

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

June 13, 2016

David Swain Agent for Reckitt Benckiser 201 W Van Buren Street Columbia City, In 46725

Subject: PRIA Label Amendment–Revision of Disinfectant Claims

Product Name: Lysol Brand Deodorizing Disinfectant Cleaner

EPA Registration Number: 777-82

Application Date: 11/13/15 Decision Number: 511286

Dear Mr. Swain;

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Jamil Mixon by phone at (703) 308-8032, or via email at: Mixon.Cletis@epa.gov.

Page 2 of 2 EPA Reg. No. 777-82 Decision No. 511286

Sincerely,

E. Midelloff

Eric Miederhoff
Product Manager 31

Regulatory Management Branch I Antimicrobials Division (7510P)

Office of Pesticide Programs

Date: June 13, 2016

Enclosure

Lysol Brand Deodorizing Disinfectant Cleaner

EPA Reg. No.: 777-82

Amendment: 11-09-2015 (version 4)
Page 1 of 5

## << Front Panel >>

## **ACTIVE INGREDIENTS:**

Alkyl (50% C <sub>14</sub> , 40% C <sub>12</sub> , 10% C <sub>16</sub> ) dimethyl benzyl ammonium chloride	0.8000%
Octyl decyl dimethyl ammonium chloride	0.1250%
Dioctyl dimethyl ammonium chloride	0.0625%
Didecyl dimethyl ammonium chloride	0.0625%
OTHER INGREDIENTS:	<u>98.9500</u> %
TOTAL:	100.0000%

## KEEP OUT OF REACH OF CHILDREN

WARNING: 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.: 777-82 EPA Est. No.: 8791-MO-1

> 09019-OH-001 09019-OH-002 312-WI-1

(See bottom or side) (for Lot/Date code)

#### << Back Panel >>

Questions? (Comments?) ( ) (Call:) 1-800-677-9218
For ingredient (and other) information, www.rbnainfo.com
Distributed by: Reckitt Benckiser, Parsippany, NJ 07054(-xxxx)

Made in U.S.A. © RB {year}

Contains no phosphates

This (bottle) (container) is made of x% post-consumer recycled plastic.

Company graphic logo HEALTH + HYGIENE + HOME Reckitt Benckiser

ACCEPTED

06/13/2016

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 777 00

777-82

<< Back Panel - Optional text >>

Recycle Symbol

(This product) meets the requirements of the OSHA Bloodborne Pathogen Standard for Decontamination

Lysol Brand Deodorizing Disinfectant Cleaner Amendment: 11-09-2015 (version 4) EPA Reg. No.: 777-82 Page 2 of 5

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

(Cleans) (Disinfects) (Deodorizes) (Concentrated Cleaning Power) (Cuts Grease) (Fresh Pine Scent) (Lemon Scent) (Makes (Up to) X Gallons (for Cleaner)) (For Commercial Use)

Cleans and disinfects all washable non-porous surfaces.

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

Deodorizes with a pleasant fresh (lemon) (pine) scent.

(This product) is recommended for use in kitchens, restrooms, storage and other areas.

Great for use on hard, non-porous (environmental) surfaces located in:

- Cafeteria
- Hotels / Motels
- Office Buildings
- Restrooms

- Day Care Centers
- Kitchen
- Restaurants
- School (College)

# WHERE TO USE: (This product) cleans:

- Appliance exteriors
- Bathtub (Tub)
- Cabinets
- Chrome / Stainless Steel Fixtures
- Counters
- Diaper Pails
- Enamel
- Finished Woodwork
- Floors
- Garbage Cans
- Glazed Ceramic Tile
- Glazed Porcelain Tile

- Glazed Tile
- High chairs
- Non-medical Chrome / Stainless Steel
- Pet Areas
- Regular & No-wax Floors
- Sinks
- **Showers**
- Storage Areas
- Stove tops
- **Tables**
- Toilet Bowls / Urinals
- Walls

Do not use full strength on acrylics or plastics. On painted surfaces, test a small inconspicuous area first.

Kills 99.9% of bacteria in (90) seconds\*\*\*

\*\*\* Kills 99.9% of (Staphylococcus aureus) (and) (Klebsiella pneumonia) on hard, non-porous surfaces in 90 seconds.

Kills (99.9% of) bacteria and viruses\*\*

Kills: {insert organisms from list on page 5}

\*\* (This product) kills Enterococcus faecalis, Escherichia coli O157:H7, (Klebsiella pneumonia), Listeria monocytogenes, Pseudomonas putida, Salmonella enterica, Salmonella enteritidis, Staphylococcus aureus, Staphylococcus aureus MRSA Herpes Simplex Virus Type 1 & 2, Human Coronavirus, Human Immunodeficiency Virus Type 1 [AIDS Virus], Influenza A2 Virus [Japan 305/57], Influenza A Virus [H1N1] (2009 Pandemic), Respiratory Syncytial Virus [RSV] on hard, non-porous (environmental) surfaces in 10 minutes.

Kills (the following) (germs) (microorganisms):

# **Bacteria**

- Enterococcus faecalis
- Escherichia coli O157:H7
- Listeria monocytogenes
- Pseudomonas putida
- Salmonella enterica
- Salmonella enteritidis Staphylococcus aureus
- Staphylococcus aureus MRSA

# Viruses<sup>†</sup>

- Herpes Simplex Virus Type 1 & 2
- Human Coronavirus
- Human Immunodeficiency Virus Type 1 [HIV-1 AIDS Virus]
- Influenza A<sub>2</sub> Virus [Japan 305/57]
- Influenza A Virus [H1N1] (2009 Pandemic)
- Respiratory Syncytial Virus

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. The term (x) is a placeholder that represents a number between 1 and 99.

Lysol Brand Deodorizing Disinfectant Cleaner

EPA Reg. No.: 777-82

Amendment: 11-09-2015 (version 4)
Page 3 of 5

**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.

**General Cleaning & Deodorizing:** Dilute ¼ cup [2 oz.] per gallon of warm water. Apply with a sponge, mop or coarse sprayer until surface is thoroughly wet. Then wipe surface clean. For heavily soiled surfaces, repeat until surface is clean. Prepare a fresh bucket of solution every time you clean or more often as needed.

**To Sanitize hard non-porous non-food contact surfaces:** Pre-clean surface. Dilute 1 cup [8 oz.] per gallon of water. Apply to surface until thoroughly wet. **To Disinfect hard non-porous surfaces:** Pre-clean surface. Dilute 1 cup [8 oz.] per ½ gallon of water. Apply to surface until thoroughly wet.

**To Sanitize hard non-porous non-food contact surfaces:** Leave for 90 seconds before wiping. **To Disinfect:** leave for 10 minutes before wiping. Rinse all food contact surfaces with clean (potable) water after use. Do not use on glasses, dishes or utensils.

**To Control (and Prevent) (the Growth of) Mildew:** Apply to pre-cleaned surface. Let surfaces remain wet for 3 minutes and then allow to air dry. Repeat application at weekly intervals or when mold and mildew growth appears. Dilute 1 cup [8 oz.] per ½ gallon of water.

**For Disinfecting Toilet Bowls:** Flush toilet bowl and then add 1 cup [8 oz.] full strength into the bowl water. Thoroughly brush all bowl surfaces and under the rim. Let stand (for at least) 10 minutes before flushing.

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 / 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 and 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.

Lysol Brand Deodorizing Disinfectant Cleaner

EPA Reg. No.: 777-82

Amendment: 11-09-2015 (version 4)
Page 4 of 5

PRECAUTIONARY STATEMENT: Hazards to Humans and Domestic Animals.

**WARNING:** Causes substantial but temporary eye injury. Harmful if absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. Wear protective eyewear [goggles, face shield, safety glasses]. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

FIRST AID	
If in Eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a Poison Control Center or doctor for treatment advice.</li> </ul>
If on Skin or Clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a Poison Control Center or doctor for treatment advice.</li> </ul>
	CONTACT NUMBER
	Questions? Comments or In case of an emergency call toll free 1-800-677-9218. container or label with you when calling a Poison Control Center or doctor or going for treatment.

<< STORAGE & DISPOSAL - Commercial / Institutional / Industrial containers >>

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

**PESTICIDE 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. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure 2 more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

Lysol Brand Deodorizing Disinfectant Cleaner

EPA Reg. No.: 777-82

Amendment: 11-09-2015 (version 4)
Page 5 of 5

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

# Disinfection - Hard non-porous surfaces

Bacteria: Enterococcus faecalis (ATCC # 828) Escherichia coli O157:H7 (ATCC # 43888) Listeria monocytogenes (ATCC # 7644) Pseudomonas putida (ATCC # 12633) Salmonella enterica (ATCC # 10708) Salmonella enteritidis (ATCC # 13076) Staphylococcus aureus (ATCC # 6538) Staphylococcus aureus MRSA (ATCC # 33592)

Viruses: Herpes Simplex Virus Type 1 (ATCC # VR-733)
Herpes Simplex Virus Type 2 (ATCC # VR-734)

Human Coronavirus (ATCC # VR-740) Human Immunodeficiency Virus Type 1

Influenza A<sub>2</sub> [Japan 305/57] (ATCC # VR-100) Influenza A Virus [H1N1] (2009 Pandemic) (CDC2009712192)

(ATCC # VR-26)

Fungi: Aspergillus niger (ATCC # 16404)

Respiratory Syncytial Virus [RSV]

## Non-Food Contact Sanitization

Bacteria: Staphylococcus aureus (ATCC # 6538) Klebsiella pneumonia (ATCC # 4352)