

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

12/12/1995

National Laboratories,
Reckitt & Colman, Inc.
225 Summit Avenue
Montvale, NJ 07645-1575

Attn: Ruth Trager,
Registration Administrator

Subject: O-Syl Di-infectant Detergent
EPA Registration No. 675-46
Your 6(a)(2) Resubmission of September 31, 1994

EPA has completed review of the forwarded product labeling revised as a result of the July 14, 1994 6(a)(2) submission for the subject registration indicating product failure against Adenovirus Type 2. In addition to the Adenovirus Type 2 revisions, the enclosed label also contained other minor label changes including the addition of FDA/EPA MOU language for medical devices. The following comments are a result of this label review.

1. The revised product labeling submitted in connection with the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. A stamped copy is enclosed for your records.

a. The deletion of the Adenovirus Type 2 claims on the product label, based upon the test data submitted under MRID 432834-01, are acceptable.

b. In the Directions For Use section of the label, (page 3 of the draft), revise the statement "This product is not to be used on any surface or instrument that (1) is introduced directly into the human body ..." to read: "This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body ...". And, at the end of this statement add the following sentence: "This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection."

Submit one copy of the finished product labeling which incorporates the preceding comments before releasing the product for shipment.

CONCURRENCES

SYMBOL	7505						
SURNAME	J. J. ...						
DATE	DEC 12 1995						

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If you should have any questions concerning this letter, you may call Robert Travaglino on (703) 305-6909.

Sincerely,



Ruth G. Douglas
Product Manager (32)
Antimicrobial Program Branch
Registration Division (7505C)

PART OF YOUR INFECTION CONTROL PROGRAM

For Use in Institutional and Industrial Facilities

O-SYL®
DISINFECTANT-DETERGENT

- GERMICIDAL* Tuberculocidal • Pseudomonacidal • Staphylocidal
- VIRUCIDAL* Against the following viruses — Herpes Simplex Type 1, Vaccinia, Influenza A₂ (Asian) and HIV-1 (AIDS Virus)
- FUNGICIDAL* Against pathogenic fungi
- FUNGISTATIC* Prevents the growth of mold and mildew

*On hard, nonporous surfaces in the presence of organic soil (5% blood serum) and 400 ppm hard water (as CaCO₃).

ACTIVE INGREDIENTS: o-Benzyl-p-chlorophenol.....7.24%
o-Phenylphenol.....2.23%

INERT INGREDIENTS*:90.53%

*Contains no phosphates.

KEEP OUT OF REACH OF CHILDREN
DANGER:

EPA Reg. No. 675-46
EPA Est. No. 777-OH-1

Corrosive. Harmful if swallowed.
Causes eye damage and skin irritation.
See side/back panel for statement of practical treatment and additional precautionary statements.

1:128

NATIONAL LABORATORIES (Logo)
L&F Products•Montvale, NJ 07645

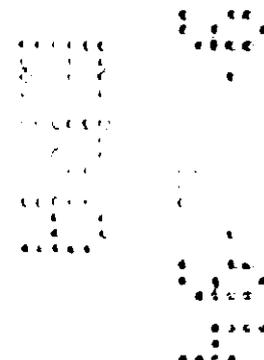
Net Contents:
6 Fl. Oz. (177 mL)
32 Fl. Oz. (1 Qt.) 946 mL
1 U.S. Gallon (3.79 Liters)
5 U.S. Gallons (18.95 Liters)
55 U.S. Gallons (208.18 Liters)

ACCEPTED
with COMMENTS
in EPA Reg. No. 675-46

DEC 12 1987

Under the Federal Insecticide, Fungicide, and Rodenticide Act, this product is registered under EPA Reg. No.

675-46



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HOW TO USE O-SYL® Disinfectant-Detergent:

O-SYL is recommended for use in hospitals, nursing homes, dental offices, and other institutional facilities, on hard, nonporous surfaces such as wheelchairs, patient bedframes, bedside tables, medical lamps, stands, and other similar equipment.

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.

O-SYL has been tested and found effective in hard water and in the presence of organic matter. O-SYL solution is in concentrated form; dilute only according to directions, following precautions indicated on this label.

To prepare proper dilution in required quantities, add full strength O-SYL to water as below:

Correct Solution Strength
0.78% (1:128, 1 oz. per gallon)

PRODUCT	WATER
8 cc	1 quart
1 oz.	1 gallon
3 oz.	3 gallons
5 oz.	5 gallons

FOR GERMICIDAL CLEANING and DEODORIZING and CONTROL of MOLD and MILDEW (including premises occupied by tubercular patients):

Fresh solution should be prepared at least daily or more often if the solution becomes diluted or soiled. Apply to environmental surfaces with sponge, mop or cloth. Maintain a thoroughly wet surface for 10 minutes. When required, remove gross filth and heavy soil prior to disinfection.

FLOORS·WALLS·CARTS·GARBAGE CANS·FIXTURES

FLOORS: Apply O-SYL solution with mop or autoscrubber. Pick up excess solution with mop or wet vacuum. Rinsing not required.

WALLS: Wipe walls at least 8 ft. up from floor with O-SYL solution. Do not rinse.

TUBERCULOSIS HYGIENE: Add 1 oz. of O-SYL to a gallon of water. Wet-mop floors daily with this solution. Wipe walls daily with cloth or sponge dampened in this solution. Maintain a thoroughly wet surface for 10 minutes.

For heavily soiled areas from vomitus, sputum, excreta, or barium accident, a precleaning step is required to remove all gross filth. 1:128 dilution of O-SYL is effective in 10 minutes at 20°C (68°F). Fresh solution should be prepared daily or more often if solution becomes soiled.

FOR CONTROLLING MOLD AND MILDEW: Clean surfaces first, then apply via mop or cloth until surface is moistened thoroughly. Do not rinse. Repeat as necessary.

EFFECTIVE IN HARD WATER AND IN THE PRESENCE OF ORGANIC MATTER.

TWO TABLESPOONFULS EQUALS ABOUT 1 FLUID OUNCE OR 30 CC.

O-SYL saves time and labor: Cleans, disinfects and deodorizes in one operation.

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 O-SYL Disinfectant-Detergent.

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.

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PRECAUTIONARY STATEMENTS: HAZARDS TO HUMAN 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. Wash thoroughly after handling. Wear goggles or face shield and rubber gloves when handling. Avoid contamination of food. Remove and wash contaminated clothing.

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. Get medical attention. If on skin, 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 OR CHEMICAL HAZARD:

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

(For sizes 1 gallon and less)

STORAGE: Store in original container in areas inaccessible to small children. Keep securely closed.

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

(For sizes greater than 1 gallon)

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.

O-SYL® Disinfectant-Detergent 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.

**AMERICA'S FOREMOST MANUFACTURER OF DISINFECTANTS AND
DISINFECTANT-DETERGENTS FOR ENVIRONMENTAL SANITATION.**

(For 6 oz., 32 oz. and 55 gallon container)

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

