

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 20 2004

Mr. Bob MacDonald
Agent
Reckitt Benckiser Inc.
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, New Jersey 07054-0225

Subject: Lysol Brand Disinfectant Deodorizing Cleaner
EPA Registration No. 777-44
Application Date: 11/18/03
Receipt Date: 11/26/03

Dear Mr. MacDonald:

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

Resubmission letter Dated 2/25/03

LABEL COMMENTS

- 1. Whenever the words "tile, porcelain or fiberglass" appear on the label, add the word "glazed" before it.

EFFICACY COMMENTS

- 1. The Agency accepts the documentation provided by your office regarding the age of the product at the time of the original efficacy testing and approves the claim of this product as a disinfectant and non-food contact sanitizer against *Staphylococcus aureus* as and *Enterobacter aerogenes*.
- 2. The label changes made at the direction of the Agency at the previous submission have been made and noted.

Please Note: Efficacy testing of this product as a disinfectant against *Pseudomonas aeruginosa* ATCC 15442 must be submitted, reviewed and accepted by the Agency before this product can be used in hospitals, nursing homes, medical clinics and other healthcare facilities. Please delete all the health care facilities from the label until the data is submitted, tested and accepted by the Agency.

CONCURRENCES								
SYMBOL	7510C							
SURNAME	J. Jones							
DATE	5-19-04							

GENERAL COMMENTS

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 Zenobia Jones at (703) 308-6198.

Sincerely,



Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510C)

Lysol® Brand Disinfectant Deodorizing Cleaner

- [Lemon Fresh] [Fresh Scent]
- [Cuts Grease]
- [Cleans, Disinfects, Deodorizes]
- [Concentrated Cleaning Power]
- [Value Pack]
- [Easy Pour Bottle]
- [Bottle is made of 25% recycled plastic†]
- [(For the half gallon size): Makes 32 Gallons]
- [(For the 1-gallon size): Makes 64 Gallons]
- [(For the 144 fl. oz. size): Makes 72 Gallons]
- [(For the 2 ½-gallon size): Makes 160 Gallons]
- [(For the 5-gallon size): Makes 320 Gallons]
- [(For the 55-gallon size): Makes 3,520 Gallons]

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 20 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 777-44

Active Ingredient:

Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chlorides.....	2.70%
Other Ingredients:	97.30%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING

See Back Panel for Additional Precautionary Statements

Net Contents:	[6 fl. oz. 177 mL]	{for 6 oz. size}
	[15 fl. oz. 443 mL]	{for 15 oz. size}
	[28 fl. oz. (1 pt. 12 fl. oz.) 828 mL]	{for 28 oz. size}
	[40 fl. oz. (1 qt. 8 fl. oz.) 1.18 Liters]	{for 40 oz. size}
	[One Half Gallon (64 fl. oz.) 1.89 Liters]	{for one half gallon size}
	[One Gallon (128 fl. oz.) 3.79 Liters]	{for one gallon size}
	[144 fl. oz. (4 qts. 16 oz.) 4.25 liters]	{for 144 oz. size}
	[2 ½ Gallons (320 fl.oz.) 9.46 Liters]	{for 2 ½ gallon size}
	[Five Gallons (640 fl. oz.) 18.93 Liters]	{for five gallon size}
	[55 Gallons (7,040 fl. oz) 208.20 Liters]	{for 55 gallon size}

Note: Bracketed[] information is optional text. Text separated by a comma(,) denotes-and/or-options. {Bracketed Text} is for administrative purposes only and will not appear on the printed label.

{Additional Bullets/Bursts/Phrases}

[LYSOL® Brand Disinfectant Deodorizing Cleaner] [This product]
[Cuts Grease!] [Disinfects!] [Deodorizes!]

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{This list of organisms is for informational purposes. The organisms may or may not be listed on the final printed label and if listed may use a different format.}

[On hard non porous inanimate environmental surfaces, this product kills the following bacteria and viruses:]

DISINFECTANT

BACTERIA:

Staphylococcus aureus
Enterococcus (Streptococcus) faecalis
Campylobacter jejuni

VIRUSES:

HIV-1 (AIDS Virus)
Influenza A₂ (Japan 305/57)

SANITIZER

NON-FOOD CONTACT SANITIZER ORGANISMS:

Staphylococcus aureus
Enterobacter aerogenes

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{Alternate Language for Sanitization Claims}

[Kills [Eliminates] 99.9% of Bacteria* in seconds.]
[Eliminates [Kills] 99.9% of Bacteria* in 30 seconds.]
[Kills [Eliminates] Bacteria*]
[Kills [Eliminates] 99.9% of Bacteria* on hard, non-porous surfaces in seconds.]
[Eliminates [Kills] 99.9% of Bacteria* on hard nonporous surfaces in 30 seconds.]
[Kills [Eliminates] Bacteria* on hard, non-porous surfaces [in seconds].]

[Fast Acting Sanitizer]

[*Kills [Eliminates] 99.9% Staphylococcus aureus [Staphylococcus], Enterobacter aerogenes on hard, non-porous surfaces in 30 seconds.] {must be on label when any bacteria claims are made.}

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{Labels with multiple uses must include the appropriate headings directly preceding the respective use directions. These headings are optional for labels with only one use pattern.}

Cleans and disinfects all washable nonporous household surfaces. Prevents mold and mildew and the odors they cause. Deodorizes with a pleasant lemon fresh scent.

[LYSOL® Brand Disinfectant Deodorizing Cleaner] [This product] is recommended for use in kitchens, bathrooms and other household areas.

{The following may be used in place of or in addition to the preceeding paragraph}

[Great] [For use] [as a DISINFECTANT [on hard nonporous surfaces] [located] [in:] [~~Day Care Centers,~~] [Hotels/Motels,] [Office Buildings,] [Bowling Alleys,] [Restaurants,] [Health Clubs,] [Schools,] [Institutional] [Restrooms] [and] [Showers,]] [as a SANITIZER [on hard nonporous surfaces] [located] [in:] [~~Day Care Centers,~~] [Hotels/Motels,] [Office Buildings,] [Bowling Alleys,] [Restaurants,] [Health Clubs,] [Schools,] [Institutional] [Restrooms] [and] [Showers]].

[LYSOL® Brand Disinfectant Deodorizing Cleaner] [This product] kills dangerous [staph] [Staphylococcus aureus] and [strep] [Enterococcus (Streptococcus) faecalis] germs, Influenza A₂ (Japan 305/57), Human Immunodeficiency Virus Type 1 (HIV-1) (AIDS Virus), Campylobacter jejuni and household germs on hard, nonporous [environmental] surfaces [in commercial areas]. Prevents mold and mildew and the odors they cause.

WHERE TO USE:

[LYSOL® Brand Disinfectant Deodorizing Cleaner] [This product] cleans regular and no wax floors, cabinets, sinks, tubs, showers, toilet bowls, tile, diaper pails, garbage cans and pet areas. On painted surfaces, test a small inconspicuous area first.

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

Directions for Use:

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

General Cleaning: Use full strength or dilute ¼ cup (2 oz.) [per] [in a] gallon of warm water. Apply with a sponge, mop or 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.

Picture
Kitchen

Picture
Bathroom

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Disinfection/Mold & Mildew Prevention: Use ¼ cup (2 oz.) [per] [in a] gallon of water. If surfaces are extremely dirty, clean first with [LYSOL® Brand Disinfectant Deodorizing Cleaner] [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 Bowl(s): Flush [toilet bowl] and then add 1-1/2 oz. full strength into the bowl water. Thoroughly swab all bowl surfaces [making sure to get] and under the rim [and] let stand [for at least] 10 minutes [then flush] [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, fiberglass, high chairs and garbage [pails] [cans], use ¼ cup (2 oz.) [per] [in a] 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.

[For hard, non-porous surfaces such as counters, sinks, exterior of refrigerators and exterior of microwaves, appliances, stove tops, faucets, cabinets, kitchen table, glass tabletops, stainless steel, chrome fixtures, fiberglass, high chairs, and garbage [pails] [cans], 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 soiled areas, a precleaning is required.]

To Prevent Mold and Mildew: Use as directed under general cleaning. Repeat application when 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/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 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

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

CLEANING PROCEDURES: Blood/body fluids must be thoroughly cleaned from surfaces/objects before application of [LYSOL® Brand Disinfectant Deodorizing Cleaner] [This product].

CONTACT TIME: Allow surface to remain wet for 10 minutes.

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

Precautionary Statements

Hazards to humans and domestic animals.

WARNING: Avoid contact with eyes. Causes eye and skin irritation. May be harmful if swallowed. For sensitive skin, use rubber gloves. Avoid contamination of food.

FIRST AID

IF IN EYES: 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: 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: If swallowed, 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). 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/DISPOSAL {For sizes 1 gallon or less.}

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

STORAGE AND DISPOSAL {For sizes over 1 gallon.}

Do not contaminate water, food or feed by storage or 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

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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 HAZARDS {For sizes 5 gallons or more}

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 about [LYSOL® Brand Disinfectant Deodorizing Cleaner] [This product]:

[Lysol® Brand Disinfectant Deodorizing Cleaner] [This product] contains no phosphorous or phosphates.

†This bottle is made of 25% post-consumer recycled plastic.

[Please encourage your state and local authorities to establish a recycling program so that this [bottle] [container] [pail] [drum] can be recycled.]

Questions? Comments? Call 1-800-677-9218.

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

[Visit us at www.reckittprofessional.com]

[Visit us at www.lysol.com/info]

[Distributed by:]



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

EPA Reg. No. 777-44

EPA Est. No. {Insert establishment number here}

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