

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 25 1994

Michele F. Herrity
National Laboratories
225 Summit Avenue
Montvale, N.J. 07645

Subject: Quatsyl 256
EPA Registration No. 675-45
MOU Compliance Amendment Dated March 29, 1994

Dear Ms. Herrity:

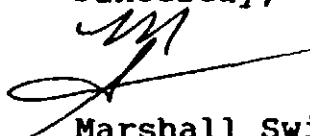
This letter responds to your amendment request to add the disclaimer statement required by the EPA/FDA June 4, 1993 Memorandum of Understanding (MOU) regarding medical devices to the Lysol Brand Disinfectant Spray product label.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, subject to the following comment. A stamped copy is enclosed for your records.

Under the recommendations for use of this product, delete "dental units". The term is vague and may be misunderstood by users.

Submit (5) copies of the final printed labeling before the product is released for shipment.

Sincerely,



Marshall Swindwell, (Acting PM 31)
Antimicrobial Program Branch
Registration Division (7505C)

CONCURRENCES							
SYMBOL	7505C						
SURNAME	PAVIAO						
DATE	4/25/94						

Front Panel

Part of Your Infection Control Program

QUATSYL 256

CLEANER DISINFECTANT

Deodorizer-Fungicide-Virucide**
For Hospital and Institutional Use
For Veterinary Hospitals and other Animal Facilities
Highly Concentrated Germicide Based on a Blend of Quaternaries

Active Ingredients:

Alkyl (C₁₄, 50%; C₁₂, 40%; C₁₆, 10%)
dimethyl benzyl ammonium chlorides..... 11.00%
Didecyl dimethyl ammonium chloride.....1.20%
Inert Ingredients:.....87.80%

KEEP OUT OF REACH OF CHILDREN

DANGER: Corrosive, Harmful if swallowed. Causes eye and skin injury. See side panel for additional precautionary statements.

EPA Registration No. 675-45
EPA Est. No. 777-OH-1

1:256

Net Contents
One Gallon (3.79 Liters)
5 Gallons (18.925 Liters)
55 Gallons (208.2 Liters)

NATIONAL LABORATORIES
L & F PRODUCTS
225 Summit Avenue
Montvale, New Jersey 07645

ACCEPTED
with COMMENTS
in EPA Letter Dated

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Under the Federal Insecticide, Fungicide, and Rodenticide Act

675-45

For Use In Institutional and Industrial Facilities
For Use In Veterinary Hospitals and Other Animal Facilities

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

This product is not to be used 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.

It cleans, disinfects, and counteracts odors./ Cleaning, disinfecting, counteracting odors.
Prepare a fresh solution daily and change solution frequently if grossly soiled or diluted. Always remove filth and heavy soil prior to use.

FOR CLEANING AND DISINFECTING: Use as follows on surfaces such as counter tops, walls, floors, etc.

DILUTION CHART
Correct Solution Strength
0.39% (1:256, 1/2 oz. per gallon)

PRODUCT	WATER
4 cc	1 quart
1/2 oz.	1 gallon
1-1/2 oz.	3 gallons
2-1/2 oz.	5 gallons

(one tablespoonful equals about 1/2 fluid oz. or 15 cc.)

1. Use 1/2 ounce (1:256) of Quatsyl 256 per gallon of water. (Provides 476 ppm quaternary active ingredients.)

2. Then apply fresh solution to surfaces with a cloth, sponge, mop or spray equipment. (Quatsyl 256 may be used in all types of pressure spraying equipment.) Allow solution to remain on surface for 10 minutes, then remove excess liquid or let it air dry.

MOLD AND MILDEW: For controlling mold and mildew on hard, nonporous environmental surfaces such as walls, floors, waste cans, counters and equipment, etc. Clean first, then apply 1/2 oz. (1:256) Quatsyl 256 solution with mop, cloth, sponge or sprayer in an amount to moisten surfaces thoroughly. Do not rinse. Repeat application as necessary to maintain control.

KILLS 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 surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus (HIV-1) (associated with AIDS).

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

675-45

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: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of Quatsyl 256.

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.

QUATSYL 256 IS: STAPHYLOCIDAL* PSEUDOMONACIDAL*

**** VIRUCIDAL*** (against Herpes Simplex Type 1, Influenza A₂ (Hong Kong), Vaccinia and Human Immunodeficiency Virus Type 1 (HIV-1) (AIDS Virus)

FUNGICIDAL* (against pathogenic fungi)

CONTROLS THE GROWTH OF MOLD AND MILDEW*

* On hard, nonporous environmental surfaces in the presence of organic soil (5% blood serum).

QUATSYL 256 is effective against:

Virucidal against the following viruses at 1:256:

Passes AOAC Use Dilution Test at 1:256 (1/2 ounce per gallon) against:

Candida albicans ATCC 10231

Corynebacterium diptheriae ATCC 11913

Enterobacter aerogenes ATCC 13048

Escherichia coli (AMC 198) ATCC 11229

Neisseria elongata ATCC 25295

Proteus vulgaris ATCC 9920

Pseudomonas aeruginosa ATCC 15442

Salmonella choleraesuis ATCC 10708

Salmonella paratyphi ATCC 9281

Salmonella schottmuelleri ATCC 10719

Serratia marcescens ATCC 8195

Shigella dysenteriae ATCC 11835

Staphylococcus aureus ATCC 6538

Streptococcus faecalis ATCC 828

Streptococcus pyogenes ATCC 12384

Streptococcus salivarius ATCC 9222

Trichophyton mentagrophytes ATCC 11913

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**** Virucidal against the following animal viruses at 1:256 dilution:**

Avian Laryngotracheitis

Bovine Respiratory Syncytial Virus

Bovine Viral Diarrhea

Canine Parainfluenza

Equine Influenza

Equine Rhinopneumonitis

Feline Rhinotracheitis

Infectious Bovine Rhinotracheitis

Infectious Bronchitis Virus (Beaudette)

Influenza A/Swine/1976/31

Parainfluenza Type 3, Bovine

Porcine Transmissible Gastroenteritis

Pseudorabies

Vesicular Stomatitis (Porcine)

Western Equine Encephalitis

SUGGESTED AREAS OF APPLICATION FOR QUATSYL 256

HEALTH CARE FACILITIES: Use a 1/2 oz. (1:256) solution of Quatsyl 256 on hard nonporous surfaces such as floors, walls, furniture, wheelchairs, patient bedframes, bedside tables, medical lamps, stands, dental units and similar equipment. Suitable for critical area disinfection such as O.R., patient care and isolation areas. Suitable for use on conductive floors.

VETERINARY: Use 1/2 oz. (1:256) solution of Quatsyl 256 in animal health care facilities on items such as operating tables, equipment, floors, walls, furniture, waste cans, display cases, washrooms, locker rooms, classrooms, kennels, cages, runs, and similar hard surfaces. Suitable for critical area disinfection such as O.R., and isolation areas. Suitable for use on conductive floors.

FOOD SERVICE AND DIETARY AREAS: Nonfood contact equipment and counters, floors, waste cans.

DAIRIES: Nonfood contact equipment, floors, walls.

FOOD PROCESSING PLANTS: Nonfood contact equipment and display cases, floors, walls, waste cans.

SUPERMARKETS: Nonfood contact equipment and counters, waste cans, floors, walls.

FAST FOOD OPERATIONS: Nonfood contact equipment, waste cans, floors, walls.

SCHOOLS: Washrooms, locker rooms, class rooms, nonfood contact equipment, walls, floors.

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS

KEEP OUT OF REACH OF CHILDREN

DANGER: Corrosive. Harmful if swallowed. Causes eye damage and skin irritation. Do not get in eyes, on skin, or on clothing. Protect eyes and skin when handling. Wear goggles or face shield and rubber gloves when handling. Avoid contamination of food. Remove and wash contaminated clothing before reuse.

STATEMENT OF PRACTICAL TREATMENT:

In case of eye contact, IMMEDIATELY flush eyes thoroughly with water, remove any contact lenses, and continue to flush eyes with plenty of water for at least 15 minutes. Call a physician immediately.

In case of skin contact, immediately wash with soap and water. If irritation persists, consult a physician.

If swallowed, promptly drink a large quantity of water to dilute the product. Get immediate medical attention.

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

PHYSICAL HAZARD

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

FOR ONE GALLON CONTAINER

STORAGE: Store in original container in areas inaccessible to small children. Keep securely closed. Do not contaminate food or feed.

DISPOSAL: Do not reuse empty container. Rinse thoroughly with water and detergent. Wrap securely and discard in trash.

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FOR 5 AND 55 GALLON CONTAINERS

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.

Quatsyl 256 is part of a system of Professional Infection Control products provided by National Laboratories. People respect the LYSOL Brand name for providing high quality and trusted surface disinfection, and gain the added benefit of a clean, sanitary environment. We invite you to call us at 1-800-677-9218, Monday through Friday, 8:30 a.m. to 4:30 p.m. (Eastern time), if you have any questions or comments on our products.

For 55 gallon drum:

This label is printed on 50% recycled paper (10% post-consumer).

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