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

FEB - 6 1989

Attention: Debra L. Rogler

Gentlemen:

Subject: Lonza Formulation R-82  
EPA Registration No. 6836-78  
Your Amended Application Dated March 22, 1988

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling.
  - a. Refer to the enclosed Efficacy Evaluation and Technical Efficacy Review - II, and revise your labeling in accordance with the labeling comments outlined there.
  - b. Refer to the enclosed document "Label Requirements for Antimicrobial Pesticides Used on Hard Surfaces Against HIV-1 (AIDS Virus)" for EPA's current labeling policy for efficacy claims. Your labeling must be revised in accordance with the requirements outlined in this policy notice.
  - c. Delete the word "milk."
  - d. Delete the statement "Measures against . . . convulsion may be needed."
  - e. Delete the statement "For Sale For Use And Storage By Maintenance Personnel Only."
2. Submit five (5) copies of your final printed labeling before you release the product for shipment.

54701:J:Leavy:LL-07:KENDCO:12/20/88:02/03/89:aw:VO:IX:AS

CONCURRENCES

SYMBOL								
SURNAME								
DATE								


6036-73

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Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

Sincerely yours,

John H. Lee   
Product Manager (31)  
Antimicrobial Program Branch  
Registration Division (TS-767C)

Enclosures

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, viruses (including HIV), fungi 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 food contact as well as 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

**Hazard:** 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 disposal.
- Do not store on side.
- Avoid creasing or impacting of side walls.

#### PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray or mixture of 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.

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.

## 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  $\text{CaCO}_3$ ) in the presence of 5% serum contamination

### Active Ingredients

Octyl decyl dimethyl ammonium chloride  
Dioctyl dimethyl ammonium chloride  
Didecyl dimethyl ammonium chloride  
Alkyl ( $\text{C}_{14}$ , 50%;  $\text{C}_{12}$ , 40%;  $\text{C}_{10}$ , 10%)  
dimethyl benzyl ammonium chloride

8.510  
3.064  
3.506  
8.680

### Inert Ingredients

78.300  
100.000

KEEP OUT OF REACH OF CHILDREN

## DANGER

### 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 milk, egg whites, gastric 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. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

### SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration No.

6836-1

EPA Establishment No.

6836-N

Net Contents

MANUFACTURED BY:

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

For Sale For Use And Storage By  
Maintenance Personnel Only

## 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 (nonporous) non-porous surfaces such as tables, chairs, countertops, sinks, tile, porcelain, and bedframes 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:

<i>Pseudomonas aeruginosa</i>	<i>Salmonella schottmulleri</i>
<i>Staphylococcus aureus</i>	<i>Streptococcus faecalis</i>
<i>Salmonella choleraesuis</i>	<i>Shigella dysenteriae</i>
<i>Escherichia coli</i>	<i>Streptococcus amnigenus</i>
<i>Streptococcus pyogenes</i>	<i>Salmonella typhi</i>
<i>Mycobacteria pneumoniae</i>	<i>Serratia marcescens</i>
<i>Enterobacter aerogenes</i>	<i>Pseudomonas cepacia</i>

**\*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 against the following viruses found on inanimate hard non-porous environmental surfaces:

HIV	Herpes Simplex Types 1 and 2
Influenza A/Brazil	Vaccinia

### Fungicidal Performance --

LONZA FORMULATION R-82 is an effective fungicide against *Dichaplyon monoglyphus* (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 Food Contact Surfaces.** At 0.5 oz. per 5.1 gallons water use LONZA FORMULATION R-82 for sanitizing and cleaning of equipment and utensils in food processing, dairy industry, bars, restaurants, institutional kitchens, meat and poultry processing plants and farms. Do not rinse with water. For heavily soiled equipment or utensils, pre-wash with Formulation R-82. Rinse with clean water, then apply recommended dilution of Formulation R-82 with a cloth, mechanical spray device (spray surface until thoroughly wetted) or immersion. Treated surfaces must remain wet for 1 minute. Prepare a fresh solution for every use. DO NOT reuse mechanically applied use solution for sanitizing.

Formulation R-82 can be used in accordance with the U.S. Public Health Service food service sanitation recommendation.

**Sanitizing Non-Food Contact Surfaces** (such as floors, walls, tables, etc.) At 0.5 oz. per 5.1 gallons use-level LONZA FORMULATION R-82 is an effective sanitizer against *Staphylococcus aureus* and *Mycobacteria pneumoniae* on hard porous and non-porous environmental surfaces. Treated surfaces must remain wet for 60 seconds.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

FEB - 6 1989

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

6836-78