

777-82

05-27-2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Bob McDonald  
Agent for Reckitt Benckiser, Inc.  
SRC Consultants  
P.O. Box 1014  
Columbia, IN 46725

MAY 27 2004

Subject: Lysol Brand Deodorizing Disinfecting Cleaner  
EPA Registration Number: 777-82  
Application Dated: 12/1/03  
Receipt Date: 12/3/03

Dear Mr. Bob McDonald:

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below:

- add non-food contact sanitizer claims
- addition of new directions for use as a non-food contact sanitizer
- update first aid statement

Acceptable Data

The submitted efficacy data is now considered acceptable as follows:

Data Requirement	Means of Support	Status
Non-food contact sanitization: <i>Staphylococcus aureus</i> and <i>Enterobacter aerogenes</i>	Submitted study, MRID 457717-01	Acceptable @ 1:64 in 5% soil for 30 seconds
Non-food contact sanitization: <i>Listeria monocytogenes</i>	Submitted study, MRID 457717-02	Acceptable @ 1:64 in 5% soil for 30 seconds

CONCURRENCES

SYMBOL	7510C							
SURNAME	J. Fork							
DATE	5/27/04							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Conditions

1. Revise page 3 of the label by changing the heading to read: "Alternate Language for Non-Food Contact Sanitization Claims".

2. Delete the claims on page 4 for *Vaccinia* and *Adenovirus Type 5* as you have not provided nor cited data to support either claim.

3. Revise page 4 of the label by deleting "Day Care Centers." Day Care Centers are associated with institutional/hospital use and you have not provided data to support the effectiveness of this product against the required organism: *Pseudomonas aeruginosa*.

4. Revise the "Where to use" section to indicate that this product is for use on "glazed porcelain" which is a hard non-porous surface.

5. Revise page 5:

A. Delete the "language for commercial labels" section as it is not necessary.

B. Delete the heading only as follows: "Language for residential labels". This one set of directions will support all uses.

C. Revise this remaining set of directions by clarifying as follows: "...bathtubs and shower stalls made of fiberglass..." deleting the stand alone term "fiberglass" which is considered a porous surface without these clarifiers.

6. Revise the Precautionary statements as indicated in the Agency letter of 4/1/03 as follows: add "Harmful if absorbed through the skin." and "...and water after handling and before eating, drinking, chewing gum or using tobacco."

7. Revise the following statement on page 7 such that it is in agreement with PR Notice 2000-5 as follows: "Do not use as a refill for Lysol Brand Disinfectant Antibacterial Kitchen Cleaner trigger spray."

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.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) and section 4(a) when the Agency requires all registrants of similar products to submit such data.

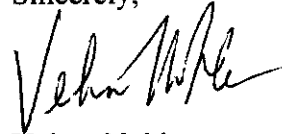
CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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 Tracy Lantz at (703) 308-6415.

Sincerely,



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

Enclosure: Stamped Label  
7510C:T. Lantz:5/27/04:777-82d

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**Lysol® Brand Deodorizing Disinfectant Cleaner**

- [Fresh Pine Scent]
- [Fresh Country Scent]
- [Mountain Air Scent]
- [Lemon Scent]
- [Easy Pour Bottle]
- [Cuts Grease]
- [Disinfects]
- [Deodorizes]
- [Cleans]
- [Concentrated Cleaning Power]
- [Big Kitchen Cleaning Jobs]
- [Not a Refill Trigger Product]
- [(For the 1-gallon size): Makes 64 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 27 2004

Under the Federal Insecticide,  
 Fungicide, and Rodenticide Act as  
 amended, for the pesticide,  
 registered under EPA Reg. No. 777-82

**Active Ingredients:**

n-Alkyl (50% C <sub>14</sub> , 40% C <sub>12</sub> , 10% C <sub>16</sub> ) dimethyl benzyl ammonium chlorides.....	0.8000%
Octyl Decyl Dimethyl Ammonium Chloride.....	0.1250%
Dioctyl Dimethyl Ammonium Chloride.....	0.0625%
Didecyl Dimethyl Ammonium Chloride .....	0.0625%
<b>Other Ingredients:</b> .....	98.9500%
<b>Total</b> .....	100.0000%

KEEP OUT OF REACH OF CHILDREN

**WARNING**

See Back [(Side)]Panel for Additional Precautionary Statements

Net Contents:	[15 fl. oz. 443 ml]	{for 15 oz. size}
	[22 fl. oz. (1 pt. 6 fl. oz.)]	{for 22 oz. size}
	[28 fl. oz. (1 pt. 12 fl. oz.) 828 ml]	{for 28 oz. size}
	[32 fl. oz. (1 qt.) 946 ml]	{for 32 oz. size}
	[35 fl. oz. (1 qt. 3 fl. oz.)]	{for 35 oz. size}
	[40 fl. oz. (1 qt. 8 fl. oz.)]	{for 40 oz. size}
	[52 fl. oz. (1 qt. 20 fl. oz.)]	{for 52 oz. size}
	[One Gallon (128 fl. oz.) 3.79 Liters]	{for one gallon size}
	[144 fl. oz. (4.25 Liters)]	{for 144 oz. 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.

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{This list of organisms is for informational purposes. The entire list of organisms may or may not be listed on the final printed label and when listed may use a different format. The minimum listing of genus and species names will be included for each organism listed. Additionally if the term "germs" is used a bacteria and virus will be listed}

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

**BACTERIA:**

- Staphylococcus aureus
- Enterococcus (Streptococcus) faecalis
- Escherichia coli
- Salmonella enteritidis
- Salmonella choleraesuis
- Listeria monocytogenes

**VIRUSES:**

- HIV-1 (AIDS Virus)
- Influenza A<sub>2</sub> (Japan 305/57)
- Herpes Simplex Type 1
- Herpes Simplex Type 2
- Respiratory Syncytial Virus

**NON-FOOD CONTACT SANITIZER ORGANISMS:**

- Staphylococcus aureus
- Enterobacter aerogenes
- Listeria monocytogenes

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**{Alternate Language for Sanitization Claims}**

[Eliminates [Kills] 99.9% of Bacteria\*\* in 30 seconds.]

[Kills [Eliminates] Bacteria\*\*]

[Eliminates [Kills] 99.9% of Bacteria\*\* on hard nonporous surfaces in 30 seconds.]

[Fast Acting Sanitizer]

[\*\*Kills [Eliminates] 99.9% Staphylococcus aureus [Staphylococcus], Enterobacter aerogenes and Listeria monocytogenes on hard, non-porous surfaces in 30 seconds.]  
{above listing of organism(s) being claimed 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.}

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

Cleans and disinfects washable, nonporous [household] surfaces. Leaves your home deodorized and smelling like the [fresh][clean][outdoor scent of the country][outdoor scent of the mountains][scent of lemons].

It cuts through grease and grime. Also kills odor-causing bacteria and mold/mildew.

Controls the growth of mold and mildew and the odors they cause. Deodorizes with a pleasant fresh [country scent][lemon scent][outdoor scent of the mountains]. [LYSOL® Brand Deodorizing Disinfectant Cleaner] [This product] is recommended for use in kitchens, bathrooms, storage and other [household] areas.

[LYSOL® Brand Deodorizing Disinfectant Cleaner] [This product] kills Staphylococcus aureus, Enterococcus (Streptococcus) faecalis and Salmonella choleraesuis, Escherichia coli, Salmonella enteritidis, Listeria monocytogenes, Influenza A<sub>2</sub> (Japan 305/57), Herpes Simples Virus Type 1 and Type 2, Respiratory Syncytial Virus, HIV-1 (AIDS Virus), ~~\_\_\_\_\_~~ and (household) germs on hard, non-porous environmental surfaces.

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

[Great] for use [as a disinfectant, sanitizer][on hard non-porous surfaces][located] in:

- |                  |                           |                  |
|------------------|---------------------------|------------------|
| Day Care Centers | Hotels/Motels             | Office Buildings |
| Restaurants      | Bowling Alleys            | Health Clubs     |
| Schools          | [Institutional] Restrooms |                  |

**WHERE TO USE:**

[LYSOL® Brand Deodorizing Disinfectant Cleaner] [This product] cleans regular and no wax floors, sinks, tubs, showers, toilet bowls, garbage cans, tile, cabinets, counters, exterior surfaces of refrigerators and appliances, stove tops, floors, walls, finished woodwork, enamel, porcelain, diaper pails, and pet areas. Do not use full strength on plastics/acrylics. On painted surfaces, test a small inconspicuous area first.

Picture	Picture	Picture	Picture
[Counter/Stove]	[Floors/Walls]	[Appliance/Cabinet]	[Kitchen Sink]

**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.

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.

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**Tough Cleaning:** Use full strength and rinse surface thoroughly.

**No Wax Floors:** Use as directed, then rinse.

**Disinfection:** Use ¼ cup (2 oz.) [per] [in a] gallon of water. If surfaces are visibly dirty, clean first with [LYSOL® Brand Deodorizing Disinfectant Cleaner] [This product]. Apply with sponge or mop to wet all surfaces thoroughly. Let stand 10 minutes, then remove excess. Rinse food preparation areas with potable water after using this product. Prepare a fresh bucket of solution every time you clean or more often as needed. For sensitive skin, wear rubber gloves.

**To Disinfect Toilet Bowl:** Remove gross filth, flush [toilet bowl] 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. Let stand [for at least] 10 minutes, [then flush] [before flushing].

### SANITIZE/DEODORIZE:

#### {Language for residential labels}

For hard nonporous surfaces such as counters, sinks, exterior of refrigerators, microwaves, and appliances, stove tops, faucets, cabinets, kitchen tables, glass table tops, (non-medical) stainless steel, chrome fixtures, 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. For heavily soiled surfaces, first clean according to GENERAL CLEANING directions. Rinse food contact areas with potable water.

#### ~~{Language for commercial labels}~~

~~For hard nonporous surfaces such as sinks, exterior of refrigerators, microwaves, and appliances, stove tops, faucets, cabinets, kitchen tables, glass table tops, (non-medical) stainless steel, chrome fixtures, fiberglass, high chairs and garbage pails [cans], apply until thoroughly wet. Let stand for 30 seconds before wiping. For heavily soiled surfaces, first clean according to GENERAL [KITCHEN] CLEANING directions. Rinse food contact areas with potable water.~~

To sanitize/deodorize: Let stand for 30 seconds before wiping

To disinfect: Let stand for 10 minutes before wiping

For heavily soiled areas, a precleaning is required.

Rinse food preparation areas with potable water.

**To Control Mold and Mildew:** Use as directed for disinfection. 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).



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**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/body fluids, use disposable latex gloves, gowns, masks or eye coverings.

**CLEANING PROCEDURES:** Blood/body fluids must be thoroughly cleaned from surfaces/objects before application of [LYSOL® Brand Deodorizing Disinfectant 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:** Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Avoid contact with skin. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

**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.

**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.

**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 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.

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.

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**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 Deodorizing Disinfectant Cleaner] [This product]:**

Contains no phosphates.

Bottle is made of 25% post-consumer recycled plastic.

Should not be used as a refill for Lysol Brand Disinfectant Antibacterial Kitchen Cleaner trigger sprayer.

[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].]

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Morris Corporate Center IV  
399 Interpace Parkway  
Parsippany, NJ 07054-0225

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