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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 3 - 1995

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

Attention: Eliot I. Harrison
 Agent for Lonza

Subject: Lonza Formulation 70-12
 EPA Registration No. 6836-33
 MOU Compliance Amendment dated January 25, 1994

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, will be acceptable provided that you make the changes listed below before you release the product for shipment bearing the amended label.

1. Specify the strain of Influenza A₂.
2. Revise Herpes Simplex Types I and II to read Herpes Simplex Types 1 and 2.

A stamped copy of your labeling is enclosed for your records. Submit five (5) copies of the final printed label prior to release of the product for shipment.

If you have any questions concerning this letter, please contact Wanda Mitchell at (703) 305-6141.

Sincerely,

Marion J. Johnson, Jr.
 Product Manager (31)
 Antimicrobial Program Branch
 Registration Division (7505C)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

Cross-contamination is of major housekeeping concern not only in hospitals, but in schools, institutions and industry. LONZA FORMULATION 70-12 is formulated for this problem area. It both cleans and disinfects effectively and is virucidal when used as directed. Its hard surface disinfecting action will reduce the hazard of cross-contamination from environmental surfaces.

When used as directed, LONZA FORMULATION 70-12 will deodorize surfaces in toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas and will inhibit the growth of mold and mildew and their odors when used as directed.

**PRECAUTIONARY STATEMENTS
HAZARDOUS 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. Avoid contamination of food.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

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). The 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 one gallon or less, use this container disposal statement.)

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

**LONZA
FORMULATION 70-12**

Highly Concentrated Germicide
Based on a Unique Blend of Quaternaries
with Organic Soil Load Tolerance
Disinfectant-Cleaner-Sanitizer-Fungicide
Mildewstat-Virucide*-Deodorizer for Hospitals
Institutional and Industrial Use

Active Ingredients

Octyl decyl dimethyl ammonium chloride	3.750%
Dioctyl dimethyl ammonium chloride	1.500%
Didecyl dimethyl ammonium chloride	2.250%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	5.000%

Inert Ingredients

87.500%
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 milk, 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. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration No. 6836-33
EPA Establishment No. 6836-IL-1
Net Contents

Manufactured by:
LONZA INC., 17-17 Route 208, Fair Lawn, NJ 07410

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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

6836-33

DIRECTIONS FOR USE

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

LONZA FORMULATION 70-12 is a proven "one-step" cleaner-disinfectant-sanitizer-fungicide-virucide in the presence of moderate amounts of organic soil

Apply LONZA FORMULATION 70-12 to walls, floors and other hard (inanimate) non-porous surfaces such as tables, chairs, countertops, sinks 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 1/2 oz. per gallon of water. Treated surfaces must remain wet for 10 minutes. At this use-level, LONZA FORMULATION 70-12 is also virucidal and fungicidal.

SANITIZING-To sanitize porous or non-porous, non-food contact surfaces, add 1/4 oz. per gallon of water.

1/2 oz. per gallon use-level. The broad spectrum activity of LONZA FORMULATION 70-12 has been evaluated in the presence of 5% serum and found to be effective against the following by the AOAC Use-Dilution test:

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

Non-Acid Toilet Bowl Disinfectant/Cleaner Application.

1. Add 0.5 oz. to the toilet bowl (0.75 gallons) and mix. Brush thoroughly over exposed surfaces and under the rim, 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 and under the rim with a cloth, mop, sponge or mechanical spray.

MOISTURE FUNGICIDAL TEST

LONZA FORMULATION 70-12 is effective against Trichophyton mentagrophytes (the athlete's foot fungus) when used on surfaces in areas such as locker rooms, showers and bath areas, exercise areas, dressing rooms, etc.

MILDEWSTATIC PERFORMANCE. At 1/2 oz./gallon, LONZA FORMULATION 70-12 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

VIRUCIDAL PERFORMANCE.

*At 1/2 oz. per gallon use-level, LONZA FORMULATION 70-12 was evaluated in the presence of 5% serum and found to be effective against the following viruses: Influenza A₂, Herpes Simplex Types I and II, HIV-1 (AIDS virus) and Vaccinia on inanimate hard, non-porous environmental surfaces.

SANITIZING NON-FOOD CONTACT SURFACES (such as floors, walls, tables, etc.) At 1/3 oz. per 2 gallon use-level, 30 second contact time, LONZA FORMULATION 70-12 is an effective sanitizing agent in waters of up to 600 ppm hardness against Staphylococcus aureus and Klebsiella pneumoniae in the presence of 5% serum on porous and non-porous environmental surfaces.

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, 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. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

***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 1/2 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 70-12.

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.

PELIGRO

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

9/26/91