

DEC 14 1992

Mr. Paul Kruger
Lehn & Fink Products Group
225 Summit Avenue
Montvale, NJ 07645

Dear Mr. Kruger:

Subject: Lysol Brand Pump Spray Disinfectant
EPA Registration No. 777-55
Your Resubmission Dated July 23, 1992 and August 12, 1992

This is in response to your resubmission of July 23, 1992 requesting a rereview of previously submitted and referenced efficacy data in support of a sanitizing claim and additional microorganisms and your submission of August 12, 1992 of revised CSFs for two alternate formulas.

The following comments apply:

EFFICACY

1. The submitted referenced data are acceptable to support effectiveness of the product as a disinfectant against *Salmonella paratyphi*, *Salmonella schottmuelleri*, *Shigella dysenteriae*, *Enterobacter aerogenes*, *Escherichia coli*, *Proteus vulgaris*, *Klebsiella pneumoniae*, *Neisseria elongata*, *Serratia marcescens*, *Staphylococcus aureus* (Penicillin resistant), *Streptococcus faecalis*, *Streptococcus pyogenes*, *Corynebacterium diphtheriae*, *Campylobacter jejuni*, *Listeria monocytogenes*, methicillin and gentamicin resistant *Staphylococcus aureus*; as a fungicide against *Candida albicans* and *Aspergillus niger*; as a tuberculocide against *Mycobacterium tuberculosis* var. *bovis* (b); and as a virucide against Echovirus type 12, Respiratory syncytial virus, Poliovirus type 1, Rotavirus, Herpes Simplex

62984:I/G:WP50:Principal:WP50 3:KEVRIC:12/03/92:01/04/93

CONCURRENCES

SYMBOL	W 75040						
SURNAME	W Kruger						
DATE	12-70						

2079

Type 2, Cytomegalovirus, Parainfluenza Type 2, Human Hepatitis A, and HIV-1 (AIDS virus) when used as an undiluted (non-pressurized) spray on hard, nonporous surfaces in the presence of 5% blood serum (and 50% whole human blood for HIV-1) for a contact time of 10 minutes at 20 °C.

- 2. The submitted referenced data are also acceptable to support effectiveness of the product as a non-food contact surface sanitizer against *Staphylococcus aureus* and *Enterobacter aerogenes* when used as an undiluted (non-pressurized) spray on hard, nonporous surfaces in the presence of 5% blood serum for a contact time of 30 seconds.
- 3. The submitted referenced confirmatory efficacy data are also acceptable to support the alternate formulations dated August 11, 1992.

CHEMISTRY

- 1. The referenced chemical identity of Perfume oil 4259-AQ submitted for product under EPA Registration No. 777-53 has been reviewed, chemical code has been assigned and is acceptable for this formulation also.
- 2. Proposed two alternate formulations with different fragrances are acceptable.
- 3. Confidential Statements of Formula dated August 11, 1992 for the alternate formulate are filled out correctly, they agree with the label claim and are acceptable.

The previously submitted Confidential Statements of Formula for these alternate formulations are withdrawn. These two Confidential Statements of Formula supersede all alternate formulations. These CSFs do not require additional efficacy data.

LABELING

Therefore, 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:

- Revise "Meets AOAC Standards" to read "Meets AOAC Standards for hospital disinfectants."

A stamped copy is enclosed for your records. Five copies of the finished labeling must be submitted before you release the product for shipment bearing the amended labeling.

If you have any further questions, please contact Ms. Barbara Pringle at (703) 305-6484.

Sincerely yours,



Ruth G. Douglas
Product Manager (32)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosure

FRONT LABEL

(R)
LYSOL PUMP SPRAY DISINFECTANT

ELIMINATES ODORS

SURFACE DISINFECTANT AND ROOM DEODORIZER

KILLS HOUSEHOLD GERMS, MOLD AND MILDEW

(ORIGINAL SCENT) (FRESH SCENT) (LIGHT SCENT)
(COUNTRY SCENT)

HOSPITAL DISINFECTANT

Meets AOAC Standards

- GERMICIDAL**
- FUNGICIDAL**
- TUBERCULOCIDAL**
- VIRUCIDAL***

**KEEP OUT OF REACH
OF CHILDREN**

**KILLS GERMS AWAY FROM
HOME.**

**WARNING: READ PRECAUTIONS & FIRST AID
ON BACK PANEL.**

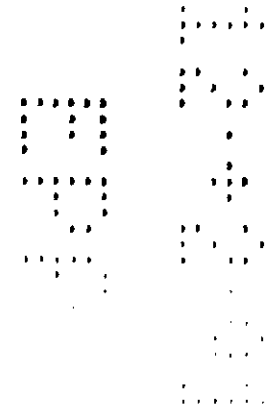
PERSONAL SIZE

NET WT. 1 FL. OZ./6 FL. OZ./8 FL. OZ./10.0 FL. OZ./10.5 FL. OZ./12.0 FL. OZ./15.0 FL. OZ.

ACCEPTED
with COMMENT
in EPA Letter Dat.

REC-14-1982

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pest(s)
registered under EPA Reg. No.
177-55



BACK LABEL

Lysol Pump Spray Disinfectant provides all the power of Lysol Spray in a revolutionary air pump. It sprays just like an aerosol but uses the air that you pump in as a propellant. Simply pump the cap and press the button (nozzle) to get a continuous, fine spray. You'll feel better about using Lysol because the spray mist is propelled by pure air that you pump in. Just pump and spray germs and odors away.

Applies to 6 oz. 8 oz. 10 oz. 10.5 oz. 12 oz. containers only.

HOW TO USE THIS CONTAINER: Pump air into container by fully raising and lowering the cap 10 to 15 times for a continuous, micro-fine mist. For a heavier mist, pump fewer times. For a finer mist, pump more. Don't worry, you can not over-pump.

HOW TO SPRAY: Air must be pumped into the container before spraying (see above). Remove the cap and press the button (nozzle) to spray. When spray becomes weak, simply pump again.

Applies to 15 oz. container only

TO DISPENSE PRODUCT: Turn spray nozzle to "on" position. Spray.

illustration

Applies to 1 oz. container only

Lysol Pump Spray Disinfectant is a convenient way to protect yourself against germs outside of the home. Use it to disinfect hard surfaces in locker rooms, public toilets, hotels and office buildings. The handy 1 oz. pump fits easily into your pocket, purse, briefcase or glove compartment and provides powerful protection against germs, anywhere you go.

Kills household germs on contact, eliminates odors in the air.

Illustration
Public Toilets

Illustration
Locker Rooms

Illustration
Hotels/
Motels

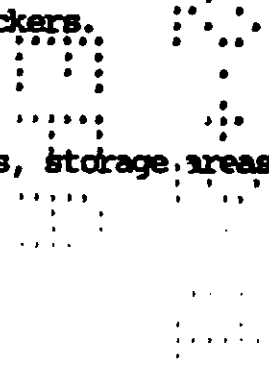
Illustration
Public Telephones

KILLS HOUSEHOLD GERMS:

Lysol Pump Spray Disinfectant kills household germs (on environmental surfaces), even odor-causing household germs, in empty garbage cans, empty hampers, bathroom basins, toilet areas, under sinks, pet areas, diaper pails, changing tables, 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, high chairs, gym lockers.

Fast/Easy/Effective

Use on finished surfaces in basements, closets, attics, laundry rooms, storage areas, vacation homes, boat interiors, trailers, shower stalls.



KILLS AND PREVENTS GROWTH OF MOLD AND MILDEW:

Excellent for controlling mold and mildew on mattresses, pillows, shower curtains, air conditioning vents, showers, bathtubs, restrooms, attics, lockers, closets, damp storage areas.

Lysol Pump Spray Disinfectant meets AOAC efficacy standards for hospital disinfectants:

	GERMICIDAL FUNGICIDAL	TUBERCULOCIDAL VIRUCIDAL*	
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
	Locker Rooms		

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

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

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

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

- | | |
|--|---|
| Salmonella choleraesuis | Aspergillus niger |
| Escherichia coli | Shigella dysenteriae |
| Proteus vulgaris | Staphylococcus aureus |
| Klebsiella pneumoniae | Enterobacter aerogenes |
| Pseudomonas aeruginosa | Mycobacterium tuberculosis var bovis (10 minutes at 20 degrees Celsius) |
| Corynebacterium diphtheriae | Streptococcus faecalis |
| Trichophyton mentagrophytes | Candida albicans |
| Streptococcus pyogenes | Salmonella schottmuelleri |
| Salmonella paratyphi | Serratia marcescens |
| Listeria monocytogenes | Campylobacter jejuni |
| Staphylococcus aureus (Penicillin resistant) | Neisseria elongata |
| Staphylococcus aureus (Methicillin and Gentamicin Resistant) | |

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 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 Pump Spray Disinfectant.

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 clean-smelling, sanitary environment.

ELIMINATES ODORS

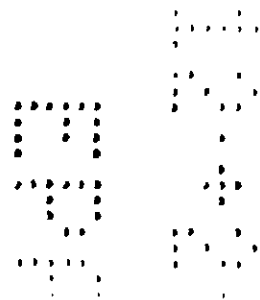
Lysol Pump Spray Disinfectant effectively deodorizes by killing the germs that cause odors. Lysol Pump Spray Disinfectant eliminates odors at their source on surfaces, and (then) in the air. Ordinary, non-germicidal sprays can't do this. To freshen smoke-filled rooms quickly, spray perimeter of room. To eliminate smoking odors retained in fabrics, spray on or around draperies, curtains and upholstered furniture. Lysol Pump Spray Disinfectant gets to the source of the odor without heavy perfume. Lysol Pump Spray Disinfectant erases bathroom and cooking odors without heavy perfume. Eliminates damp musty odors in the basement or in areas where air doesn't circulate. Eliminates tobacco, pet and bathroom odors, freshens drapes, carpets, bedding, closets, garbage bins, upholstery and shoes.

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

TO DISINFECT: Hold container upright, 6" to 8" from surface. Spray pre-cleaned surface 2 to 3 seconds until covered with mist. Allow to stand ten minutes in order to air dry. To control mold and mildew and their odors: clean surface prior to application. Repeat applications as necessary.

TO DEODORIZE: Hold container upright. Spray center of room. Spray on surfaces as needed.

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 container 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.



REFILL AVAILABLE

8079

TO REFILL:

Applies to 6 oz. 8 oz. 10 oz 10.5 oz. and 12 oz only.

Time to purchase a Lysol Pump Spray Disinfectant refill



Refill Line For optimal performance, do not fill beyond this point.

This package contains (six, eight, ten, ten and one half or twelve) ounces of Lysol Pump Spray Disinfectant. The air space above the refill (dotted) line is necessary for the spray system to work correctly.

Refill over sink to avoid spills. Remove cap, unscrew ring, and remove spray unit from original container. Pour in refill. Do not fill above refill line. Overfilling will result in a wet spray. Replace ring and spray unit, tightly screwing back into place. Refill the container frequently. If you keep your Lysol Pump Spray container at least one-third full at all times, you will not have to pump as much to maintain the desired mist.

IMPORTANT:

USE ONLY LYSOL PUMP SPRAY DISINFECTANT (REFILL) IN THIS PACKAGE.

PRECAUTIONARY STATEMENTS:

Hazards to humans and domestic animals.

WARNING: Avoid contact with eyes and food. Do not ingest.

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: Do not store or use near fire, sparks or flame. Do not spray on polished wood, rayon fabrics, leather, or acrylic plastics.

STORAGE/DISPOSAL:

Store in areas inaccessible to small children. Refill container only with Lysol Pump Spray Disinfectant. If not refilling, simply discard.

Lysol Pump Spray Disinfectant is germicidal when used as directed for disinfection, but differs in composition from other Lysol Brand Products.

ACTIVE INGREDIENTS: o-Phenylphenol 0.1%, Ethanol 82.0%
INERT INGREDIENTS: 17.9%

L&F Products
Montvale, NJ 07645

Questions about this product?

Call 1-800-228-4722

EPA REG. NO. 777-55

EPA EST. NO. 777-IL-1 (See bottom)

NJ-2, OH-1

33590 MA-1

11525-IL-01, RI-01

46229-NY-1

BACK LABEL OF REFILL CONTAINER (ONLY)

Reuse your Lysol Pump Spray Disinfectant container by refilling it with this convenient and economical refill package (pouch).

TO REFILL THE PUMP SPRAY CONTAINER:

REMOVE

ILLUSTRATION

POUR

ILLUSTRATION

USE

ILLUSTRATION

Applies to 6 oz., 8 oz., 10 oz., 10.5 oz., 12 oz. only.

1. Remove cap, unscrew ring, and remove spray unit from empty Lysol Pump Spray Container.

2. Unscrew cap on Lysol Pump Spray Disinfectant Refill (Pouch Pack) and pour contents into empty container up to the refill line. Do not fill above refill line. Overfilling will result in a wet spray.

3. Replace ring and spray unit, tightly screwing back into place. Pump 10 to 15 times before use for a continuous, micro-fine spray.

TO REFILL THE TRIGGER SPRAYER CONTAINER:

REMOVE

ILLUSTRATION

OPEN

ILLUSTRATION

1. Unscrew trigger unit. Remove from bottle.

2. Hold refill pouch gently in one hand. With scissors, cut along dotted line.

POUR

ILLUSTRATION

USE

ILLUSTRATION

Applies to 15 oz. container only.

3. Insert plastic funnel into trigger sprayer container. Pour entire contents of refill pouch into the empty trigger sprayer bottle. Refill over sink to avoid spills. Rinse any spills with water.

4. Remove funnel and replace trigger unit, tightly screwing into place.

