

675-55

12/30/2009

1/13



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

DEC 30 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Sally Hayes, Agent for Reckitt Benckiser, Inc.
SRC, Scientific & Regulatory Consultants, Inc.
P.O. Box 1014
Columbia City, IN 46725

Subject: Notification per PR Notice 95-2
Lysol Brand Disinfectant S. A. Cleaner
EPA Registration Number: 675-55
Application Date: December 3, 2009
Receipt Date: December 8, 2009

Dear Ms. Hayes:

This acknowledges receipt of your notification, submitted under the provisions of PR 95-2 and FIFRA section 3 (c) 9.

Proposed Notification:

Labeling revision in accordance with EPA guidance for labeling against Pandemic 2009 H1N1.

General Comments:

The notification is acceptable. A copy has been inserted in your file for future reference.

Should you have further questions concerning this letter, please contact me at 703-308-6416 or by email at mcfalane.jacqueline@epa.gov or Killian Swift by telephone at 703-308-6346 or by email at swift.killian@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in cursive script that reads "Jacqueline McFarlane".

Jacqueline McFarlane
(Acting) Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)



United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 675-55	2. EPA Product Manager ShaRon Carlisle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) LYSOL Brand Disinfectant S.A. Cleaner	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Reckitt Benckiser Morris Corporate Center IV 399 Interpace Parkway Parsippany, NJ 07054 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of (optional text additions in regards to Influenza A virus and Pandemic 2009 H1N1) per PR Notice 95-2. This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Sally Hayes	Title Agent for Reckitt Benckiser, Inc.	Telephone No. (include Area Code) (260) 244-6270
2. Signature 		6. Date Application Received (Stamped)
3. Title Agent for Reckitt Benckiser, Inc.		
4. Typed Name Sally Hayes		
5. Date 12/04/09		

37

3/1

SRC

Scientific & Regulatory

Consultants, Inc.

December 3, 2009

Ms. ShaRon Carlisle (PM34)
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, 4th Floor
One Potomac Yard
2777 S Crystal Drive
Arlington, VA 22202

SUBJECT: Notification (Influenza A and Pandemic 2009 H1N1) per PR Notice 95-2
LYSOL® Brand Disinfectant S.A. Cleaner
EPA Reg. No.: 675-55

Dear Ms. Carlisle:

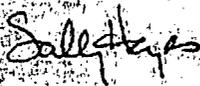
On behalf of our client Reckitt Benckiser, Inc., enclosed is a notification in compliance with the recent Agency "Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)." This is a Notification per PR Notice 95-2; therefore, no PRIA fee is required.

The new statements, as specified in the guidance, have been added to the current accepted label as optional text. No additional changes to the existing label have been made. This application contains claims consistent with the statements in Section III of the EPA Guidance, therefore meeting the criteria for the Agency's expedited review of 20 business days.

This notification, as stipulated by the guidance, is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action, and penalties under sections 12 and 14 of FIFRA.

Please contact me at (260) 244-6270 or at shayes@srconsultants.com if you have any questions.

Sincerely,



Sally Hayes
Agent for Reckitt Benckiser, Inc.

Cc: M. Pisculli

P.O. Box 1014
Columbia City, IN 46725

www.srconsultants.com

Phone: 260-244-6270
Fax: 260-244-6273

4/13

<< Front Panel >>

ACTIVE INGREDIENT:
Citric Acid. 2.50%
OTHER INGREDIENTS: 97.50%
TOTAL: 100.00%

KEEP OUT OF REACH OF CHILDREN
WARNING: See back (side) panel for additional precautionary statements.

NET CONTENTS: 32 FL. OZ. (1 QT.) (946 mL)
 128 FL. OZ. (1 GAL.) (3.79 L)
 144 FL. OZ. (1.125 GLA.) (4.25 L)

(2) (bottles) 32 FL. OZ. (1 QT.) 946 mL TOTAL: 64 FL. OZ. (2 QT.) 1.89 L
(3) (bottles) 32 FL. OZ. (1 QT.) 946 mL TOTAL: 96 FL. OZ. (3 QT.) 2.84 L
(4) (bottles) 32 FL. OZ. (1 QT.) 946 mL TOTAL: 128 FL. OZ. (4 QT.) 3.79 L

<< Sticker Pack – must include all unit of measurement as stated above >>

(New) Refill Pack	
Refill (Bottle):	oz. [(PT / QT / GAL) (mL / L)]
Trigger (Bottle):	oz. [(PT / QT / GAL) (mL / L)]
Total (Pack):	oz. [(QT / GAL) (L)]

<< Front or Back Panel >>

EPA Reg. No.: 675-55
EPA Est. No.: 777-NJ-2 8791-MO-1 09019-OH-1 09019-OH-2
See bottom or side (for Lot/Date code)

NOTIFICATION
Date Reviewed: 12/29/09
Reviewed By: *[Signature]*

<< Back Panel >>

Questions? (telephone symbol) **(Call:) (1-800-228-4722) (1-800-677-9218)**
For ingredient (and other) information (www.lysol.com) (www.reckittprofessional.com) (www.spreadinghealth.com)
Made in U.S.A. © RBI (year)
Distributed by: Reckitt Benckiser Inc., Parsippany, NJ 07054(-xxxx)
Contains no phosphates
This (bottle) (container) is made of x% post-consumer recycled plastic.

<< Back Panel - Spanish translation of >>:

Important: For directions for use and first aid instructions in Spanish, please call {insert phone number}

<< Back Panel – Optional text >>

Important facts (about this product) Recycle Symbol
Encourage your local authorities to establish a program to recycle this (bottle) (container).
Learn more about (the importance of good hygiene habits) (and the many ways that Lysol® is promoting good hygiene habits) (for your family and community) go to www.spreadinghealth.com

<< Back Panel – Optional text for Professional Use products only >>

Graphic Symbol (Hospital Disinfectant – Meets AOAC Standards)
Part of your infection control program
(This product) meets the requirements of the OSHA Bloodborne Pathogen Standard for Decontamination
(This product) meets AOAC Germicidal Spray efficacy standards for hospital disinfectants;

NSF certification symbol:



Company graphic Logo:



<< Introductory 6-mos. claims – may only appear on graphic labels for the first 6 months the product is on shelf >>

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.

8/13

<< Front or Back Panel – Disinfecting claims – use as bullet point or in paragraph format >>

An effective disinfectant cleaner (on non-food contact surfaces) and deodorizer (for use in the) (bathroom) (restroom)
An effective disinfectant cleaner (on non-food contact surfaces) and deodorizer for use on {insert use sites from pg. 8}
Cleans and prevents mold and mildew
Effective: Cleans, shines, deodorizes and disinfects washable (bathroom) (restroom) surfaces and fixtures
Effective against: (the) common cold, infectious diarrhea, athlete's foot fungus, salmonella**
Effectively cleans, shines and disinfects (washable hard, non-porous surfaces in) {insert use sites from pg. 8}
Eliminates odors caused by bacteria
Kills 99.9% of bacteria and viruses**
Kills 99.9% of germs**
Kills 99.9% of mold
Kills 99.9% of viruses and bacteria**
Kills Athlete's Foot Fungus in the (bathroom) (restroom)
Kills bacteria while it cleans tough (bathroom) (restroom) messes*
Kills (Disinfects) common (household) bacteria and (viruses) (fungi) without bleaching**
Kills (Disinfects) common (household) germs without bleaching**
Kills (Eliminates) bacteria*
Kills (Eliminates) bacteria and viruses**
Kills (Eliminates) germs**
Kills Echovirus Type 12, Hepatitis A, Herpes Simplex Virus Type 1 & 2, Influenza A2 [Japan 305/57], Poliovirus Type 1 and Rotavirus WA in 5 minutes
Kills germs**
Kills germs and controls the (spread) (growth) of fungi and mold**
Kills germs that ordinary cleaners don't**
Kills germs while it cleans**
Kills germs while it cleans tough (bathroom) (restroom) messes**
Kills (household) bacteria (and sanitizes without bleaching)*
Kills mold
Kills more than 99.9% of bacteria and viruses**
Kills odor-causing bacteria (in the) (bathroom) (restroom)*
Kills Rhinovirus Type 39 and Rotavirus WA in 30 seconds
Kills viruses†
On hard, non-porous, inanimate environmental surfaces, this product kills (the following bacteria, fungi and viruses):
{insert microorganisms from pg. 7}
Prevents (Controls) mold and mildew growth
Prevents the growth of mold and mildew
Prevents the spread of harmful (household) germs**

<< Back Panel – Disinfection claim qualifier >>

* Kills (99.9% of) (Campylobacter jejuni) (Enterococcus faecalis) (Enterococcus faecium) (Escherichia coli O157:H7) (Pseudomonas aeruginosa) (Salmonella enterica) (Staphylococcus aureus) (and) (Streptococcus pyogenes) (on hard, non-porous surfaces) (in 10 minutes).

** Kills (99.9% of) (Campylobacter jejuni) (Enterococcus faecalis) (Enterococcus faecium) (Escherichia coli O157:H7) (Pseudomonas aeruginosa) (Salmonella enterica) (Staphylococcus aureus) (Streptococcus pyogenes) and (Adenovirus Type 2) (Echovirus Type 12) (Hepatitis A) (Herpes Simplex Virus Type 1 & 2) (Human Immunodeficiency Virus Type 1 [HIV-1 AIDS Virus]) (Influenza A2 [Japan 305/57]) (Parainfluenza Type 2) (Poliovirus Type 1) (Respiratory Syncytial Virus [RSV]) (Rhinovirus Type 39) (Rotavirus WA) (and) (Trichophyton mentagrophytes) (on hard, non-porous surfaces) (in 10 minutes).

† Kills (Adenovirus Type 2) ((Echovirus Type 12) (Hepatitis A) (Herpes Simplex Virus Type 1 & 2) (Human Immunodeficiency Virus Type 1 [HIV-1 AIDS Virus]) (Influenza A2 [Japan 305/57]) (Parainfluenza Type 2) (Poliovirus Type 1) (Respiratory Syncytial Virus [RSV]) (Rhinovirus Type 39) (and) (Rotavirus WA).

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The product label must identify the specific bacteria, virus, fungus & mold.

<< This page is for information purposes only – unless otherwise noted. >>

<< Disinfection - Hard non-porous surfaces >>

<< Bacteria >>	(ATCC # 29428) (ATCC # 828) (ATCC # 6569) (ATCC # 43888) (ATCC # 15442) (ATCC # 10708) (ATCC # 6538) (ATCC # 12384)	Campylobacter jejuni Enterococcus faecalis Enterococcus faecium Escherichia coli O157:H7 Pseudomonas aeruginosa Salmonella (choleraesuis) enterica Staphylococcus aureus Streptococcus pyogenes
<< Virus >>	(ATCC # VR-846) (ATCC # VR-42) (ATCC # VR-733 & 734) (ATCC # VR-100) (ATCC # VR-92) (ATCC # VR-26) (ATCC # VR-340) (ATCC # VR-2018)	Adenovirus Type 2 Echovirus Type 12 Hepatitis A Herpes Simplex Virus Type 1 & 2 Human Immunodeficiency Virus Type 1 [HIV-1 AIDS Virus] Influenza A ₂ [Japan 305/57] (flu virus) <u>Influenza A H1N1 [2009][Pandemic]</u> Parainfluenza Type 2 Poliovirus Type 1 Respiratory Syncytial Virus [RSV] Rhinovirus Type 39 (common cold) Rotavirus WA (infectious diarrhea)

<< Fungi >>	(ATCC # 9533)	Trichophyton mentagrophytes (Athlete's Foot Fungus)
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<< Fungistatic - Hard non-porous surfaces >>

<< Fungi >>	(ATCC # 16404)	Aspergillus niger (mold & mildew)
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<< Sanitization - Non-Food Contact Surfaces >>

<< Bacteria >>	(ATCC # 13048) (ATCC # 51299) (ATCC # 43888) (ATCC # 6538) (ATCC # 33592)	Enterobacter aerogenes Enterococcus faecalis [VRE] Escherichia coli O157:H7 Staphylococcus aureus Staphylococcus aureus [MRSA]
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Symbol Designation – used on product labels:

Single asterisk (*)	bacteria*	used for identifying disinfection against specific bacteria.
Dagger (†)	viruses†	used for identifying disinfection against specific viruses.
Double asterisk (**)	germs**	used for identifying disinfection against specific bacteria and virus or fungi.
Triple asterisk (***)	sanitizes***	used for all claims of sanitization
Double Dagger (††)	allergens††	used for identifying the removal of specific non-living allergens

NOTE: Bracketed information is denoted as: << directive >>, { insert as noted }, (optional text), [required qualifier].
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11
 13

<< Soil / Odor / Surface / Use Sites - May be listed on product label in plural form >>

Soils / Odors: (Graphic – depicting soil)

Bathtub rings	Grime	Mud	Soap scum
Calcium stains	Hard water stains	Outdoor grime	Stains (soils)
Dirt	Lime scale	Pest stains	Toothpaste stains
Fingerprints	Mildew stains	Rust stains	Tough Soils
Grease	Mineral stains	Smudges	Urine stains

Non-living Allergens:

Cat dander allergens	Dog dander allergens	Hair
Cockroach matter allergens	Dust mite matter allergens	Pet dander allergens
Cockroach debris	Dust mite debris	Pet dander
Cockroach matter	Dust mite matter	Pet hair
Cockroach particles	Dust mite particles	Pollen particle allergens

Non-Food Contact Surface Types: (~ specify Non-Medical or Fixture)

Chrome ~	Glass	Laminated plastic	Stainless steel ~
Crystal	Glazed ceramic	Linoleum	Synthetic Marble
Enamel	Glazed porcelain	Metal	Vinyl
Fiberglass fixtures	Glazed tile		

Hard Non-porous Surfaces: (Graphic – depicting use site)

Appliance exterior	Floor (linoleum)	Shelves (drawers)
Bathtub (tub)	Floor (vinyl)	Shower (door) (vinyl curtain)
Cabinet	Floor (no-wax)	Shower (stall) (area)
Changing table	Garbage (can) (pail) (container)	Sink (basin)
Counter (Countertop)	Glazed ceramic tile	Stove (stovetop)
Crib	Glazed porcelain tile	Table (tabletop)
Diaper pail	Highchair (non-food contact are)	Toilet bowl exterior (Urinal)
Door knob (handle)	Light fixtures	Vanity top
Exhaust (fan) (hood)	Metal blinds	Washable walls
Faucet (chrome / stainless steel)	Non-medical (chrome / stainless steel)	Window (windowsill)
Fixture (chrome / stainless steel)	Painted woodwork	Other hard, non-porous, non-food contact surfaces
Floor (glazed tile)	Plastic laundry (basket) (hamper)	

Household Use Sites: (Graphic – depicting use site)

Basemet	Den / Study	Home / House	Living room
Bathroom	Family room	Household area	Playroom
Bedroom	Garage	Kitchen	

Professional Use Sites:

Cafeteria	Health Care Facility	Kitchen	Restaurant
Day Care Center	Hospital	Nursing Home	Restroom
Dental Office	Hotel / Motel	Office Building	School
Doctors Office	Infirmary	Physicians Office	

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