

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

PM 31

675-54

11/19/98

1 of 5

NOV 19 1998

Reckitt & Colman Inc.
1655 Valley Road
Wayne, NJ 07474

ATTENTION: Bruce Paoletta

SUBJECT: LYSOL® Brand Heavy Duty Cleaner Disinfectant Concentrate
EPA Registration Number 675-54
Your Amendment Dated: August 24, 1998

This is to acknowledge that your amendment submitted in conjunction with the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to add additional text is acceptable subject to the following conditions.

- 1) On page two the sentence "LYSOL Brand Heavy Duty Disinfectant concentrate is a one step disinfectant cleaner that kills Staphylococcus (staph) and Streptococcus (strep) germs..." must be revised. Your label must list the genus and species of each organism. Revise as follows: "LYSOL Brand Heavy Duty Disinfectant concentrate is a one step disinfectant cleaner that kills *Staphylococcus aureus* and *Streptococcus pyogenes*..."
- 2) On page two in the second paragraph revise the phrase "...disinfect and deodorize tub & shower areas and other hard surfaces in hotels..." to read as follows "...disinfect and deodorize tub & shower areas and other hard *nonporous* surfaces in hotels..."
- 3) On page two in the third paragraph change "ceramic bathroom tile" to read "*glazed* ceramic bathroom tile" and "ceramic tile floors" to read "*glazed* ceramic tile floors".
- 4) On page five in the second paragraph revise "Add 4 oz. full strength into the bowl..." to read "Add 4 oz. *of product* full strength into the bowl..."

CONCURRENCES							
SYMBOL	7510 ● c						
SURNAME	J. Lundy						
DATE	11/18/98						

5) Your product is categorized as Tox I for Eye Irritation and Tox II for Skin Irritation. Thus the following statement must be included in the "Precautionary Statements":

"Wash thoroughly with soap and water after handling."

6) The Agency toxicologist has recommended an "If Swallowed" statement which differs from your label text. You may retain your present statement if it is based on a medical opinion. Provide us with the basis for your statement.

At the present time the following two statements must be added to your "If Swallowed" statement: *"Do not give anything by mouth to an unconscious person."* and *"Avoid alcohol."*

7) Revise the "Storage and Disposal" statement for the 5 and 55 gallon containers by changing the subheading "Storage" to read *"Pesticide Storage"*.

8) Please submit a final printed label before you release this product for shipment.

A stamped copy of the label is enclosed for your records.

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



Velma Noble
 Product Manager (31)
 Regulatory Management Branch I
 Antimicrobials Division (7510W)

7510C:T.Lantz:11/18/98:675-54C

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

FRONT LABEL

**LYSOL® Brand
Heavy Duty Cleaner Disinfectant Concentrate**

- For Hospital and Institutional Use
- Disinfects and Deodorizes
- Cuts Through Tough Soils
- Non Abrasive
- Fresh Citrus Lime Scent

ACTIVE INGREDIENT: n-Alkyl (C₁₄ 50%, C₁₂ 40%, C₁₆ 10%) dimethyl benzyl ammonium chloride.....3.44%

INERT INGREDIENTS:96.56%

TOTAL:100.00%

EPA Reg. No. 675 - 54
 EPA Est. No. 777-NJ-2, 8791-MO-1 (See Bottom (Side))

KEEP OUT OF REACH OF CHILDREN

DANGER:

Causes eye damage and skin irritation.
 See side label for additional precautions and statement of practical treatment.

Reckitt & Colman Inc.,
 Montvale, NJ 07645

Net Contents:
 6 Fl. Oz. (177.42 mL)
 1 Gallon (3.79 Liters)
 5 Gallons (18.95 Liters)
 55 Gallons (208.2 Liters)

**ACCEPTED
 with COMMENTS
 in EPA Letter Dated:**

NOV 15 1988

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

675-54

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BACK LABEL

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LYSOL® Brand
Heavy Duty Cleaner Disinfectant Concentrate

675-54

Deodorizer, Fungicide, Virucide*
Kills odor causing bacteria and pathogenic fungi
Controls the growth of mold and mildew
Deodorizes with a fresh citrus lime fragrance

LYSOL® Brand Heavy Duty Cleaner Disinfectant Concentrate is a one step disinfectant cleaner that kills Staphylococcus (staph) and Streptococcus (strep) germs, athlete's foot fungus, and controls (inhibits) the growth of mold and mildew and the odors they cause. Its deep cleaning action penetrates tough soils including body oils and soap scum, yet it contains no harsh abrasives. The non acid formula removes even stubborn bathtub rings and leaves a clean, fresh scent.

LYSOL Brand Heavy Duty Cleaner Disinfectant Concentrate has been formulated to thoroughly clean, disinfect and deodorize tub & shower areas and other hard surfaces in hotels, motels, hospitals, nursing homes, clinics, health clubs, resorts, cruise ships, day care centers, dental offices, and other health care facilities, including:

- ceramic bathroom tile • sinks • toilet bowls and surfaces • garbage cans • bathtubs • shower stalls • chrome and clear acrylic plastic fixtures • porcelain • FORMICA® • ceramic tile floors

This product is not recommended for use on polished marble. For other surfaces, spot test in an inconspicuous area.

FORMICA® is a registered trademark of the Formica Corporation.

BACTERICIDAL • FUNGICIDAL • VIRUCIDAL* (Test culture with 5% blood serum. Use-dilution in 400 ppm hard water)

Kills the following germs/microorganisms:

Bacteria

- | | |
|-------------------------------|--|
| • Salmonella paratyphi | • Staphylococcus aureus |
| • Salmonella choleraesuis | • Klebsiella pneumoniae |
| • Salmonella typhi | • Serratia marcescens |
| • Salmonella schottmuelleri | • Enterococcus faecalis |
| • Shigella dysenteriae | • Streptococcus salivarius |
| • Brevibacterium ammoniagenes | • Streptococcus pyogenes |
| • Enterobacter aerogenes | • Corynebacterium diphtheriae |
| • Escherichia coli 0157:H7 | • Proteus mirabilis |
| • Proteus vulgaris | • Pseudomonas cepacia |
| • Neisseria elongata | • Pseudomonas aeruginosa |
| | • Acinetobacter calcoaceticus |
| | • Staphylococcus aureus
(methicillin resistant) |

BACK PANEL CONTINUED

Fungi

- Candida albicans
- Trichophyton mentagrophytes
- Aspergillus niger

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BACK PANEL CONTINUED

Viruses*

- Herpes simplex Type 1 and Type 2
- Influenza A₂ (Japan)
- HIV-1 (AIDS Virus)
- Rotavirus
- Respiratory Syncytial Virus

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DILUTION CHART

Dilution Ratio	Quantities Needed	
	Product	Water
1:32	1 oz.	32 oz.
	4 oz.	1 gal.
1:16	2 oz.	32 oz.
	8 oz.	1 gal.
1:8*	4 oz.	32 oz.
	16 oz.	1 gal.
1:4	8 oz.	32 oz.
	32 oz.	1 gal.

* For Pseudomonacidal activity (For Hospital(s) and other health care facilities) Dilute 1:8

Proper dilution provides maximum cleaning benefits and product economy.

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

Prepare a fresh solution daily and change solution frequently if heavily soiled or diluted. Product is proven effective in hard water (up to 400 ppm) in the presence of 5% blood serum contamination.

FOR GENERAL DISINFECTION: Remove heavy soil and gross filth prior to disinfection, as per General Cleaning instructions. For broad spectrum disinfection, dilute 1:32 in water (1/2 cup per gallon), apply with cloth or sponge and thoroughly wet surface for 10 minutes, then remove excess. **For Pseudomonacidal activity (for hospital and other health care facilities) dilute 1:8.

FOR GENERAL CLEANING: LIGHT SOIL: Use a 1:32 solution for routine maintenance when heavy soil buildup is not a problem. **MEDIUM SOIL:** Use solution of 1:8 to 1:16 for areas of moderate soil. **TOUGH SOIL BUILDUP:** For stubborn soil or heavy buildup, such as soap scum and body oils on bathtubs or shower walls, a solution of 1:4 is recommended.

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BACK PANEL CONTINUED

TO CONTROL MOLD AND MILDEW: Clean surfaces first. Use as directed on wet surfaces; let stand 10 minutes, then remove excess. Repeat application weekly or when needed.

FOR CLEANING AND DISINFECTING TOILET BOWLS: Prior to disinfection, remove all heavy soil and flush toilet. Add 4 oz. full strength into the bowl water (1:25 dilution). Thoroughly swab all bowl surfaces and under the rim. Let stand 10 minutes and then flush.

KILLS HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) (AIDS VIRUS) 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 surface/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 protection.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of LYSOL® Brand Heavy Duty Cleaner Disinfectant Concentrate.

CONTACT TIME: Allow surface to remain wet for 10 minutes.

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

RECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS.

DANGER: Corrosive. Causes eye damage and skin irritation. Do not get in eyes, on skin, or Clothing. Wear appropriate eye protections and rubber gloves. May be harmful if swallowed. Remove contaminated clothing and wash before reuse.

STATEMENT OF PRACTICAL TREATMENT: If splashed in eyes, immediately remove contact lenses and rinse eyes with plenty of water for at least 15 minutes. Get medical attention. If splashed on skin, immediately wash with plenty of soap and water. If irritation persists, call a physician. If swallowed, call a physician or poison control center. Drink 1 or 2 glasses of water to dilute the product. Do not induce vomiting.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

For 1 Gallon or less:

STORAGE/DISPOSAL: Store in original container in areas inaccessible to small children. Keep securely closed. Do not reuse empty container. Rinse thoroughly with water and detergent. Discard in trash.

BACK PANEL CONTINUED

For 5 and 55 Gallon Containers:

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal.

STORAGE: Store in original container in areas inaccessible to small children. Keep securely closed.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Please encourage your state and local authorities to establish a recycling program so that this bottle/pail/drum can be recycled.

For 55 Gallon Containers: This label is printed on 50% recycled paper (10% post-consumer).

Contains no phosphates.

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