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675-54

10/16/97

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobial Division (7505W)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:

675-54

Date of Issuance:

OCT 15 1997

Term of Issuance:

Conditional

NOTICE OF PESTICIDE:

- Registration
- Reregistration

(under FIFRA, as amended)

Name of Pesticide Product: LYSOL
Brand Heavy Duty
Cleaner Disinfectant
Concentrate

Name and Address of Registrant (include ZIP Code):

Reckitt & Colman, Inc.
One Phillips Parkway
Montvale, NJ 07645-1575

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7) A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the following label changes:

a. Revise the EPA Registration Number to read, "EPA Reg. No. 675-54.

b. The proposed label should contain a Note to Physician containing the statement, "Probable mucosal damage may contraindicate the use of gastric lavage." Further information may include the following, at the applicant's

Signature of Approving Official: PM-31/AD/OPP

Date:

OCT 15 1997

CONCURRENCES

SYMBOL	SURNAME	DATE					
15710W	Perry	10-15-97					

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discretion:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

3. The identity of "Fragrance 922760" was not included in this submission and it may not be used in this product until the identity is received and reviewed for its acceptance for use in this product.

Submit five final printed copies of labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

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

Sincerely,



Velma Noble
Acting Product Manager 31
Regulatory Management Branch I
Antimicrobial Division

Attachment

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FRONT LABEL

February 12, 1997 DRAFT

**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 (C ₁₄ 50%, C ₁₂ 40%, C ₁₀ 10%) dimethyl benzyl ammonium chloride.....	3.44%
INERT INGREDIENTS:	96.56%
TOTAL:	100.00%

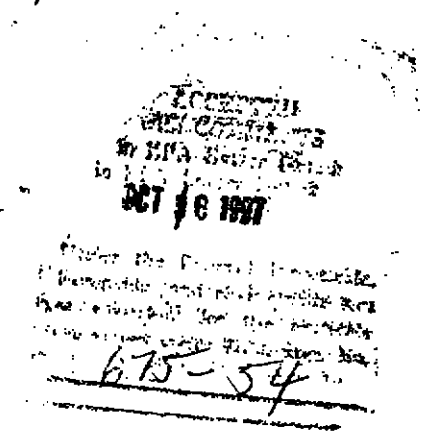
**KEEP OUT OF REACH OF CHILDREN
DANGER**

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

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

Wackitt & Colman Inc.
Montvale, NJ 07645

EPA Reg. No. 675 -
EPA Est. No. 777-NJ-2,8791-MO-1 (SEE BOTTOM(SIDE))



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BACK LABEL

February 12, 1997 DRAFT

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

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.

YSOL 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 o FUNGICIDAL o 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) |

Fungi

- Candida albicans
- Trichophyton mentagrophytes
- Aspergillus niger

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BACK PANEL CONTINUED

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Viruses*

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

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.

**A dilution of 1:8 is required for pseudomonacidal activity

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.

TO CONTROL MOLD AND MILDEW: Clean surfaces first. Using a 1:32 dilution, 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. of product 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.

G/k

BACK LABEL CONTINUED

February 12, 1997 DRAFT

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.

PRECAUTIONARY 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 protection and rubber gloves. May be harmful if swallowed. Remove contaminated clothing and wash before reuse.

STATEMENT OF PRACTICAL TREATMENT (FIRST AID): 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.

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.