UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 17, 2015

Amanda Landolt
Regulatory Operations Lead
Reckitt Benckiser
Morris Corporate Center IV
Parsippany, NJ 07054-0225

Subject: PRIA Label Amendment – Addition of Target Organisms
Product Name: Lysol Brand Heavy Duty Cleaner Disinfectant Concentrate
EPA Registration Number: 675-54
Application Date: June 17, 2015
Decision Number: 506335

Dear Ms. Landolt,

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.

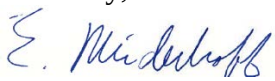
A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or 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 Cletis Jamil Mixon by phone at (703) 308-8032, or via email at mixon.cletis@epa.gov.

Sincerely,



Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

<< Front Panel >>

ACTIVE INGREDIENT:

Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) 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.: 777-MO-001 09019-OH-001 777-PA-001
0312-WI-3 09019-OH-002 777-GA-001
See bottom or side (for Lot/Date code)

<< Back Panel >>

Questions? (✆) (Comments?) (Call:) (1-800-677-9218) (1-800-560-6619)
For ingredient (and other) information, www.rbnainfo.com
Made in U.S.A. © RB {year}
Distributed by: Reckitt Benckiser, Parsippany, NJ 07054(-xxxx)
Contains no phosphates
This (bottle) (container) is made of x% post-consumer recycled plastic.
Company graphic logo

Reckitt Benckiser HEALTH · HYGIENE · HOME

ACCEPTED
11/17/2015
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 675-54

NSF certification symbol {Listed 123497}

NSF LISTED (XXXXXX)

<< Back Panel – Optional text >>

Recycle Symbol
(This product) meets the requirements of the OSHA Bloodborne Pathogen Standard for Decontamination
(This product) meets AOAC Germicidal efficacy standards for hospital disinfectants

NOTE: Bracketed information is denoted as: << directive >>, { insert as noted }, (optional text), [required qualifier].
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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.

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

For Hospital and Institutional Use
For Commercial Use
Disinfects & Deodorizes
Cuts through Tough Soils
Non-Abrasive
Fresh Citrus Lime Scent
(Deodorizer) (Fungicide) (Virucide†)
Kills odor-causing bacteria and fungi
Kills the following (germs) (microorganisms) ({insert organisms – see pg. 6-7})
Controls the growth of mold and mildew
Deodorizes with a fresh citrus lime fragrance

(This product) ({insert Lysol® Brand Name}) is a 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, glazed porcelain, glazed ceramic tile floors.

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

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

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

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

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

BACTERICIDAL – FUNGICIDAL – VIRUCIDAL†

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<< 2009 PANDEMIC H1N1 >>

Kills Pandemic 2009 H1N1 Influenza A Virus

Kills Pandemic 2009 H1N1 Influenza A Virus (formerly called Swine Flu)

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A Virus. This product (product name) is a broad-spectrum, hard surface disinfectant that has been shown to be effective against (Influenza A Virus tested and listed on the label) and is expected to inactivate all Influenza A Viruses including Pandemic 2009 H1N1 (formerly called Swine Flu).

(This product) has demonstrated effectiveness against Influenza A Virus and is expected to inactivate all Influenza A Viruses including Pandemic 2009 H1N1 Influenza A Virus.

(This product) has demonstrated effectiveness against (Influenza A Virus tested and listed on the label) and is expected to inactivate all Influenza A Viruses including Pandemic 2009 H1N1 (formerly called Swine Flu).

<< Terminal Sterilant Statement – qualified metal surfaces >>

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

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:
Pre-clean surfaces.
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, use a solution of 1:4.

For General Disinfection: Pre-clean surfaces. 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 (Burkholderia cepacia), (and) (Adenovirus Type 2), (Rotavirus), (Aspergillus niger) (and) (Trichophyton mentagrophytes) dilute 1:8.)

****For Hospital/Healthcare Disinfection:** Pre-clean surfaces. Dilute 1:8 in water, let stand for 10 minutes, then remove excess.

To Control Mold & Mildew: Clean surfaces first. Using a 1:8 dilution wet surfaces, let stand 10 minutes, then remove excess. Repeat application weekly or when needed.

For Cleaning and Disinfecting Toilet Bowls: Pre-clean surfaces. 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. 4 oz.	1 Quart (32 oz.) 1 Gallon (128 oz.)
1:16	2 oz. 8 oz.	1 Quart (32 oz.) 1 Gallon (128 oz.)
1:8 (**)(^^)	4 oz. 16 oz.	1 Quart (32 oz.) 1 Gallon (128 oz.)
1:4	8 oz. 32 oz.	1 Quart (32 oz.) 1 Gallon (128 oz.)
** For Pseudomonacidal activity (in Hospitals and other Health Care Facilities) dilute 1:8.		
^^ For Burkholderia cepacia, Adenovirus Type 2, Rotavirus, Aspergillus niger, and Trichophyton mentagrophytes) dilute 1:8		

Prepare a fresh solution daily and change solution frequently if heavily soiled or diluted.

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 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 5 minutes.

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

PRECAUTIONARY STATEMENT: Hazards to Humans and Domestic Animals.
DANGER: Corrosive. 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.

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	• 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	• 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)(1-800-560-6619). 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.

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. 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:
This pesticide is toxic to fish, aquatic invertebrates, oysters and shrimp.

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

Disinfection - Hard non-porous surfaces

<< 10-min Disinfection Bacteria>>	Acinetobacter baumannii [MDR] (Multi-drug Resistant)	ATCC # 19606
	Acinetobacter calcoaceticus	ATCC # 17902
	Bordetella pertussis	ATCC # 12743
	Burkholderia cepacia	ATCC # 25416
	Corynebacterium ammoniagenes	ATCC # 6872
	Corynebacterium diphtheria	ATCC #11913
	Enterobacter aerogenes [MDR] (Multi-Drug Resistant)	ATCC # 29751
	Enterococcus faecalis	ATCC # 828
	Enterococcus faecium [MDR] (Multi-Drug Resistant	ATCC # 51559
	Escherichia coli ESBL (Extended-Spectrum beta-lactamase)	ATCC # BAA-196
	Escherichia coli O157:H7	ATCC # 43888
	Haemophilus influenzae	ATCC # 33930
	Klebsiella pneumoniae	ATCC # 9997
	Klebsiella pneumoniae NDM-1 (New Delhi metallo-beta lactamase 1 positive)	ATCC # CDC1000527
	Legionella pneumophila	ATCC # 33153
	Listeria monocytogenes	ATCC # 19117
	Neisseria elongata	ATCC # 25295
	Proteus mirabilis	ATCC # 25933
	Proteus vulgaris	ATCC # 9920
	Pseudomonas aeruginosa	ATCC # 15442
	Salmonella (choleraesuis) enterica	ATCC # 10708
	Salmonella enterica serovar Paratyphi B	ATCC # 8759
	Salmonella enterica serovar Paratyphi B (formerly schottmuelleri)	ATCC # 10719
	Salmonella typhi	ATCC # 6539
	Serratia marcescens	ATCC # 8195
	Shigella dysenteriae	ATCC # 11835
	Staphylococcus aureus	ATCC # 6538
	Staphylococcus aureus [MRSA] (Methicillin Resistant)	ATCC # 33592
	Staphylococcus epidermidis	ATCC # 12228
	Streptococcus pneumoniae [PRSP]	ATCC # 700677
	Streptococcus pyogenes	ATCC # 12384
	Streptococcus salivarius	ATCC # 7073
<<5-min Disinfection – Viruses>>	Adenovirus Type 2†	ATCC # VR-846
	Cytomegalovirus†	ATCC # VR-538
	Hepatitis B Virus (HBV) †	
	Hepatitis C Virus (HCV) †	
	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 Virus [Hong Kong] †	ATCC # VR-544
	2009-H1N1 Influenza A Virus (Novel H1N1, Strain	ATCC # CDC 2009712192

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	A/Mexico/4108/2009) †	
	Pseudorabies virus†	ATCC # VR-135
	Rabies Virus†	ATCC # VR-139
	Resperiatory Syncytial Virus [RSV] †	ATCC # VR-26
	Rotavirus WA†	ATCC # VR-2018
	SARS-Associated Coronavirus†	ATCC # CDC 200300592
<<10-min Disinfection - Fungi>>	Aspergillus niger	ATCC # 6275
	Candida albicans	ATCC # 10231
	Trichophyton mentagrophytes	ATCC # 9533

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