

DEC 12 1994

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

Attn: Ruth Trager,
Registration Administrator

Subject: Con-O-Syl Disinfectant Detergent
EPA Registration No. 675-27
Your 6(a)(2) Resubmission of August 31, 1994

The submitted 6(a)(2) type test data indicating product failure against Adenovirus Type 2 and the resultant revised product labeling has completed review. Also reviewed were additional product virucidal test data with corresponding label revisions which were included in this submission. The following comments are a result of these reviews.

1. The submitted test data indicating product failure against Adenovirus Type 2 is acceptable and the consequent deletion of these claims on the product label is satisfactory.

2. The submitted virucidal data (MRID's 433651-01 through 433561-05) are acceptable to support the product effectiveness as a virucide against HIV-1 (AIDS virus), Human Cytomegalovirus Parainfluenza Type 2, Herpes simplex virus Type 2, and Respiratory syncytial viruses when used at a 1:256 dilution on hard, non-porous surfaces in the presence of moderate amounts of organic soil and 400 ppm hard water for a contact time of 10 minutes at room temperature.

3. The revised product labeling enclosed with this submission is acceptable subject to the comments listed below. A stamped copy is enclosed for your records.

a. In the product description given on page 2 of the draft label, revise the first part of the sentence "It meets A.O.A.C. efficacy standards for hospital disinfectants: ..." to: "It meets A.O.A.C. Use Dilution Test Standards for hospital disinfectants: ...".

CONCURRENCES

SYMBOL	750 SC							
SURNAME	Trager							
DATE	DEC 12 1994							

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.

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

Sincerely,



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

3 7 7

FRONT PANEL

PART OF YOUR INFECTION CONTROL PROGRAM

**CON-O-SYL®
DISINFECTANT DETERGENT**

- Germicidal
- Tuberculocidal
- Virucidal* (see back label)
- Fungicidal

ACCORDANCE
with CONSENTS
in EPA L. 100-100000

DEC 12 1980

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

675-27

ACTIVE INGREDIENTS:	o-Phenylphenol	11.75%
	o-Benzyl-p-chlorophenol	7.82%
INERT INGREDIENTS*:	80.43%

*Contains no phosphates.

KEEP OUT OF REACH OF CHILDREN

DANGER:

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

EPA Reg. No. 675-27
EPA Est. No. 777-OH-1

1:256

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)

CON-O-SYL® DISINFECTANT DETERGENT

CON-O-SYL® Disinfectant Detergent is recommended for use in hospitals, nursing homes, dental offices, and other institutional facilities, on hard, nonporous surfaces such as floors, walls, woodwork, vinyl fabric upholstered furniture, conductive flooring, counters, wheelchairs, patient bed frames, bedside tables, medical lamps, stands, dental chairs, and other similar equipment.

It meets A.O.A.C. efficacy standards for hospital disinfectants: Germicidal*, Tuberculocidal*, Virucidal*, and Fungicidal*.

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

On environmental surfaces CON-O-SYL® Disinfectant Detergent kills the following bacteria and fungi**:

Pseudomonas aeruginosa ATCC 15442	Proteus vulgaris ATCC 9920
Salmonella choleraesuis ATCC 10708	Klebsiella pneumoniae ATCC 9997
Staphylococcus aureus 209 ATCC 6538	Neisseria elongata ATCC 25295
Staphylococcus aureus 80/81 (Penicillin resistant)	Serratia marcescens ATCC 8195
Mycobacterium tuberculosis var. bovis (BCG)	Streptococcus faecalis ATCC 828
Salmonella paratyphi ATCC 9281	Streptococcus pyogenes ATCC 12384
Salmonella schottmuelleri ATCC 10719	Streptococcus salivarius ATCC 9222
Shigella dysenteriae ATCC 11835	Corynebacterium diphtheriae ATCC 11913
Enterobacter aerogenes ATCC 13048	Candida albicans ATCC 10231
Escherichia coli AMC 198 (ATCC 11229)	Trichophyton interdigitale ATCC 640
	Aspergillus Niger ATCC 6275

** Tested in both 400 ppm hard water and in deionized water.

CON-O-SYL® Disinfectant Detergent also kills the following lipophilic viruses*:

Herpes Simplex Type 1 & Type 2
 Human Immunodeficiency Virus Type 1 (HIV-1) (AIDS Virus)
 Influenza A₂ (Japan)
 Parainfluenza Type 2
 Respiratory Syncytial virus
 Vaccinia
 Cytomegalovirus

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 Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

5 9 7

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 CON-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.

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.

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

Correct Solution Strength
0.39% (1:256, ½ oz. per gallon)

PRODUCT	WATER
4 cc	1 quart
½ oz.	1 gallon
1½ oz.	3 gallons
2½ oz.	5 gallons

One tablespoon equals about ½ fl. oz. or 15cc.

To prepare dilution in required quantities, add full strength to water as above.

For GERMICIDAL CLEANING and DEODORIZING and CONTROL of MOLD and MILDEW: Fresh solution should be prepared at least daily or more often if the solution becomes diluted or soiled. Apply to environmental surfaces with mop, cloth, or sponge. Maintain a thoroughly wet surface for 10 minutes. If surfaces are heavily soiled, clean first with CON-O-SYL® Disinfectant Detergent.

Floors: Apply CON-O-SYL® Disinfectant Detergent solution with mop or autoscrubber. Pick up excess solution with mop or wet vacuum. Rinsing not required.

Walls: Wipe walls at least 8 feet up from floor with CON-O-SYL® Disinfectant Detergent solution. Do not rinse.

Vinyl Upholstered Dental Chairs and Examination Tables: Apply CON-O-SYL® Disinfectant Detergent solution with a cloth to thoroughly wet surfaces. Wipe dry.

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS

KEEP OUT OF REACH OF CHILDREN

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

STATEMENT OF PRACTICAL TREATMENT:

In case of eye contact, IMMEDIATELY flush eyes with plenty of 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 plenty of water. 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 larger 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 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.

CON-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 product.

(For 6 oz. and 32 oz. sizes)

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

