5-23-2001 777-68 UNITE STATES ENVIRONMENTAL PROTECTI AGENCY

MAY 2 3 2001

Reckitt Benckiser, Inc. 1653 Valley Road Wayne, NJ 07047

Subject: Lysol Brand Pre-Moisten Bathroom Touch-Ups Disinfecting Wipes EPA Registration No. 777-68 Letter Dated February 23, 2001

Attn: Bruce Paolella Sr. Regulatory Affairs Specialist

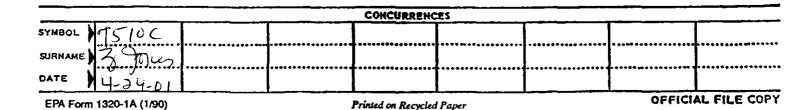
The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable; however, please refer to the Agency's February 9, 2001 letter regarding incorporating certain changes in your label. For instance, on page three (3) of the label, delete all references to "Toilets, but not "Toilet Seats". Also, in your use directions, i.e., The fast convenient way to clean and disinfect hard surfaces anywhere you travel", you need to add the following language: "rinse food contact surfaces with a clean potable water rinse after using this product". Where there is mentioned on the label about use of this product to sanitize hard non-porous surfaces, that phrase need to be qualified to read "... To sanitize hard non-porous non-food surfaces".

A stamped copy of the label is enclosed for your records. Submit one (1) copy of the final printed label before this product its released for shipment.

If you have any questions concerning the comments in this letter, you should contact Zenobia Jones at (7030 308-6198.

Sincerely,

Velma Noble Product Manager 31 Regulatory Management Branch 1 Antimicrobial Division (7510C)



Lysol Brand Pre-Mois.cned Bathroom Touch-Ups Disinfecting Wik

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**EPA Registration Number: 777-68** 

Revised: 02/26/01

New*	Contents
Lysol ® Brand	16 Individually Wrapped
	Pre-Moistened Towelettes
	(8" x 5 ¼") (Box)
Pre-Moistened	
Bathroom	
Touch-Ups	20 (25) (35) Pre-Moistened
	Towelettes
Disinfecting Cleaning Wipes	(8" x 5 ¼") (7" x 8") (Pouch)

**Disinfecting Cleaning Wipes** 

25 (35) Pre-Moistened Towelettes (7 <sup>1</sup>/<sub>2</sub>" x 10) (Canister)

Ready to Use (Economy Size) (Bonus Size) (Travel Size) (Pack) (Citrus) (Summer Fresh) (Spring Waterfall) (Country) (Scent)

HOSPITALS	HOTELS	AIRPORTS
NURSING HOMES	RESTAURANTS	MALLS
CLINICS	DAY CARE CENTERS	GAS STATIONS
DENTAL OFFICES	PHYSICIAN OFFICES	PUBLIC REST ROOMS
SCHOOLS	HEALTH CLUBS	PUBLIC TELEPHONES
VETERNIARY	AMBULANCES	DIAPER CHANGING COUNTERS
OFFICES	BOWLING ALLEYS	KENNELS

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

Toilet Seats Kitchen, Bathroom Glazed Tile, Enamel Storage areas Counters	Exterior of Toilets Showers, Tubs Cabinets Diaper Changing Counte Diaper Pails	Sinks Telephones Walls, Floors ors Garbage Cans High Chairs	Nursery Laundry Room Glazed Porcelain Pet Areas Table Tops
Counter Tops (Resealable Pouch Inside)	with C	CEPTED OMMENTS Letter Dated:	
Quick	MAY 2	3 2001	
<ul><li>Convenient</li><li>Portable</li></ul>	Fungicide, and amended for t	eral Insecticide, I Rodenticide Act <b>as</b> the pesticide, ler EPA Reg. No. 77	77-68
ACTIVE INGREDIENT: Alkyl (50% c 14, 40%, C Dimethyl Benzyl Ammon	12, 10% C12)		Keep Out of Reach Of Chiltiten
INERT INGREDIENTS TOTAL		99.72%	Panel for additional Precautionary Statements
EPA Reg. No. 777-68 EPA Est. No. 777-1L-1, 7	77-NJ-2, 052631-NJ-001,	777-NY-001	
*Will only be used for 6 r	nonths from date of introd	luction	ι

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

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# 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.

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 777-68

Kills (more than - or - even greater than - or - >) (99.99%) 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) in 30 seconds.

Sanitizes (Kitchen) (Household) (Bathroom) 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. After treatment rinse with potable water. Do not use this product on utensils, dishes, or glasses.

Lysol Brand Pre-Moistened Bathroom Touch-ups Disinfecting Cleaning Wipes Kill the following bacteria.

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

Revised: 02/26/01

MAY 2 3 2001

ACCEPTED

with COMMENTS in EPA Letter Dated: Lysol Brand Pre-Moi, ....ed Bathroom Touch-Ups Disinfecting Wip

**EPA Registration Number: 777-68** 

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Revised: 02/26/01

#### **Bacteria & Fungi:**

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

Viruses:

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

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)<sup>\*1</sup> 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, Floors, Diaper Changing Counters, Toilets, 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, Floors. Diaper Changing Counters. Toilets, 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).

# with COMMENTS in EPA Letter Dated:

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

MAY 2 3 2001 Under the Federal Insecticide. Pangicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 777-68.

Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Cleaning Wipes are the convenient of a 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.

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.

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

Lysol Brand Pre-Moi. And Bathroom Touch-Ups Disinfecting Wip

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ACCENTE 102/26/01 with COMMENTS in EPA Letter Dated:

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(Back)

New\*

Under the Federal Insecticide, Pangicice, and Rodenticide Act as amended, for the pesticide, Cleaning Wipostered under FDB Park

Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Cleaning WiegStered under EPA Reg. No. 777-68 (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, and telephones in malls restaurants, gas stations, airports, rest stops, and (public) (places) (facility) where germs or bacterial may be of concern.

#### ALTERNATE LANGUAGE

The (fast) (convenient) way to (clean) and (disinfect) (sanitize) hard non-porous surfaces. Use them in toilet areas, 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.

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 (sanitizing) hard non-porous 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. 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.

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

# 

TO SANITIZE Non-Food Contact SURFACES (INCLUDING TOILET SEATS): ,,,,, Use a fresh towelette to thoroughly wet surface. Allow surface to remain wet for 30 seconds. Allow to air, dry. For heavily soiled surfaces, repeat sanitizing directions. Not intended for personal hygiene.

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

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ACCEPTED	
h COMMENTS	

TO (CLEAN) (AND) (DISINFECT TOILET SEAT) (OTHER BATHROOWS URFACES): Use a fresh towelette to wipe (toilet seat) (surface). Allow surface to remain we) for 10 minutes. To disinfect heavily soiled surfaces, repeat with a clean towelette.

(Do not Flush Down Toilet)

Under the Federal Insecticide, Pungicide, and Rodenticide Act as amended, for the pesticide, registered under FDA bases and act

registered under EPA Reg. No. 777-68 Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Cleaning Wipes meets efficacy standards for (hospital type) disinfectant (sanitizing) wipes. Kills Influenza A2 and Herpes Simplex Type 1 viruses and Enterococcus (streptococcous) faecalis germs. Inhibits mold and mildew in damp and musty places.

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.

<u>CLEANING PROCEDURES</u>: 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 Surfaces: Use a fresh towelette to wipe surfaces. Toss dirty wipe away. Do not flush down toilet. Allow surface to remain wet for 30 seconds. To sanitize heavily soiled surfaces, repeat with a clean towelette. NOT INTENDED FOR PERSONAL HYGIENE.

To Disinfect Hard Non-Porous Surfaces: Use a fresh towelette. Wipe surface and allow to remain wet for 10 minutes. Toss dirty wipe away. Do not flush down toilet. To disinfect heavily soiled surfaces, repeat with a clean towelette. For Food contact surfaces such as counters and tables, rinse with potable, water. Do not use on dishes, glasses, or utensils.

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

Lysol Brand Pre-Mois Ined Bathroom Touch-Ups Disinfecting Wip

EPA Registration Number: 777-68

. Revised: 02/26/01

#### PRECAUTIONARY STATEMENTS:

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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

**First** Aid: In case of eye contact, IMMEDIATELY flush eyes thoroughly with water, remove any contact lens, and continue to flush eyes with plenty of water for at least 15 minutes. Call physician if irritation persists.

Storage /Disposal: Dispose of wipe in trash after use. Do not flush. 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.

(BACK) (Packet Label)

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

ACTIVE INGREDIENT:	
Alkyl (50% c 14, 40%, C12, 10% C12)	
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.

ACCEPTED with COMMENTS in EPA Letter Dated:

Under the Federal Insecticide,

Fangicide, and Rodenticide Act as amended, for the pesticide,

MAY 2 3 2001

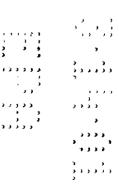
registered under EPA Reg. No. 777-68

CONTAINER DISPOSAL: Discard empty envelope in trash

EPA Reg. No. 777-68 EPA Est. No. 52631-NJ-001

Net Contents: One Towelette

Reckitt Benckiser Inc. 1655 Valley Road Wayne, New Jersey 07474



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