or when new growth appears."
- 3) Under "To Prevent Mold and Mildew" on page 3, revise the directions to read first statement to read "Use as directed under Disinfection/Mold & Mildew Prevention. Repeat application every seven day or when new growth appears."

4) Under subheading, "Disposal of Infectious Materials" on page 3, revise the

CONCURRENCES				
SYMBOL	STATEMENT SUCH THAT IT IS IN COMPLIANCE WITH 40 CFR 155.2000-5, Mandatory Labeling, by deleting the term, "should" and stating "must"			
SURNAME				
DATE				

Data Summary

Even though the skin sensitization study, Local Lymph Node Assay, has not been validated for testing of mixtures, it will be considered acceptable for this product formulation because this issue was recently raised, and you and the laboratory were not aware of it.

Study	MRID	Toxicity	Status
Acute Oral Toxicity	472334-01	IV	Acceptable
Acute Dermal Toxicity	472334-02	IV	Acceptable
Acute Inhalation	472334-03	IV	Acceptable
Primary Eye Irritation	472334-04	I	Acceptable
Primary Skin Irritation	472334-05	IV	Acceptable
Dermal Sensitization	472334-06	Sensitizer	Acceptable

General Comments:

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

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

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

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland on (703) 308-6224 or Velma Noble on 703-308-6233.

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Sincerely,

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

Enclosure: Acute Toxicity Review dated 1/14/07

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SYMBOL							
SURNAME							
DATE							

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<< Front Panel >>

ACTIVE INGREDIENT:

Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chloride	2.90%
OTHER INGREDIENTS:	97.10%
TOTAL:	100.00%

KEEP OUT OF REACH OF CHILDREN

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

NET CONTENTS:	6 FL. OZ.	(177 mL)
	15 FL. OZ.	(443 mL)
	28 FL. OZ. (1 PT. 12 FL. OZ.)	(828 mL)
	32 FL. OZ. (1 QT.)	(946 mL)
	40 FL. OZ. (1 QT. 8 FL. OZ.)	(1.18 L)
	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.: 777-44
EPA Est. No.: 8791-MO-1
See bottom or side (for Lot/Date code)

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JAN 25 2008
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No
777-44

<< Back Panel >>

Questions? Comments? Call: (1-800-677-9218) (1-800-228-4722)
(or) Visit us at (www.reckittprofessional.com) (www.lysol.com)
Made in U.S.A. © RBI (year)
Distributed by: Reckitt Benckiser Inc., Parsippany, NJ 07054-xxxx
Important facts (about this product):
Contains no phosphates (or phosphorous)
This (bottle) (container) is made of x% post-consumer recycled plastic.

<< Back Panel – Optional text >>

Company Logo (Reckitt Benckiser Professional)
Recycle Symbol
Kosher Certification Symbol
NSF Certification Symbol
Monday – (thru) Friday, 8:45 a.m. – (to) 4:30 p.m. (Eastern time)

Please encourage your state and local authorities to establish a recycling program so that this (bottle) (container) can be recycled.

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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<< Marketing claims >>

(Cleans) (Disinfects) (Deodorizes)
(Concentrated Cleaning Power)
(Cuts Grease)
(Easy Pour Bottle)
(Fresh Scent) (Lemon Scent)
(Makes x Gallons)
(Value Pack)

Cleans and disinfects all washable non-porous (household) surfaces. Prevents mold and mildew and the odors they cause. Deodorizes with a pleasant (lemon) (fresh) scent. (This product) is recommended for use in kitchens, bathrooms and other (household) areas.

Great for use as a disinfectant (on hard, non-porous surfaces) located in (Day Care Centers) (Hotels/Motels) (Office Buildings) (Restaurants) (Health Clubs) (Schools) (Institutional) (Restrooms) (and) (Showers).

Great for use as a sanitizer (on hard, non-porous surfaces) located in (Day Care Centers) (Hotels/Motels) (Office Buildings) (Restaurants) (Health Clubs) (Schools) (Institutional) (Restrooms) (and) (Showers).

WHERE TO USE: (This product) cleans regular and no wax floors, cabinets, sinks, tubs, showers, toilet bowls, glazed tile, diaper pails, garbage cans and pet areas. On painted surfaces, test a small inconspicuous area first.

WHERE TO USE:

- Bathroom
- Floors
- Glazed Tile
- Pet Areas
- Woodwork
- Cabinets
- Garbage Cans
- Kitchen
- Storage Area
- Enamel
- Glazed Porcelain
- No Wax Floors
- Walls

<< Sanitizing -- Hard, non-porous surface claims >>

Fast acting sanitizer

Kills (Eliminates) 99.9% of bacteria in seconds***

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

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

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

*** Kills (Eliminates) 99.9% of (Staphylococcus aureus) (and) (Enterobacter aerogenes) on hard, non-porous surfaces in 30 seconds.

<< Disinfecting -- Hard, non-porous surface claims >>

Kills (Eliminates) bacteria

On hard, non-porous (inanimate environmental) surfaces, this product kills the following bacteria and viruses:

(Campylobacter jejuni) (Enterococcus faecalis) (and) (Staphylococcus aureus)
(Human Immunodeficiency Virus Type 1 [HIV-1 AIDS Virus]) (and) (Influenza A₂ [Japan 305/57])

(This product) kills (Staphylococcus aureus) (Enterococcus faecalis) (Influenza A₂ [Japan 305/57]) (Human Immunodeficiency Virus Type 1 [HIV-1 AIDS Virus]) (Campylobacter jejuni) (and) (household) germs on hard, non-porous (environmental) surfaces (in commercial areas). Prevents mold and mildew and the odors they cause.

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

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

To Open Child Resistant Cap: Hold bottle firmly with one hand on a flat surface. With other hand, while pushing down on top of cap, turn cap counterclockwise. Avoid squeezing bottle when opening. To reseal, twist cap clockwise until tightly closed.

General Cleaning: Use full strength or dilute ¼ cup [2 oz] per gallon of warm water. Apply with a sponge, mop or (course) sprayer until surface is thoroughly wet. Then wipe surface clean. For heavily soiled surfaces repeat until surface is clean. When using full strength rinse thoroughly.

Tough Cleaning: Use full strength on tar, gum, oil, lipstick, hard grease and scuff marks, then rinse.

No-Wax Floors: Use as directed under General Cleaning, then rinse.

Disinfection / Mold & Mildew Prevention: Use ¼ cup [2 oz] per gallon of water. If surfaces are extremely dirty, clean first with (this product). Apply with sponge or mop, let stand 10 minutes, then remove excess. Rinse food preparation areas with water. Prepare a fresh bucket of solution every time you clean or more often as needed.

For Disinfecting Toilet Bowls: Flush toilet bowl and then add 1-1/2 oz full strength into the bowl water. Thoroughly swab all bowl surfaces and under the rim. Let stand (for at least) 10 minutes before flushing.

Sanitize / Deodorize: For hard, non-porous surfaces (such as) (counters) (sinks) (refrigerators) (microwaves) (appliances) (stove tops) (faucets) (cabinets) (kitchen tables) (glass tabletops) (stainless steel / chrome fixtures) (glazed fiberglass) (high chairs) (and) (garbage cans) use ¼ cup [2 oz] per gallon of water, apply until thoroughly wet. Let stand for 30 seconds before wiping. Rinse food preparation areas with water. If surfaces are heavily soiled, first clean surfaces with this product according to the General Cleaning directions.

Sanitize / Disinfect: For hard, non-porous surfaces (such as) (counters) (sinks) (exterior of refrigerators and microwaves) (appliances) (stove tops) (faucets) (cabinets) (kitchen table) (glass tabletops) (stainless steel / chrome fixtures) (glazed Fiberglass) (high chairs) (and) (garbage cans) apply until thoroughly wet. **To Sanitize:** Let stand for 30 seconds before wiping. **To Disinfect:** Let stand for 10 minutes before wiping. For heavily soiled areas, a pre-cleaning is required.

To Prevent Mold and Mildew: Use as directed under General Cleaning. Repeat application when necessary.

KILLS HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 [HIV-1 AIDS Virus] ON PRE-CLEANED ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS, in settings where 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 protection.

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 [redacted] be autoclaved and disposed of according to local regulations for infectious waste disposal.

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PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals

DANGER: Corrosive. Causes irreversible eye damage. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Do not get in eyes, on skin or on clothing. Wear protective eyewear [safety glasses/goggles]. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove and wash contaminated clothing before reuse. Keep out of reach of children.

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">• Remove 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 a 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) (1-800-228-4722). 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 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 original container in areas inaccessible to small children. Keep securely closed.

DISPOSAL: Do not reuse container. 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.

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