

675-54

07/25/2011

1/7

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Mary C. Pisculli
Reckitt Benckiser LLC
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NY 07054-0225

JUL 25 2011

SUBJECT: Lysol Brand Heavy Duty Cleaner Disinfectant Concentrate
EPA Registration Number: 675-54
Application Dated: April 25, 2011
Receipt Date: April 26, 2011

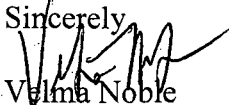
Dear Ms. Pisculli

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

- Updating master text label:
 - 1) Incorporate Agency's comments from June 5, 2009 approved master text label
 - 2) Incorporated previously approved Notifications/Non-Notifications
 - 3) Adding NSF listing number, that was inadvertently left off the previous master label text

General Comments

Your accepted stamped label is attached. Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0109 or Velma Noble at (703) 308-6233.

Sincerely


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

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

87

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

(This product) is a concentrate. Always dilute in accordance with label instructions.

For General Cleaning:

Light Soil: Use a 1:32 solution for routine maintenance when heavy soil build-up is not a problem.

Medium Soil: Use solution of 1:8 to 1:16 for areas of moderate soil.

Tough Soil Build-Up: For stubborn soil or heavy build-up, such as soap scum and body oils on bathtubs / shower walls, use a solution of 1:4.

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 in Hospitals and other Health Care facilities dilute 1:8.

To Control Mold & 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 (this product) full strength into the bowl water [1:25 dilution]. Thoroughly brush all bowl surfaces and under the rim. Let stand 10 minutes and then flush.

DILUTION CHART			
To prepare proper dilutions, add (this product) full strength to water as below.			
Dilution Ratio	(This product)	Water	
1:32	1 oz.	1 Quart	(32 oz.)
	4 oz.	1 Gallon	(128 oz.)
1:16	2 oz.	1 Quart	(32 oz.)
	8 oz.	1 Gallon	(128 oz.)
1:8 **	4 oz.	1 Quart	(32 oz.)
	16 oz.	1 Gallon	(128 oz.)
1:4	8 oz.	1 Quart	(32 oz.)
	32 oz.	1 Gallon	(128 oz.)

** For Pseudomonacidal activity (in Hospitals and other Health Care Facilities) dilute 1:8.

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

Proper dilution provides maximum cleaning benefits and product economy.

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 / body fluids; and in which the surfaces / objects likely to be soiled with blood / 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 [AIDS Virus] ON SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS:

PERSONAL PROTECTION: When handling items soiled with blood / body fluids, use disposable latex gloves, gowns, masks and eye protection.

CLEANING PROCEDURES: Blood / body fluids must be thoroughly cleaned from surfaces / objects before application of (this product).

CONTACT TIME: Allow surfaces / objects to remain wet for 10 minutes.

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

NOTE: Bracketed information is denoted as: << directive >>, { insert as noted }, (optional text), [required qualifier].
The term "this product" used throughout this document may be replaced with the marketed product brand name.
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.

6/7

PRECAUTIONARY STATEMENT: Hazards to Humans and Domestic Animals.

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear protective eye wear [goggles, face shield or safety glasses], protective clothing and rubber gloves. May be harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove contaminated clothing and wash before reuse.

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 a 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
CONTACT NUMBER	
Questions? Comments or In case of an emergency call toll free 1-800-677-9218. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

STORAGE AND DISPOSAL

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

PESTICIDE 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: Non-refillable container. Do not reuse or refill this container. 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.

ENVIRONMENTAL HAZARDS:

This pesticide is toxic to fish, aquatic invertebrates, oysters and shrimp.

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7/7

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Disinfection - Hard non-porous surfaces

Bacteria:	Acinetobacter calcoaceticus	ATCC # 15473
	Brevibacterium ammoniagenes	ATCC # 6871
	Burkholderia (Pseudomonas) cepacia	ATCC # 35254
	Corynebacterium diphtheriae	ATCC # 11913
	Enterobacter aerogenes	ATCC # 13048
	Enterococcus faecalis	ATCC # 828
	Escherichia coli O157:H7	ATCC # 43888
	Klebsiella pneumoniae	ATCC # 9997
	Neisseria elongata	ATCC # 25295
	Proteus mirabilis	
	Proteus vulgaris	ATCC # 9920
	Pseudomonas aeruginosa	ATCC # 15442
	Salmonella (choleraesuis) enterica	ATCC # 10708
	Salmonella paratyphi	ATCC # 9281
	Salmonella schottmuelleri	ATCC # 10719
	Salmonella typhi	ATCC # 6539
	Serratia marcescens	ATCC # 8195
	Shigella dysenteriae	ATCC # 11835
	Staphylococcus aureus	ATCC # 6538
	Staphylococcus aureus [MRSA] (Methicillin Resistant)	ATCC # 33592
Streptococcus pyogenes	ATCC # 12384	
Streptococcus salivarius	ATCC # 9222	
Viruses:	Herpes Simplex Virus Type 1	ATCC # VR-733
	Herpes Simplex Virus Type 2	ATCC # VR-734
	Human Immunodeficiency Virus Type 1	
	Influenza A ₂ Virus [Japan 305/57]	ATCC # VR-100
	Respiratory Syncytial Virus [RSV]	ATCC # VR-26
	Rotavirus WA	ATCC # VR-2018
Fungi:	Aspergillus niger	ATCC # 6275
	Candida albicans	ATCC # 10231
	Trichophyton mentagrophytes	ATCC # 9533

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