

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Washington, D.C. 20460

June 19, 2008

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Jennifer DeCarlo
Regulatory & Registration Compliance Specialist
Reckitt Benckiser, Inc.
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NJ 07054-0225

Subject: Lysol Brand Disinfectant-Bleach-Plus
EPA Registration No. 777-102
Application Date: March 20, 2008
Receipt Date: March 24, 2008

Dear Ms. DeCarlo:

The following amendments, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable with the comments listed below:

Proposed Amendments

- Addition of non-FIFRA marketing text
Update net contents
Update CRC pictograms for product cap
Addition of non-refillable container statement to Storage & Disposal instructions

General Comments

Based on a review of the material submitted, the following comments apply:

1. On page 2 of the proposed label, the following claims are comparative must be removed after six months: "Better squirting than before", "Designed for better dispensing", "Quicker to open", "Improved coverage", "Better bowl coverage than before", "Better reach under the rim".

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

Should you have any questions or comments concerning this letter, please contact Wanda Henson at (703) 308-6345.

Sincerely,

Emily H. Mitchell
Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

CONCURRENCES

Table with 8 columns and 3 rows for tracking approvals. Includes handwritten initials and dates.

2 8 9

<< 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	30 FL. OZ.	(1 PT. 14 FL. OZ.)	887 mL
	24 FL. OZ.	(1 PT. 8 FL. OZ.)	709 mL	32 FL. OZ.	(1 QT.)	946 mL
	26 FL. OZ.	(1 PT. 10 FL. OZ.)	768 mL	36 FL. OZ.	(2 PT. 4 FL. OZ.)	1,064 L
	28 FL. OZ.	(1 PT. 12 FL. OZ.)	828 mL	40 FL. OZ.	(1 QT. 8 FL. OZ.)	1.18 L

(2)	24 FL. OZ.	(1 PT. 8 FL. OZ.)	709 mL	TOTAL:	48 FL. OZ. (1 QT. 1 PT.)	1.42 L
(4)	32 FL. OZ.	(1 QT.)	946 mL	TOTAL:	1 GAL. (4 QTS.)	3.79 L
(6)	32 FL. OZ.	(1 QT.)	946 mL	TOTAL:	1.5 GAL. (6 QTS.)	5.68 L
(4)	40 FL. OZ.	(1 QT. 8 FL. OZ.)	1.18 L	TOTAL:	1.25 GAL. (5 QTS.)	4.73 L
(6)	40 FL. OZ.	(1 QT. 8 FL. OZ.)	1.18 L	TOTAL:	1.87 GAL. (7.48 QTS.)	7.08 L

<< Front or Back Panel >>

EPA Reg. No.:	777-102	68777-NY-1
EPA Est. No.:	777-NJ-2	75371-IN-1
	11525-IL-1	312-WI-1
	8791-MO-1	09019-OH-001
	046813-CN-006	09019-OH-002
	55179-IN-1	8155-OH-1
	71354-NC-001	

See bottom or side (for Lot/Date code)

**ACCEPTED
with COMMENTS
EPA Letter Dated:**

JUN 19 2008

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 777-102**

<< Back Panel >>

Questions? Comments? Call: (1-800-228-4722) (1-800-677-9218)

(or) Visit us at (www.lysol.com) (www.reckittprofessional.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-Optional text >>

Monday – Friday, 8:45 a.m. – 4:30 p.m. (Eastern time)

Company Logo (Reckitt Benckiser Professional)

Recycle Symbol

Important facts (about this product)

Encourage your local authorities to establish a program to recycle this (bottle) (container).

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 Claims – use as bullet point or in paragraph format >>

<<Introductory 6-mos. claims >> (New) (Improved) (Formula) (Angle Neck Bottle) (Cap) (Fragrance)
(Easy Grip Bottle) (Pack) (Package) (Scent) (Size)

<< Packaging Claims >>

(Bonus) (Economy) (Great) (Mega) (Super) (Trial) (Value) (Pack) (Size)
(Bonus x %) (Bonus x oz) (x oz at x oz Price) (x oz for the price of x oz) (x% discount) (x % more free)
(Bonus 50%) (50% Free) (16oz. for Free) (32oz. for the price of 16oz.)
(Bonus 40%) (40% Free) (16oz. for Free) (40oz. for the price of 24oz.)
(Bonus 33%) (33% Free) (8oz. for Free) (32oz. for the price of 24oz.) (24oz. for the price of 16 oz.)
(Bonus 25%) (25% Free) (8oz. for Free) (40oz. for the price of 32oz.)
(Buy x get x free) (x% discount) (x% more free)
(2 x 24oz.) (3 x 24oz.)
(Money back guarantee) (Your # 1 choice) (Take the Lysol® Challenge) (Try it yourself) (or) (Get your money back)
(2 PACK) (4 PACK) (6 PACK) (Great Value) (Multi-Pack) (One for each bathroom) (Place 1 in each bathroom)
(Buy me again) (Contains up to x uses) (Removable cap) (Repurchase time) (Shopping time) (Time to replace)
Angle neck bottle (for easy under-the-rim cleaning)
Easy (Easier) to squeeze cap
(Unique) Angle neck bottle for hard to reach areas
(Unique) Angle neck bottle reaches under the rim

Best value bottle
Better squirting than before
Contains up to x uses
Convenient cap
Designed for (more) (better) dispensing
Easy to close
Easy to reach under the rim
Easy to use (bottle)
Helps reach under the rim
Long (angle) neck bottle (reaches under the rim)
Non-drip (Less drip)
Non-removable cap
Quicker to open
Specially designed angle neck – gets all the way under the rim

<< Marketing Claims >>

(Bactericidal) (Cleans) (Deodorizer) (Deodorizes) (Disinfectant) (Disinfects) (Sanitizes) (Shines) (Thick Clinging)
(Thick Formula) (Thick Gel) (Thick Liquid) (Toilet Bowl Cleaner) (Formula)

2 in 1 (Formula): (Cleans, Disinfects)
3 in 1 (Formula): (Cleans, Disinfects, Deodorizes) (Cleans, Disinfects, Refreshes) (Cleans, Disinfects, Sanitizes)
Triple Action (Formula): (Cleans, Disinfects, Deodorizes)
4 in 1 (Formula): (Cleans, Disinfects, Deodorizes, Sanitizes)

(Maximum coverage)
(Maximum bowl coverage)
(Improved coverage)
(Maximum) (Max) (Improved) (Bowl) (Coverage) (Clean) (Cleaning action)
(Improved) (Better) (Bowl) (Coverage) than (Liquid Bleach) (APC) (other TBC)
(Better) (Improved) bowl coverage than before
Coats the entire bowl
Better reach under the rim

Brightens as it cleans
Clean Fresh Scent
Cleans & Deodorizes

Note: Bracketed information is denoted as: <<directive>>, {insert as noted}, (optional text), [required qualifier].
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The product label must identify the specific bacteria*, virus*, fungus* & mold*.

Cleans as it disinfects
 Cleans & disinfects above and below the waterline
 Cleans, disinfects and deodorizes even under the rim
 Cleans, disinfects and sanitizes the bowl
 Cleans everyday toilet bowl dirt and grime
 Cleans with the power of bleach
 Clings around the bowl
 Clings to the bowl to remove tough stains
 Confidence of Lysol®
 Contains a detergent cleaner plus chlorine bleach
 Controls toilet odors
 Deep Down Clean!
 Disinfectant Power of Lysol
 Disinfects, deodorizes and kills odor-causing bacteria
 Disinfects under the rim
 Disinfects with Bleach
 Economy Size
 Effective
 For a bright (shiny) (white) (clean) toilet bowl
 For better results, use at least (once) (twice) a week
 For use in (toilet bowls) (bidets) (and) (urinals)
 Fresh Clean Scent
 Gives you (full) (complete) (total) disinfection inside the toilet
 Great for everyday (cleaning), (deodorizing) (and) (disinfecting)
 Great whitening power
 Has a clean (fresh) (pleasant) scent
 Leaves a fresh clean scent
 Leaves toilet bowl sparkling clean and disinfected
 Maximum power (cleaner) (cleaning)
 No hard scrubbing
 Nonabrasive formula (won't scratch your bowl)
 Power of Bleach

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

Powerful cleaning formula
Safe for white and colored bowls
Thick liquid coats the bowl for better cleaning.
Thick liquid formula sticks to the bowl for better cleaning
This product contains no phosphates and is germicidal when used as directed for disinfecting.
This product meets AOAC Use-Dilution efficacy test standards for hospital disinfectants.
Toilet Bowl Cleaner
Toilet odor control
Total disinfection for inside your toilet (above and below the waterline)
Use daily to help maintain a clean, fresh & shiny bowl (even under the rim).
Whitens (Brightens) your toilet bowl
Will not harm plumbing or septic systems

<< Cleaning Claims >>

(Helps) (Removes) Toilet Rings

<< Sanitizing / Disinfecting Claims – front panel >>

Effective against: {insert organisms}
Kills 99.9% of bacteria***
Kills Germs**
Kills (99.9% of) bacteria and viruses**
Kills household germs**
Kills odor causing bacteria*
Kills viruses†

<< Sanitizing / Disinfecting Claims – back panel qualifiers >>

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

** Kills (Campylobacter jejuni), (Enterococcus faecalis), (Pseudomonas aeruginosa), (Salmonella enterica), (Staphylococcus aureus), (Herpes Simplex Virus Type 1 & 2), (Human Immunodeficiency Virus Type 1 [AIDS virus]), (Rhinovirus Type 39), (Rotavirus WA), (Aspergillus niger) (and) (Trichophyton mentagrophytes).

* Kills (Campylobacter jejuni), (Enterococcus faecalis), (Pseudomonas aeruginosa), (Salmonella enterica) (and) (Staphylococcus aureus).

† Kills (Herpes Simplex Virus Type 1 & 2), (Human Immunodeficiency Virus Type 1 [AIDS virus]), (Rhinovirus Type 39), (and) (Rotavirus WA).

<< Site / Surface / Soils >>

Use Site: (Clinics) (Day Care Centers) (Dental Offices) (Doctor Offices) (Health Care Facilities) (Homes) (Households) (Hospitals) (Hotels / Motels) (Infirmaries) (Institutions) (Laboratories) (Nursing Homes) (Office Buildings) (Physician's Offices) (Restaurants) (Schools)

Use Surface: (Vitreous china) (Porcelain) (toilets) (bidets) (urinals)

Soils: (Organic soils)

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<< Back Panel >>

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label before using product.

Apply Carefully - Contains Bleach

Lysol Brand TBC with Bleach should not be used or placed on toilet bowl lids, vanities, sinks, bathtubs, cabinets, countertops, rugs, etc. Clean up spills and drips immediately. Will not harm plumbing or septic systems.

To Open Child Resistant Cap: Hold bottle firmly with one hand on a flat surface. With other hand, squeeze sides of cap where symbols indicate and turn counterclockwise. **(Do not remove cap.) Avoid squeezing bottle when opening.** To reseal, turn cap clockwise until tightly closed.

To Open Child Resistant Cap: Hold bottle firmly with one hand on a flat surface. With other hand, while pushing down on top of cap, turn cap counterclockwise. **Avoid squeezing bottle when opening.** To reseal, twist cap clockwise until tightly closed.

<< Non-removable cap >>

To Open Child Resistant Cap: Hold bottle firmly with one hand. **DO NOT SQUEEZE BOTTLE WHEN OPENING.** With other hand:
1. Place fingers on marked ridges on opposite sides of cap.
2. Squeeze cap firmly and turn counterclockwise until it stops. **Do not remove cap.**
3. To reseal, squeeze cap again and turn clockwise until tightly closed.

<< Removable cap >>

To Remove Child Resistant Cap: Hold bottle firmly with one hand. **DO NOT SQUEEZE BOTTLE WHEN OPENING.** With other hand:
1. Place fingers on marked finger pads on opposite sides of cap.
2. Squeeze cap firmly and turn counterclockwise to unscrew.
3. Remove cap. 4. To reseal, replace cap and turn clockwise until tightly closed.

<< Optional Side panel pictograms - can only be used in conjunction with required back panel instructions >>

<< Non-removable >>



1. Place fingers on marked cap ridges.
 2. Squeeze cap firmly and turn counterclockwise until it stops. **Do not remove cap.**
 3. To reseal, squeeze cap again and turn clockwise.
- DO NOT squeeze bottle when opening.**

<< Removable - 1 >>



1. Place fingers on marked cap finger pads.
 2. Squeeze cap firmly and turn counterclockwise to unscrew.
 3. Remove cap.
 4. To reseal, replace cap and turn clockwise.
- DO NOT squeeze bottle when opening.**

<< Removable - 2 >>



<< Pictogram text >>

To Open Child Resistant Cap:

1. Place fingers on marked cap ridges.
 2. Squeeze cap firmly and turn counterclockwise until it stops. **Do not remove cap**
 3. To reseal, squeeze cap again and turn clockwise.
- DO NOT squeeze bottle when opening.**

To Remove Child Resistant Cap:

1. Place fingers on marked cap finger pads.
 2. Squeeze cap firmly and turn counterclockwise to unscrew.
 3. Remove cap.
 4. To reseal, replace cap and turn clockwise.
- DO NOT squeeze bottle when opening.**

To Remove Child Resistant Cap:

1. Place fingers on marked cap finger pads.
 2. Squeeze cap firmly and turn counterclockwise to unscrew.
 3. Remove cap.
 4. To reseal, replace cap and turn clockwise.
- DO NOT squeeze bottle when opening.**

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

<< Back Panel >>

To Clean, Disinfect & Sanitize (follow these easy steps):

1. Flush toilet to remove any excess dirt.
2. Direct (Add) ¾ cup (6 oz.) of product inside bowl to completely coat the sides of the bowl and under the rim. **Clean up spills and drips immediately. Do not close toilet bowl lid.**
3. **Disinfect:** Let stand for at least 5 minutes. **Sanitize:** Let stand for 30 seconds.
4. Brush entire bowl to wet surfaces thoroughly, including under the rim, and flush.
5. Rinse brush in fresh water after use. Repeat if necessary.

To Clean, Disinfect & Sanitize: Flush toilet to remove any excess dirt. Direct (Add) ¾ cup (6 oz.) of product inside bowl to completely coat the sides of the bowl and under the rim. Clean up spills and drips immediately. **Do not close toilet bowl lid. Disinfect:** Let stand for at least 5 minutes. **Sanitize:** Let stand for 30 seconds. Brush entire bowl to wet surfaces thoroughly, including under the rim, and flush. Rinse brush in fresh water after use. Repeat if necessary.

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 OF SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS:

PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks or 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 should be autoclaved and disposed of according to local regulations for infectious waste disposal.

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<< IMPORTANT: Organisms must be identified by genus & species. >>

<< Disinfection - Hard Non-porous Surfaces >>

<< Bacteria >>	Campylobacter jejuni Enterococcus (Streptococcus) faecalis Pseudomonas aeruginosa Salmonella (choleraesuis) enterica Staphylococcus aureus	(ATCC # 29428) (ATCC # 838) (ATCC # 15442) (ATCC # 10708) (ATCC # 6538)
<< Virus >>	Herpes Simplex Virus Type 1 & 2 Human Immunodeficiency Virus Type 1 [HIV-1 AIDS virus] Rhinovirus Type 39 Rotavirus WA	(ATCC # VR-733 & VR-734) (ATCC # VR-340) (ATCC # VR-2018)
<< Fungi >>	Aspergillus niger (mold & mildew) Trichophyton mentagrophytes (Athlete's Foot Fungus)	(ATCC # 6275 & 16404) (ATCC # 9533)

<< Sanitization - Hard Non-porous, Non-food Contact Surfaces >>

<< Bacteria >>	Campylobacter jejuni Enterobacter aerogenes Escherichia coli Listeria monocytogenes Pseudomonas aeruginosa Salmonella (choleraesuis) enterica Staphylococcus aureus Vibrio cholerae	(ATCC # 29428) (ATCC # 13048) (ATCC # 43888) (ATCC # 19111) (ATCC # 15442) (ATCC # 10708) (ATCC # 6538) (ATCC # 11623)
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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 Dagger (††)	soils††	used for identifying cleaning of specific soils
Double asterisk (**)	germs**	used for identifying disinfection against specific bacteria and virus or fungi.
Triple asterisk (***)	sanitizes***	used for all claims of sanitization

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<< Back Panel >>

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.

<< **NOTE:** First Aid statement may not appear in "box" format for 16 oz individual container do to label constraint. >>

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 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) (1-800-677-9218). Have the product container or label with you when calling a Poison Control Center or doctor, or going for treatment.	

<< Physical and Chemical Hazard language >>

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 and Disposal language – Household containers >>

STORAGE AND DISPOSAL: Store in original container out of reach of small children. Keep securely closed in a cool, well-ventilated area. Nonrefillable container. Do not reuse or refill this container. Wrap bottle and discard or offer for recycling, if available.

<< Storage and Disposal language – Professional containers >>

STORAGE AND DISPOSAL:

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

STORAGE: Store in original container in a cool, well-ventilated area, inaccessible to small children.

DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Wrap bottle and discard or offer for recycling, if available.

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