

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 4 1994

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

Subject: Lysol Brand Disinfectant Spray
EPA Registration No. 777-53
MOU Compliance Amendment Dated March 14, 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 comments. A stamped copy is enclosed for your records.

1. On page 2, side panel, delete "dental units". The term is vague and may be misunderstood by users.
2. On page 3, side panel, in the paragraph immediately preceding "Directions for Use", delete the word "superior" from the sentence that reads in part: "People respect the Lysol name, recognize Lysol for proving superior surface disinfection...."

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

If you have questions or concerns, you may contact me at (703) 305-7964.

Sincerely,

Ruth Douglas, (PM 32)
Antimicrobial Program Branch
Registration Division (7505C)

CONCURRENCES

| | | | | | | | |
|---------|---------|------------|--|--|--|--|--|
| SYMBOL | H-7505C | 7505C | | | | | |
| SURNAME | Wells | Thompson | | | | | |
| DATE | 3/25/94 | 4 APR 1994 | | | | | |

2 9 5

FRONT PANEL

Part of Your Infection Control Program

LYSOL® BRAND DISINFECTANT SPRAY

ELIMINATES ODORS

SURFACE DISINFECTANT AND ROOM DEODORIZER

KILLS HOUSEHOLD GERMS, MOLD AND MILDEW

ANTIBACTERIAL ACTION

KILLS VIRUSES*, BACTERIA

(REGULAR SCENT) (ORIGINAL SCENT) (FRESH SCENT) (LIGHT SCENT)
(SCENT II) (COUNTRY SCENT) (MOUNTAIN SCENT) (MOUNTAIN AIR SCENT)

NET WT. 6 OZ. / 12 OZ. / 18 OZ. / 19 OZ.

READ PRECAUTIONS &
FIRST AID ON BACK PANEL

WARNING: KEEP OUT OF REACH OF
CHILDREN

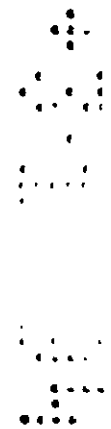
ACCEPTED
with COMMENTS
in EPA Letter Dated:

1. 4 APR 1996

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

777-53

BEST AVAILABLE COPY



Lysol Brand Disinfectant Spray
SIDE PANELS - PAGE 2

ELIMINATES ODORS

Lysol Spray deodorizes by killing the germs that cause odors. Lysol Spray eliminates odors at their source and in the air. Ordinary, non-germicidal sprays can't do this. To eliminate odors retained in fabrics, spray on draperies, curtains and upholstered furniture. Lysol Spray "gets to the source" of the odor without heavy perfume. Eliminates damp musty odors in the basement or in areas where air doesn't circulate.

To deodorize: Hold can upright. Spray on surfaces as needed.

ANTIBACTERIAL ACTION / KILLS HOUSEHOLD GERMS

Lysol Spray has antibacterial action and kills viruses and bacteria on environmental surfaces in your home and in public places. Lysol Spray kills household germs/microorganisms (on environmental surfaces), even-odor-causing household germs, in empty garbage cans, recycling bins, empty hampers, bathroom basins, toilet areas, under sinks, pet areas, diaper pails, sick rooms, showers, bathtubs, sinks, patient's chairs, telephones, lamps, examination tables, whirlpools, desks, saunas, patio furniture, operatories, stretchers, waiting rooms, patient's rooms, laboratories, cuspidors, door handles, wheel chairs, counters, dental units.

Fast/Easy/Effective

Use on finished surfaces in basements, closets, attics, laundry rooms, storage areas, summer cottages, vacation homes, boat and car interiors, shower stalls. Excellent for controlling mold and mildew on mattresses, pillows shower curtains and books.

KILLS AND PREVENTS THE GROWTH OF MOLD AND MILDEW IN:

Air conditioning vents, showers, bathtubs, restrooms, attics, lockers, closets, damp storage areas.

Lysol® Brand Disinfectant Spray meets AOAC efficacy standards for ~~disinfectants~~ **disinfectants**:

**GERMICIDAL
FUNGICIDAL**

**TUBERCULOCIDAL
VIRUCIDAL***

**APPROVED
EPA Letter Dated
APR 1994**

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

FOR USE IN:

- | | | | |
|----------------|---------------------|---------------|--------------------|
| Hospitals | Day Care Centers | Hotels/Motels | Kennels |
| Nursing Homes | Physicians' Offices | Restaurants | Veterinary Offices |
| Clinics | Health Clubs | Schools | Bowling Alleys |
| Dental Offices | Ambulances | Restrooms | Office Buildings |

On environmental surfaces, Lysol Spray kills staph and strep germs, athlete's foot fungus and hydrophilic and lipophilic viruses* such as:

- | | |
|------------------------------|---|
| Influenza Type B (Hong Kong) | Poliovirus Type 1 |
| Rhinovirus 39 | Respiratory Syncytial Virus |
| Influenza Type A2 (Japan) | Adeno Type 2 |
| Echovirus Type 12 | Vaccinia |
| Herpes Simplex Types 1 & 2 | Human Immunodeficiency Virus Type 1 (AIDS VIRUS)** |
| Rotavirus | Hepatitis A |
| Cytomegalovirus | |
| Parainfluenza Type 2 | |
| Aspergillus Niger | |
| Canine parvovirus | |

**Tested in the presence of 50% whole human blood

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LYSOL BRAND DISINFECTANT SPRAY - PAGE 3

Lysol® Brand Disinfectant Spray also kills the following bacteria and fungi on environmental surfaces:

- | | |
|--|--------------------------------------|
| Salmonella choleraesuis | Shigella dysenteriae |
| Escherichia coli | Staphylococcus aureus |
| Proteus vulgaris | Enterobacter aerogenes |
| Klebsiella pneumoniae | Mycobacterium tuberculosis var bovis |
| Pseudomonas aeruginosa | Streptococcus faecalis |
| Corynebacterium diphtheriae | Candida albicans |
| Trichophyton mentagrophytes | Salmonella schottmuelleri |
| Streptococcus pyogenes | Serratia marcescens |
| Salmonella paratyphi | Campylobacter jejuni |
| Listeria monocytogenes | Neisseria elongata |
| Staphylococcus aureus (Penicillin resistant) | |
| Staphylococcus aureus (Methicillin and Gentamicin Resistant) | |

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 surfaces/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 coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of LYSOL BRAND Disinfectant SPRAY.

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.

Now, more than ever, infection control is a major concern of yours, your staff and patients. People respect the Lysol name, recognize Lysol for providing superior surface disinfection, and gain the added benefit of a clean-smelling, sanitary environment.

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

TO DISINFECT: Hold can upright, 6" to 8" from surface. Spray precleaned surfaces 2 to 3 seconds until covered with mist. Allow to stand 10 minutes in order to air dry. To control mold and mildew and their odors: Clean surface prior to application. Spray surface until covered with mist. Repeat applications as necessary.

TO SANITIZE NON-FOOD CONTACT SURFACES: To sanitize surfaces (such as toilet seats, etc.) remove gross filth or heavy soil prior to application of the product; Hold can upright 6" to 8" from surface. Spray surface 2 to 3 seconds until covered with mist. Allow to stand 30 seconds. Wipe surface with a clean, dry cloth or sponge.

ACCEPTED
with COMMENTS
to EPA Letter Dated

APR 1994

Under the Federal Insecticide,
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amended, for the pesticide
registered under EPA Reg. No.

777-53

BEST AVAILABLE COPY

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LYSOL BRAND DISINFECTANT SPRAY - PAGE 4

The following language is only for products with medical devices listed on the label:
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.

PRECAUTIONARY STATEMENTS:

Hazards to humans and domestic animals.

WARNING: Avoid contact with eyes and food.

FIRST AID: 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. Get medical attention if irritation persists.

PHYSICAL HAZARDS:

Flammable: Contents under pressure. Do not use near fire, sparks or flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F. may cause bursting. Do not use on polished wood furniture, rayon fabrics, leather or acrylic plastics.

STORAGE/DISPOSAL: Store in original container in areas inaccessible to small children. Replace cap and discard in trash. Do not puncture or incinerate. Do not reuse empty container.

Lysol® Brand Disinfectant Spray is germicidal when used as directed for disinfection but differs in composition from other Lysol Brand products.

ACTIVE INGREDIENTS: o-Phenylphenol 0.1%, Ethanol 79.0%
INERT INGREDIENTS: 20.9%

EPA REG. NO. 777-53
EPA EST. NO. 777-IL-1, NJ-2
11525.IL-01 (See bottom)

**REGISTERED
with COMMENTS
in EPA Letter Docket**

APR 1986

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

777-53

Contains no CFC's or other ozone depleting substances.
Federal regulations prohibit CFC propellants in aerosols.

Questions about this product? Call 1-800-228-4722.
This can is made from an average of 25% recycled steel (10% post consumer).

Lysol Brand Disinfectant Spray is part of a system of 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, 8:45 a.m. to 4:30 p.m. (Eastern time), if you have any questions or comments on our products.

Please encourage your state and local authorities to establish a recycling program so that this can may be recycled.

Made in USA DOT 2P

L & F Products
Montvale, NJ 07645