

FEB 25 1991

Lonza, Inc.
17-17 Route 208
Fair Lawn, NJ 07410

Attention: Joseph R. Robinson

Gentlemen:

Subject: Lonza Formulation R-82
EPA Registration No. 6836-78
Your Submission Dated October 15, 1990
EPA Received Date November 9, 1990

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you submit five (5) copies of your final printed labeling before you release the product for shipment.

However, at the next printing, or within one (1) year--whichever comes first, please make the following label revisions:

1. Revise the statement "Lonza Formulation R-82 is a one-step disinfectant cleaner that is effective against a broad spectrum . . ." to read "Lonza Formulation R-82 is a one-step disinfectant cleaner that is effective against a broad spectrum of bacteria, is virucidal* (including HIV-1), fungicidal, and . . ."
2. Under the heading "Non-Acid Toilet Bowl Disinfectant Cleaner," revise "Brush over exposed surfaces . . ." to read "Brush thoroughly over exposed surfaces and under the rim . . ."
3. Under item 2, and after the wording "to exposed surfaces" add "including under the rim . . ."

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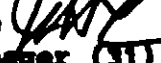
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If you have any further questions concerning this letter, please contact Karen M. Leavy at (703) 557-3966.

Sincerely yours,

John H. Lee 
Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosure

BEST AVAILABLE COPY

Cross-contamination is of major housekeeping concern not only in hospitals, but in schools, institutions, and industry. LONZA FORMULATION R-82 has been formulated to aid in the reduction of cross-contamination in these areas.

LONZA FORMULATION R-82 is a one-step disinfectant cleaner that is effective against a broad spectrum of bacteria, is virucidal* (including HIV-1), fungicidal, and inhibits the growth of mold and mildew and their odors when used as directed.

LONZA FORMULATION R-82 is an effective one-step sanitizer-cleaner for use on non-food contact surfaces. When used as directed, LONZA FORMULATION R-82 will deodorize surfaces in toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause mal odors.

Precautionary Statements

Hazards to Humans and Domestic

Animals

DANGER

Keep out of reach of children. Corrosive. Causes eye and skin damage. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed or absorbed through skin. Avoid contamination of food.

Storage and Disposal

- Do not contaminate water, food, or feed by storage or disposal.
- Do not store on side.
- Avoid creasing or impacting of side walls.

PESTICIDE DISPOSAL

Side wastes are acutely hazardous. Improper disposal of excess side, spray or mixture of rinsate is a violation of Federal Law. If 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.

Metal Container: Triple rinse (or equivalent), then offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(If container is 1 gallon or less, use this container disposal statement.)

Do not reuse empty container (bottle, can, bucket). Wrap container and put in trash.

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6826-78

LONZA FORMULATION R-82

Disinfectant-Cleaner-Sanitizer-Fungicide
Mildewstat-Virucide*-Deodorizer

for Hospitals, Institutional and Industrial Use

Effective in hard water up to 400 ppm hardness
(calculated as CaCO_3) in the presence of
5% serum contamination

Active Ingredients

Octyl decyl dimethyl ammonium chloride	6.510%
Dioctyl dimethyl ammonium chloride	2.604%
Didecyl dimethyl ammonium chloride	3.906%
Alkyl (C_{14} , 50%; C_{12} , 40%; C_{10} , 10%) dimethyl benzyl ammonium chloride	8.680%

Inert Ingredients

78.300%

100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER

PELIGRO

Statement of Practical Treatment

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse.

If swallowed, drink promptly a large quantity of egg whites, gelatin solution; or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration No.

6836-78

EPA Establishment No.

6836-IL-1

Net Contents

MANUFACTURED BY:

LONZA INC., 17-17 Route 208, Fair Lawn, N.J. 07410

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Directions for Use

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

LONZA FORMULATION R-82 is a proven "one-step" disinfectant—cleaner—sanitizer—fungicide—mildewstat—virucide which is effective in water up to 400 ppm hardness in the presence of 5% serum contamination.

Apply LONZA FORMULATION R-82 to walls, floors and other hard (inanimate), non-porous surfaces such as tables, chairs, countertops, sinks, tile, porcelain, toilet bowls, urinals and bidets with a cloth, mop or mechanical spray device so as to thoroughly wet surfaces. For heavily soiled areas, a preliminary cleaning is required. Prepare a fresh solution daily or when use-solution becomes visibly dirty.

Disinfection — to disinfect hard, non-porous surfaces, add 0.5 oz. per gallon of water. Treated surfaces must remain wet for 10 minutes. The activity of LONZA FORMULATION R-82 has been evaluated in the presence of 5% serum and 400 ppm hard water by the AOAC use dilution test and found to be effective against a broad spectrum of gram negative and gram positive organisms as represented by:

Pseudomonas aeruginosa
Staphylococcus aureus
Salmonella choleraesuis
Escherichia coli
Streptococcus pyogenes
Klebsiella pneumoniae
Enterobacter aerogenes
Salmonella schottmuelleri
Streptococcus faecalis
Shigella dysenteriae
Brevibacterium ammoniagenes
Salmonella typhi
Serratia marcescens
Pseudomonas cepacia

Non-Acid Toilet Bowl Disinfectant/Cleaner Application

1. Add 0.5 oz. to the bowl (0.75 gallon) and mix. Brush over exposed surfaces, allow to stand for 10 minutes and flush.
2. Empty toilet bowl or urinal and apply a 0.5 oz./gal. use-solution to exposed surfaces with a cloth, mop, sponge or mechanical spray.

"VIRUCIDAL PERFORMANCE"

At 0.5 oz. per gallon use-level, LONZA FORMULATION R-82 was evaluated in the presence of 5% serum and 400 ppm hard water for a contact time of 10 minutes at room temperature (20-25°C) against the following viruses found on inanimate hard non-porous environmental surfaces:

HIV-1 (AIDS virus)
Influenza A/Brazil
Herpes Simplex Types 1 and 2
Vaccinia

*KILLS HIV 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 human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

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

"CONTACT TIME: Leave surface wet for 10 minutes with 0.5 oz. per gallon use-solution."

CLEANING PROCEDURE: Blood and other body fluids containing HIV must be thoroughly cleaned from surfaces and objects before application of LONZA FORMULATION R-82.

PERSONAL PROTECTION: Clean-up should always be done wearing protective latex gloves, gowns, masks and eye protection.

DISPOSAL OF INFECTIOUS MATERIAL: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

Fungicidal Performance —

LONZA FORMULATION R-82 is an effective fungicide against Trichophyton mentagrophytes (the athlete's foot fungus) when used on surfaces in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities at 0.5 oz./gallon.

Mold and Mildew Control. At 0.5 oz./gallon, LONZA FORMULATION R-82 will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, non-porous surfaces (as indicated in general instructions above). Allow to dry on surface and repeat when mildew growth returns.

Sanitizing-Non-Food Contact Surfaces (such as floors, walls, tables, etc.). At 0.5 oz. per 5.5 gallon use-level, LONZA FORMULATION R-82 is an effective sanitizer against *Staphylococcus aureus* and *Klebsiella pneumoniae* on hard porous and non-porous environmental surfaces. Treated surfaces must remain wet for 60 seconds.

PELIGRO:

SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.

10/90

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