

777-68

9/11/2003

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SEP 11 2003

Bruce Paoella
Senior Regulatory Affairs Specialist
Reckitt Benckiser Inc.
1655 Valley Road
Wayne, NJ 07474-0943

Subject: Lysol Brand Pre-Moistened Bathroom Touch-Up Disinfectant Wipes
EPA Registration No. 777-68
Amendment Dated: June 16, 2003
EPA Received Date: June 16, 2003

Dear Mr. Bruce Paoella,

The following amendment submitted in connection with registration under section 3(c)(7)(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, is acceptable with the following conditions.

Proposed Amendment

- Amendment to revise the Master Label in accordance with PR Notice 2001 for First Aid.

Conditions

As previous requested on Agency letter dated April 11, 2003.

1. Throughout your label, references are made to the use of this product on Household surfaces, yet the label does not have "homes" listed as a use site. If you want to continue use of this phrase you must add residential homes as a use site on page one of the proposed master label.
2. Delete the claim "For use on Household Surfaces only" on page four of the proposed label, since this product is used in a variety of places.
3. Delete the word "bacterial" from the disinfecting sanitizing directions for travel size cleaning wipes on page four. The label should read "bacteria."

CONCURRENCES

SYMBOL	7510(c)							
USERNAME	A. Peter							
DATE	9/11/03							

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General Comments

Submit graphics for depicting areas of use by notification.

A stamped label is enclosed for your records. Please submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling. If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch1
Antimicrobial Division (7510c)

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EPA Registration Number: 777-68

Revised: 06/16/03

New*	<u>Contents</u>
Lysol ® Brand	16 Individually Wrapped
More Wipes(!) 70ct	Pre-Moistened Towelettes
(30) (70) Pre-Moistened Towelettes	(8" x 5 3/4") (Box)
Pre-Moistened	
Bathroom	
Touch-Ups	20 (25) (30) (35) (45) (70) Pre-Moistened
	Towelettes
Disinfecting Cleaning Wipes	(8" x 5 3/4") (7" x 8") (Pouch)
	25 (30) (35) (45) (70) Pre-Moistened
	Towelettes
	(7 1/2" x 10) (7.5 x 10)(Canister)
Large Size Disinfecting cloths	15 (30) (45) (56) (60) (75) wet cloths
	(8.5" x 10") (7.5 X 8) (7.5 X 8)
Ready to Use	
(Economy Size) (Bonus Size) (Travel Size) (Pack)	
(Citrus) (Summer Fresh) (Spring Waterfall) (Country) (Lemon)(Scent) (Breeze)	

ACCEPTED
With COMMENTS
in EPA Letter Dated:
SEP 11 2003

HOSPITALS	HOTELS	AIRPORTS	Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, Reg. No. 777-68 and under EPA Reg. No. 777-68
NURSING HOMES	RESTAURANTS	MALLS	
CLINICS	DAY CARE CENTERS	GAS STATIONS	
DENTAL OFFICES	PHYSICIAN OFFICES	PUBLIC REST ROOMS	
SCHOOLS	HEALTH CLUBS	PUBLIC TELEPHONES	
VETERINARY	AMBULANCES	DIAPER CHANGING COUNTERS	
OFFICES	BOWLING ALLEYS	KENNELS	

The quick and easy way to (clean and) sanitize the following hard non-porous non-food contact surfaces (anywhere you travel):

The quick and easy way to (clean and) disinfect the following hard, non-porous surfaces (anywhere you travel): Rinse food contact surfaces with clean potable water after using this product. *Do not use this product on utensils, dishes or glasses.*

Toilet Seats	Exterior of Toilets	Sinks	Nursery
Kitchen, Bathroom	Showers, Tubs	Telephones	Laundry Room
Glazed Tile, Enamel	Cabinets	Walls	Glazed Porcelain
Storage areas	Diaper Changing Counters	Garbage Cans	Pet Areas
Counters	Diaper Pails	High Chairs	Table Tops
Counter Tops			

(Resealable) (Pouch) (Inside)
 Pull Up Here

- Quick Disinfects
- Convenient Sanitizes
- Portable

ACTIVE INGREDIENT:	
Alkyl (50% c 14, 40%, C12, 10% C16)	
Dimethyl Benzyl Ammonium Chlorides.....	0.28%
INERT INGREDIENTS.....	99.72%
TOTAL.....	100.00%

Keep Out of Reach
 Of Children
CAUTION: See (side) (back)
 Panel for additional
 Precautionary Statements

EPA Reg. No. 777-68
 EPA Est. No. 777-IL-1, 777-NJ-2, 052631-NJ-001, 777-NY-001, 41925-WI-001

Note: Bracketed () information is optional text. Text separated by a comma (,) denotes and/or options.

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*Will only be used for 6 months from date of introduction

Box (Pouch) (Canister) Label

ALTERNATE LANGUAGE

Optional Disinfectancy Related – bullets/bursts/sentences – Front or Back Panel

Ready to use, convenient; the quick and easy way to (clean and) disinfect (sanitize) (toilet seats) (toilet exteriors)(and other) hard non-porous surfaces.

Kills (99.9%) (of) household bacteria in 30 seconds.

Kills (99.9% of) (bacteria) (germs) in 30 seconds.

Hospital Type (disinfectant) (disinfection).

Starts killing (bacteria) (germs) on contact.

Kills more than – or – even greater than – or - > (99.9%) of household germs – and / or – bacteria – and/or- viruses** -and/or- fungi –and/or- mold.

Kills more than –or- even greater than –or- > 99.9% of household germs such as Salmonella choleraesuis (Salmonella) – Staphylococcus aureus (Staph) – Pseudomonas aeruginosa (Pseudomonas) – Trichophyton mentagrophytes (Athletes foot fungus) and Enterococcus (Streptococcus) faecalis.

Kills 99.9% of Staphylococcus aureus (Staph) (Klebsiella pneumoniae) Campylobacter jejuni, Salmonella choleraesuis, and Eschericia coli in 30 seconds.

Sanitizes (Kitchen) (Household) (Bathroom) hard non-porous surfaces in 30 seconds.

Kills (99.9%) of (bacteria) (germs) (viruses**) in 30 seconds.

Kills (kitchen) (household) (bathroom) (germs) (bacteria) (viruses**) (fungi) (mold).

Disinfects –or- kills common household germs –and/or- bacteria –and/or- viruses** -and/or- fungi –and/or- mold.

** Viruses: Influenza A2 (Japan), Herpes Simples Type 1.

An effective disinfectant (sanitizer) for use in kitchen, bathroom, bedroom, and other (household) areas.

This product is a mildewstat and will effectively inhibit the growth of mildew on hard non-porous surfaces.

Disinfects hard non-porous food contact surfaces such as counters and tables. Rinse food contact surfaces with potable water after using this product. Do not use this product on utensils, dishes, or glasses.

Lysol Brand Pre-Moistened Bathroom Touch-ups Disinfecting Cleaning Wipes Kill the following bacteria, viruses and fungi:

Graphics: Pictures depicting areas of use.

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Organism (s) Product Disinfects against:

Bacteria & Fungi:

- Staphylococcus aureus (Staph)
- Enterococcus (Streptococcus) faecalis
- Salmonella choleraesuis (Salmonella)
- Pseudomonas aeruginosa
- Trichophyton mentagrophytes (Athletes foot fungus)
- Mold and Mildew
- Klebsiella pneumonia

Viruses:

- Herpes Simplex Type 1
- Human Immunodeficiency Virus Type 1 (HIV - 1)
- Influenza A2 (Japan)

Organism (s) Product Sanitizes against:

Bacteria:

- Staphylococcus aureus
- Klebsiella pneumoniae
- Campylobacter jejuni
- Escherichia coli
- Salmonella choleraesuis

Optional Disinfectancy Related – bullets/bursts/sentences – Front or Back Panel

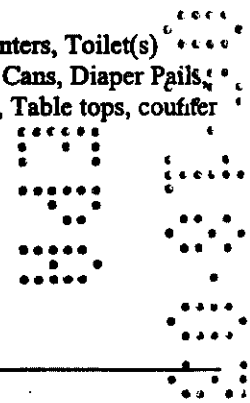
One Step (Cleaning and) Disinfecting

Hospital, Nursing Home, Clinic(s), Dental Office(s), School, Veterinary Office (s)¹ Bowling Alley, Hotel, Restaurant, Day Care Center, Physician's Office, Health Club, Ambulance, Kennel (s), Airport, Malls, Gas Station, Public Restroom(s), Public Telephone, Diaper Changing Counter(s), Kitchen, Bathroom, Household (Disinfectant) (Sanitizer).

(Disinfects) (Sanitizer): Toilet Seats, Kitchens, Bathrooms, Laundry Rooms, Walls, Diaper Changing Counters, Toilet seats (toilet exteriors), Sinks, Showers, Tubs, Glazed Tile, Enamel, glazed Porcelain, Garbage Cans, Diaper Pails, Nursery, Telephones, (Non wood)(Finished) Cabinets, Storage Areas, Pet Areas, Non-wood High Chairs, Table tops, counter tops (counters).

- The quick and easy way to (clean) (and) disinfect (sanitize).
- Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Cleaning Wipes (clean) (and) (disinfect) (sanitize) the following surfaces:

Toilet Seats, Kitchens, Bathrooms, Laundry Rooms, Walls, Diaper Changing Counters, Toilet(s) exteriors, Sinks, Showers, Tubs, Glazed Tile, Enamel, Glazed Porcelain, Garbage Cans, Diaper Pails, Nursery, Telephones, Cabinets, Storage Areas, Pet Areas, Non-wood High Chairs, Table tops, counter tops (counters) (anywhere you travel).



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Quick
 Portable
 Convenient
 Easy to Use
 Great for touch-up cleaning
 Easy to carry around the house
 Not for personal hygiene
 For use on Household surfaces only

Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Cleaning Wipes are the convenient way to (clean and) disinfect (sanitize) household surfaces. Each pre-moistened, disposable wipe, kills germs – even the germs that cause odors. Great for use in your kitchen, bathroom, and throughout the house. Rinse food contact surfaces with a clean potable water rinse after using this product.

Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Cleaning Wipes are also great on the “go” in restaurants, public restrooms, public telephones, or diaper changing stations.

(Back)

New*

Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Cleaning Wipes
 (Travel Size)

The fast convenient way to (clean) and (disinfect) (sanitize) hard non-porous surfaces anywhere (you) (travel). Use them on bathroom surfaces, toilet seats (toilet exteriors), and telephones in malls restaurants, gas stations, airports, rest stops, and (public) (places) (facility) where germs or bacterial may be of concern. (Rinse food contact surfaces with clean potable water rinse after using this product) (For food contact surfaces such as counters and tables, rinse with potable water). Do not use on dishes, glasses, or utensils.

ALTERNATE LANGUAGE

The (fast) (convenient) way to (clean) and (disinfect) (sanitize) hard non-porous surfaces. Use them (in bathroom areas), (on) (toilet exteriors), under sinks, sick rooms, showers, bath tubs, patient chairs, examination tables, garbage pails, operatories, stretchers, laboratories, cuspidors, door handles, wheel chairs, counters, and other places where germs, or bacteria may be a concern. (Rinse food contact surfaces with clean potable water rinse after using this product) (For food contact surfaces such as counters and tables, rinse with potable water). Do not use on dishes, glasses, or utensils.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument 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 enter 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.

New* Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Cleaning Wipes are the convenient way to (clean) (and) (disinfect) (sanitize) hard non-porous surfaces.

For general (cleaning)(and) (disinfecting) hard non-porous surfaces.
 For general (cleaning)(and)(sanitizing) hard non-porous non-food contact surfaces.

New*Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Cleaning Wipes are the (convenient) way to (clean) (and) disinfect (sanitize) your household surfaces.
 Each pre-moistened disposable wipe (is treated with a special cleaner that actually) kills germs – even the germs that cause odors – wherever you use it. No bottles, no sponges, no mess.

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Effective disinfecting (sanitizing) has never been faster or easier. Unplug small electrical appliances before (use) (cleaning) (disinfecting) (with this product). Not recommended for polished or bare wood surfaces.

Directions for Use: It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Pull up tab and remove large cover. Remove inner tab loop from cover hinge. Insert loop into opening. Thread first sheet in center of roll through loop. Replace cover. Pull loop back through opening. Pull each sheet up and slightly to the side. Always snap lid securely shut between uses to prevent moisture loss.

Peel back the front label slowly. Remove towelette as needed. Reseal pouch by firmly running thumb over the label.

(OR)

Open pouch by peeling back the seal. Remove one Lysol Brand pre-Moistened Bathroom Touch-Ups Disinfecting Wipe and reseal pouch to avoid moisture loss. Use abrasive side for tougher soils and soft side for light duty cleaning. Throw away soiled wipe when done.

TO CLEAN HARD SURFACES (INCLUDING TOILET SEATS): Use a fresh towelette to wipe surface. Toss dirty wipe away.

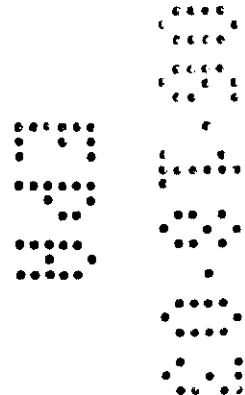
TO SANITIZE Non-Food Contact SURFACES (INCLUDING TOILET SEATS): Use enough fresh towelettes to thoroughly wet surface(s). Allow surface to remain wet for 30 seconds. Allow surface(s) to air dry. To sanitize heavily soiled surfaces, preclean surfaces using a fresh towelette.

Not intended for personal hygiene.

TO (CLEAN) (AND) (DISINFECT TOILET SEAT) (OTHER BATHROOM SURFACES): Use enough fresh towelettes to thoroughly wet surface(s), (toilet seat) (surface). Allow surface to remain wet for 10 minutes. Allow surface(s) to air dry. To disinfect heavily soiled surfaces, repeat with a clean towelette.

Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Cleaning Wipes meets efficacy standards for (hospital type) disinfectant (sanitizing) wipes. Kills Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, Enterococcus (streptococcus) faecalis (bacteria), Influenza A2 and Herpes Simplex Type 1 viruses. Inhibits mold and mildew in damp and musty places.

(Not for personal Hygiene)



Note: Bracketed () information is optional text. Text separated by a comma (,) denotes and/or options.

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KILLS HIV-1 ON PRECLEANED 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 Human Immunodeficiency 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: Thoroughly clean blood and other body fluids from surfaces and objects with wet towelette. Use second towelette to disinfect.

CONTACT TIME: Allow to stand 10 minutes.

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

ALTERNATE DIRECTIONS FOR USE:

To Open Package: Open cap lid and pull up firmly on lid to remove the entire cap from the canister. Locate wipe at the center of the roll and insert corner of wipe through opening in lid. **DO NOT PUSH FINGER THROUGH OPENING.** Replace lid. Pull sheet up and slightly to side. Always snap lid securely shut between uses to prevent moisture loss.

To Sanitize Hard Non-Porous Non-Food Surfaces: Use enough fresh towelettes to thoroughly wet surface(s). Allow surface(s) to air dry. Toss dirty wipes away. Allow surface to remain wet for 30 seconds. To sanitize heavily soiled surfaces, preclean surfaces using a fresh towelette.

To Disinfect Hard Non-Porous Surfaces: Use enough fresh towelettes to thoroughly wet surfaces. Wipe surface and allow to remain wet for 10 minutes. Allow surface(s) to air dry. Toss dirty wipe away. To disinfect heavily soiled surfaces, preclean surfaces using a fresh towelette. For Food contact surfaces such as counters and tables, rinse with potable water. Do not use on dishes, glasses, or utensils.

NOT INTENDED FOR PERSONAL HYGIENE.

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Veterinary Practice/Kennels/Animal Care Facilities: For disinfecting hard, non-porous surfaces including equipment, utensils, cages, kennels, instruments etc. Remove all animals and feeds from the premises, crates, cages, and enclosures. Remove all litter, droppings, and manure from floors, walls, and surfaces occupied or traversed by animals. Empty all troughs, racks and other feeding/watering appliances. Thoroughly clean surfaces with soap or detergent and rinse with water. Saturate surfaces and allow to stand 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, and dried. Thoroughly scrub all treated feed racks, automatic feeders, and watering appliances with soap or detergent, and rinse with portable water before use.
 *Not recommended for glass, mirrors, polished or bare wood surfaces.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: May cause eye irritation. Avoid contact with eyes. Wash hands after use.

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.
Contact Number	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-228-4722 for emergency medical treatment information.	

Storage /Disposal: Dispose of wipe in trash after use. Close lid between uses to retain moisture. Do not reuse empty container. Offer empty container for recycling. If recycling is not available, discard container in trash.

(OR)

Store unopened package in a cool dry place in areas inaccessible to small children. Dispose of wipe in trash after use. Reseal (Close) lid between uses to retain moisture. Do not reuse empty container. Discard in trash.

Alternate Label Language for Scrubbing Wipe

2 sides 1 for scrubbing, 1 for wiping.

30 wet wipes 7.5" x 7.5"

(Product Name) are the convenient way to clean and disinfect your household surfaces. Each pre-moistened disposable wipe has a scrubbing side for (tough stains)(tough jobs) (like) soap scum and grease and a softer side for wiping away everyday messes. No bottles, no sponges, no mess. Effective cleaning and disinfecting has never been faster or easier (more convenient). Not recommended for polished or bare wood surfaces.

Additional Cleaning and Disinfecting Claims

Disinfects

(Quickly)(Removes)(Bacteria)(fungi) (and) (virus) (asterisk to listed on page 3)

Effective against (Bacteria, fungi and virus listed on page 3)

One-Step (cleaning) and/or (Disinfecting)

Cleans and/or disinfects and/or deodorizes

Clean(s) with the power of Lysol® Brand

Controls Mold and Mildew

Cuts grease

Leaves a fresh (Lemon)(Citrus)(Floral)(Herbal)(Scent)

Kills odor-causing bacteria

Eliminates Odors



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For Heavy Duty Wipe

Cleans soap scum and baked on grease
Build-In Scrubbing Fibers help clean away tough stains (like soap scum) – and – (baked on grease)
Built-in (Micro) scrubbing fibers
Disinfects and cleans tough stains
Two-in-one wipe
2- in 1- wipe

Other Label Language

Value pack
Value size
Great Value
Pop-Up-Cap
Refill Pack
Perfect Size for (Kitchens) (and) (Bathrooms)
(5) (10) more (extra) wipes
Bonus size
Quilted wipe
Now with Quilted wipe
Tub Pack

General Label Claims

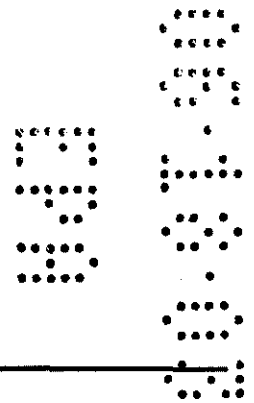
Flushable (wipe) (s) (!)
Now Flushable (Wipe) (s) (!)
Just wipe and flush the germs away (!)
Just clean and flush the germs away (!)

Plumbing Claims

Will not harm septic systems
Will not harm your plumbing

Additional Instruction Claims

Never flush more than two wipes at a time
Never flush any wipe (s) when other matter is present in the (toilet) bowl
For best flushability, flush one wipe at a time
Do not flush any wipe (s) if plumbing system is not working (well) (optimally)
Do not flush any wipe (s) if plumbing system is not in optimal working condition.



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Packet Size

(BACK) (Packet Label)

Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Cleaning Wipes

ACTIVE INGREDIENT:

Alkyl (50% c 14, 40%, C12, 10% C16)

Dimethyl Benzyl Ammonium Chlorides.....0.28%

INERT INGREDIENTS.....99.72%

TOTAL.....100.00%

Keep Out of Reach
Of Children

CAUTION: See
Panel for additional
Precautionary Statements

Does not include weight of dry wipe

See outer container for additional precautions and directions for use.

CONTAINER DISPOSAL: Discard empty envelope in trash

EPA Reg. No. 777-68

EPA Est. No. 777-IL-1, 777-NJ-2, 052631-NJ-001, 777-NY-001, 41925-WI-001

Net Contents: One Towelette

Questions? Comments? Call 1-800-228-4722

Or visit us at www.lysol.com

Reckitt Benckiser Inc.

(1655 Valley Road)

Wayne, New Jersey 07474

