

777-83

6/11/2013

1/14



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 11, 2013

David Swain
Agent for Reckitt Benkiser
Scientific and Regulatory Consultants, Inc.
P.O. Box 1014
Columbia City, IN 46725

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: PRIA (D-47263)
Lysol Brand Disinfectant Bleach Plus
EPA Registration No. 777-83
Application Dated: January 17, 2013
Receipt Dated: January 22, 2013

Dear Mr. Swain:

This acknowledges the receipt of your Amendment application dated January 17, 2013 in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended is **acceptable**.

Submission and Proposed Changes

Amend the label and submit supporting efficacy data for disinfecting Feline Calicivirus (surrogate for Norovirus) and *Clostridium difficile*. Also add additional minor marketing claims. The original label was dated on January 17, 2013, and updated on June 3, 2013 (pin punch 06/03/13).

Comments and Conditions:

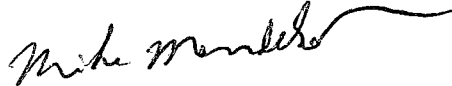
Based on the efficacy studies submitted, the latest amended label dated June 03, 2013 (pin punch 06/03/13) is **acceptable**.

A stamped copy of the label with comments is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

This amendment and a copy of this letter have been inserted in your file for future reference.

If you have any questions or comments concerning this letter, please contact David Liem at liem.david@epa.gov or call (703) 305-1284.

Sincerely,



Mike Mendelsohn
Acting Product Manager - Team 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

Att: Accepted Stamp label

<< FRONT PANEL >>

ACTIVE INGREDIENT:

Sodium Hypochlorite..... 2.0%

OTHER INGREDIENTS: 98.0%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING: Eye and skin irritant. See back (side) panel for additional precautionary statements and first aid.
Use only in well ventilated areas.

NET CONTENTS:	16 FL. OZ. (1 PT.)	(473 mL)	32 FL. OZ. (1 QT.)	(946 mL)
	17 FL. OZ. (1 PT. 1 FL. OZ.)	(502 mL)	36 FL. OZ. (1 QT. 4 FL. OZ.)	(1.06 L)
	22 FL. OZ. (1 PT. 6 FL. OZ.)	(650 mL)	38 FL. OZ. (1 QT. 6 FL. OZ.)	(1.12 L)
	24 FL. OZ. (1 PT. 8 FL. OZ.)	(709 mL)	40 FL. OZ. (1 QT. 8 FL. OZ.)	(1.18 L)
	26 FL. OZ. (1 PT. 10 FL. OZ.)	(768 mL)	51 FL. OZ. (1 QT. 19 FL. OZ.)	(1.5 L)
	28 FL. OZ. (1 PT. 12 FL. OZ.)	(828 mL)	64 FL. OZ. (2 QTS.)	(1.89 L)
	30 FL. OZ. (1 PT. 14 FL. OZ.)	(887 mL)	128 FL. OZ. (1 GAL.)	(3.79 L)
	(2) 24 FL. OZ. (1 PT. 8 FL. OZ.)	(709 mL)	TOTAL: 48 FL. OZ. (1 QT. 1 PT.)	1.43 L

<< FRONT / BACK PANEL >>

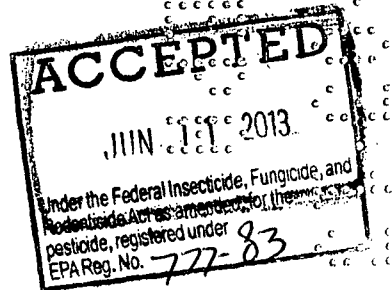
EPA Reg. No.: 777-83
EPA Est. No.: 777-NJ-2 046813-CN-6 68777-NY-1 75371-IN-1 09019-OH-1
8791-MO-1 71354-NC-1 11525-IL-1 312-WI-1 09019-OH-2
(See bottom or side) (for Lot / Date code) 55179-IN-1 312-WI-3 8155-OH-1

<< BACK PANEL >>

Questions? (Call:) (1-800-228-4722) (1-800-677-9218)
For ingredient (and other) information, (www.rbna.info.com)
Distributed by: Reckitt Benckiser, Parsippany, NJ 07054(-xxxx)
Made in {insert country} © {year} RB
Contains no phosphates
This (bottle) (container) is made of 25% post-consumer recycled plastic.



Company graphic logo



<< FRONT / BACK PANEL - Optional text >>

Recycle Symbol
Important facts (about this product)
Encourage your local authorities to establish a program to recycle this (bottle) (container).

IMPORTANT: For directions for use and first aid instructions in Spanish, please call 1-877-843-3817.
Spanish Translation:
IMPORTANTE: Para instrucciones de uso y primeros auxilios en español por favor llame al 1-877-843-3817.

Learn more about (the importance of good hygiene habits) (and) (the appropriate use of disinfectants) (in good hygiene) (and) (the many ways that Lysol® is promoting good hygiene habits) (for your family and community) go to www.spreadinghealth.com

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4/19

<< NOTE: Any claim may appear on either FRONT / BACK panel in bullet / paragraph format – Unless otherwise noted. >>

<< INTRODUCTORY 6-mos. CLAIMS – will only appear on graphic label for the first 6 months product is on shelf >>

(New) (Improved) (Formula) (Scent) (Easy Grip Bottle) (New & Improved)

<< PACKAGING CLAIMS >>

(Bonus) (Economy) (Great) (Mega) (Super) (Trial) (Value) (Pack) (Refill) (Size) (Place 1 in each bathroom)
(Bonus x %) (Bonus x oz) (x oz at x oz Price) (x oz. for the price of x oz.) (x % discount) (x % more free)
(Money back guarantee) (Your # 1 choice) (Take the Lysol® Challenge) (Try it yourself) (or) (Get your money back)

<< MARKETING CLAIMS >>

(3-in-1) (4-in-1) (4 Way) (Action) (5 in 1) (All-in-1) (Cleaning Power) (Mold & Mildew Remover) (with Bleach) (Multi-Action) (Multi-Clean) (Multi-Purpose) (Multi-Surface) (One-Step Cleaner Sanitizer) (Power) (Power Foam) (Triple Action) (Cleaner) (With Bleach)

(Bathroom) (Floor) (Glass & Surface) (Kitchen) (Restroom) (Cleaner) (Deodorizer) (Deodorizes) (Disinfects) (Disinfectant) (Disinfecting) (Sanitizer) (Sanitizes) (Complete) (Easy) (Easy to use) (Effective) (Express) (Extreme) (Fast) (Quick) (Quick & Easy) (Ready to Use) (Streak-free) (Streak-free formula) (Total) (Versatile) (Clean) (Cleaner) (Cleaning) (Degreaser) (Degreases) (Beautiful) (Bright) (Brilliant) (Clean & Fresh) (Glistening) (See-through) (Streak-free) (Shine) (Cleans) (and) (Shines) (Grease releaser) (with Grease release action)

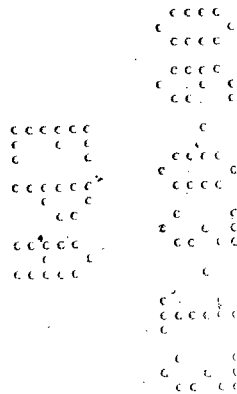
(Antibacterial) (Bactericidal*) (Bactericide*) (Cleaner) (Deodorizer) (Germicidal**) (Virucidal†)

(x%) Better at (cutting) (removing) (eliminating) (tough) (kitchen) (grease) (soap scum)
(x%) Better than ever on (tough) grease (and) (soap scum)

Brightens (and whitens in seconds) (as it cleans)
Cleans (better than ever) (with the power of bleach)
Confidence of Lysol®

Contains a detergent cleaner plus chlorine bleach
Contains the most (effective) (fast-acting) grease cutters
Deep Down Clean!
Developed for food service (and general housekeeping)

Disinfects as it cleans
Express Clean & Fresh
Extreme white clean
Fast acting brightener
Fresh Clean Scent
Great for everyday (cleaning), (deodorizing) (and) (disinfecting)
Great whitening power
Has a clean (fresh) (pleasant) scent
Immediate whitening action
Leaves a (bright) (brilliant) (vibrant) shine
Lysol's best (ever) (grease) (and) (soap scum) (remover) (cleaner)
Multi Purpose Cleaner with Bleach (for Kitchens & Bathrooms) (for Kitchens & Restrooms) (for Kitchen(s) & Bath(s))
Nonabrasive formula (rinses away easily)



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7/14

<< **SANITIZING CLAIMS – Hard, non-porous, non-food contact surfaces** >>

Fast acting sanitizer

Kills bacteria on hard, non-porous surfaces in seconds***

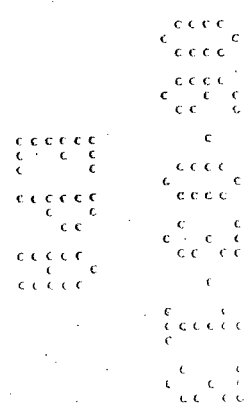
Kills (Eliminates) 99.9% of bacteria in 30 seconds***

Kills (Eliminates) 99.9% of bacteria on hard, non-porous surfaces in 30 seconds***

Sanitizes in 30 seconds: (Campylobacter jejuni) (Enterobacter aerogenes) (Escherichia coli O157:H7) (Listeria monocytogenes) (Pseudomonas aeruginosa) (Salmonella enterica) (Staphylococcus aureus) (and) (Vibrio cholerae).

<< **SUPPORTING CLAIM QUALIFIER – must appear before 'Directions For Use' on Back Panel label** >>

*** Kills 99.9% of (Campylobacter jejuni) (Enterobacter aerogenes) (Escherichia coli O157:H7) (Listeria monocytogenes) (Pseudomonas aeruginosa) (Salmonella enterica) (Staphylococcus aureus) (and) (Vibrio cholerae) on hard, non-porous surfaces in 30 seconds.



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9/14

<< USE DIRECTIONS >>

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

Apply Carefully - Contains Bleach

Avoid contact with clothes, fabric, wood, rubber, carpet, painted / paper surfaces, non-porous vinyl surfaces, and finished floors. Rinse immediately after use on metal to avoid pitting or discoloration. Prolonged contact with metal, old porcelain, plastic laminate and marble may cause discoloration.

To Operate: Turn nozzle counter clockwise to preferred usage.

To Operate: Turn nozzle to ("ON") (desired) position.

(To Operate:) **To Open:** Lift tab up, push back and press tab down to lock into open position.
To Close: Release tab from locked position, push tab down and snap closed.

To Refill (Bottle): Remove trigger sprayer. Pour in product from refill container and replace trigger.

To Refill (Bottle): Remove trigger unit from empty bottle and attach to new bottle.

To Clean (/ Deodorize) (/ Remove Allergens††): (Spray) (Apply to) surface until thoroughly wet. Wipe with a clean cloth or sponge and then rinse.

To Clean (Lime Scale) (Soap Scum) (and) (Greasy Soil): Allow product to sit 15-20 seconds to penetrate soil before wiping clean. Repeat if necessary.

To Sanitize / Disinfect: Pre-clean surface. (Spray) (Apply to) surface until thoroughly wet.

To Sanitize: Leave for 30 seconds before wiping. **To Disinfect:** Leave for 5 minutes before wiping. Rinse all food contact surfaces with water after use. If the vapors bother you, leave the room while the product is working.

Kills Mold & Mildew: Apply to pre-cleaned surface. Let surface remain wet for 5 minutes and then allow to air dry. Repeat application at weekly intervals or when mold and mildew growth appears.

To Clean No-wax Floors: Mix 1 cup [8 oz.] of product per 1 gallon of water; mop until clean. Rinse for the best shine.

<< ADVISORY STATEMENTS >>

Can be used in cleaning tools that recommend the use of (this product).
Do not use on eating/cooking utensils, glasses/dishes or cookware.
Rinse bathtub / shower surfaces with water after using product.

If the last portion (of this product) is difficult to dispense, turn trigger 180° to face opposite direction; this will ensure full use of its contents.

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10/14

This product has been tested and found effective against the following micro-organisms:

Bacteria & Virus			
<< Disinfection - Hard, non-porous surfaces >>			
Bacteria (5 minutes)		Viruses (5 minutes)	
	<u>ATCC No.</u>		<u>ATCC No.</u>
Enterococcus faecalis	(838)	Herpes Simplex Virus Type 1	(VR-733)
Pseudomonas aeruginosa	(15442)	Herpes Simplex Virus Type 2	(VR-734)
Salmonella enterica	(10708)	Human Immunodeficiency Virus Type 1	n/a
Staphylococcus aureus	(6538)	Rhinovirus Type 39 (common cold)	(VR-340)
Clostridium difficile (C. difficile)	(43598)	Rotavirus WA (infectious diarrhea)	(VR-2018)
		Respiratory Syncytial Virus[RSV]	(VR-26)
Bacteria (3 minutes)		Viruses (30 seconds)	
Campylobacter jejuni	(29428)	Human Immunodeficiency Virus Type 1	n/a
		Rhinovirus Type 39 (common cold)	(VR-340)
		Rotavirus WA (infectious diarrhea)	(VR-2018)
		Norovirus (Feline Calicivirus as surrogate)	(VR-782)
<< Fungicidal – Hard, non-porous surfaces >>		<< Mildew Fungistat – Hard, non-porous surfaces >>	
Fungi (5 minutes)		Fungi (3 minutes)	
	<u>ATCC No.</u>		<u>ATCC No.</u>
Aspergillus niger	(6275)	Aspergillus niger	(16404)
Trichophyton mentagrophytes	(9533)		
<< Sanitization – Hard, non-porous, non-food contact surfaces >>			
Bacteria (30-seconds)		<u>ATCC No.</u>	
Campylobacter jejuni	(29428)		
Enterobacter aerogenes	(13048)		
Escherichia coli O157:H7	(43888)		
Listeria monocytogenes	(19111)		
Pseudomonas aeruginosa	(15442)		
Salmonella enterica	(10708)		
Staphylococcus aureus	(6538)		
Vibrio cholerae	(11623)		

Symbol Designation – used on product labels		
Single asterisk (*)	Bacteria * / Fungi	Used for identifying disinfection against specific bacteria or fungi
Dagger (†)	Viruses †	Used for identifying disinfection against specific viruses
Double asterisk (**)	Germes **	Used for identifying disinfection against specific bacteria & viruses / fungi
Triple asterisk (***)	Sanitizes ***	Used for identifying sanitization against bacteria
Double dagger (††)	Allergens ††	Used for identifying the removal of specific non-living allergens

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11/14

<< SOILS / ODORS / SURFACES / USE SITES – May be listed on product label in the singular or plural form >>

Soils: (Graphic - depicting soil)

Food stains	Grime	Mildew stains	Soap scum
General soils	Grease (Greasy soils)	Mold stains	Tough soils
<u>Bathtub rings</u>			

Non-living Allergens:

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

Hard Non-porous Surfaces: (Graphic - depicting surface)

Appliance exterior	Food Carts	Refrigerator / Freezer exterior
Cabinet (non-wood)	Garbage (Can)(Pail)(Container)	Shower (Shower Stall)
Counter (Countertop)	Glazed Ceramic Tile	Sink
Faucet	Glazed Porcelain Surface	Stove (Stovetop)
Fiberglass Fixtures	Sealed Grout	Toilet exterior
Fixtures (Chrome / Stainless Steel)	Highchair (non-wood)	Tub (Bathtub)
Floors (No-wax)	Kitchen Table	(Glazed Tiled) Wall
Floors (Sealed Ceramic Tile)	Microwave exterior	Vinyl Shower Curtain
Floors (Vinyl)	Non-medical (Chrome / Stainless Steel)	Water Fountain

Household Use Sites: (Graphic - depicting site)

Bathroom	Family Room	^ Kitchen	Nursery
Bedroom	Garage	Laundry Room	Play Room
Den / Study	Home / House	Living Room	Storage area / room
^ Dining Room			

^ This product is not approved for use on food-contact surfaces.

Commercial Use Sites:

^ Cafeteria	Health Care Facility	Nursing Home	Restroom
Day Care Center	Hospital	Office Building	School
Dental Office	Hotel / Motel	Physicians Office	^ Food Service Areas
Doctor's Office	Infirmery	^ Restaurant	

^ This product is not approved for use on food-contact surfaces.

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12/14

<< Additional USE DIRECTIONS (claim specific) – Specific to Commercial Branded products Only >>

<< TERMINAL STERILANT STATEMENT – qualified metal surfaces >>

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

<< TERMINAL STERILANT STATEMENT – unqualified metal surfaces >>

This product is not to be used as a terminal sterilant / high level disinfectant on any surface that ⁽¹⁾ is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body; or ⁽²⁾ contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enters normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

<< HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 [HIV-1 AIDS Virus] >>

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 or body fluids; and in which the surfaces / objects likely to be soiled with blood or 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 ON SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS:

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

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME: Allow surface / object to remain wet for 30 seconds.

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

<<FOR COMMERCIAL LABELS WITH CLOSTRIDIUM DIFFICILE CLAIM>>

PERSONAL PROTECTION: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

CLEANING PROCEDURE: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the disinfectant product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

INFECTIOUS MATERIALS DISPOSAL: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

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13/14

<< PRECAUTIONARY / PHYSICAL-CHEMICAL HAZARD / FIRST AID / STORAGE & DISPOSAL >>

PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals

WARNING: Causes eye and skin irritation. Do not get in eyes, on skin or on clothing. Vapors may irritate. Use only in well-ventilated areas. Avoid prolonged breathing of vapors. Not recommended for use by persons with heart conditions or chronic respiratory problems such as asthma, emphysema or obstructive lung disease. Harmful if swallowed. For sensitive skin or prolonged use, wear rubber gloves. Wash after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID	
If in Eyes	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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
If Inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a Poison Control Center or doctor for further treatment advice.
CONTACT NUMBER	
Questions? Comments or In case of an emergency call toll free (1-800-228-4722) (1-800-677-9219) Have the product container or label with you when calling a Poison Control Center or doctor, or going for treatment.	

PHYSICAL AND CHEMICAL HAZARDS: This product contains bleach. Do not mix with other (household) chemicals such as products containing ammonia, toilet bowl cleaners or acid cleaners as hazardous gases may be released.

<< STORAGE & DISPOSAL – Residential containers >>

<< Trigger bottle >>

STORAGE AND DISPOSAL: Store in a cool, well-ventilated area, inaccessible to children. Keep securely closed. Refillable container. Do not reuse or refill except as described in the directions for use. Refill trigger bottle only with this product. If not refilling, discard in trash or offer for recycling, if available.

<< Pourable container >>

STORAGE AND DISPOSAL: Store in a cool, well-ventilated area, inaccessible to children. Keep securely closed. Non-refillable container. Do not reuse or refill this container. Discard in trash or offer for recycling, if available.

<< 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 a cool, well-ventilated area, inaccessible to children. Keep securely closed.

PESTICIDE DISPOSAL: To avoid waste, use all material in this container according to label directions. Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse (or equivalent). Follow pesticide disposal instructions for rinsate. Then discard in trash or offer for recycling, if available.

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