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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 21 1995

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

Attention: Eliot I. Harrison  
Agent for Lonza

Subject: Lonza Disinfectant Cleaner 30-3  
EPA Registration No. 6836-22  
MOU Compliance Amendment dated January 25, 1995

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 labeling changes listed below before you release the product for shipment bearing the amended label.

1. Remove the statement "For Sale For Use and Storage By Maintenance Personnel Only."
2. Under the heading "DIRECTIONS FOR USE", remove the wording "General Classification".
3. Under the heading "AOAC Fungicidal Test" provide the use dilution for fungicidal action.
4. Under the "Virucidal" heading, specify whether the Herpes simplex is Type 1 or Type 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

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Cross contamination is of major housekeeping concern not only in hospitals, but in schools, institutions and industry. LONZA DISINFECTANT-CLEANER 30-3 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. Also, this product will inhibit the growth of mold and mildew and their odors when used as directed.

Precautionary Statements

Hazards to Humans and domestic animals

**WARNING**

Keep out of reach of children. May cause severe eye irritation or eye damage. Causes skin irritation. Do not get in eyes, on skin, or on clothing. Harmful 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 OR DISPOSAL
- OPEN DUMPING IS PROHIBITED
- DO NOT REUSE EMPTY CONTAINER

**PESTICIDE DISPOSAL**

PESTICIDE OR RINSATE THAT CANNOT BE USED OR CHEMICALLY REPROCESSED SHOULD BE DISPOSED OF IN A LANDFILL APPROVED FOR PESTICIDES OR BURIED IN A SAFE PLACE AWAY FROM WATER SUPPLIES.

**CONTAINER DISPOSAL**

TRIPLE RINSE (OR EQUIVALENT) AND DISPOSE IN AN INCINERATOR OR LANDFILL APPROVED FOR PESTICIDE CONTAINERS, OR BURY IN A SAFE PLACE.

**GENERAL**

CONSULT FEDERAL, STATE OR LOCAL DISPOSAL AUTHORITIES FOR APPROVED ALTERNATIVE PROCEDURES SUCH AS LIMITED OPEN BURNING.

**LONZA  
DISINFECTANT CLEANER (30-3)**

Disinfectant-Cleaner-Sanitizer-Fungicide  
Mildewstat-Virucide\* -Deodorizer  
with Organic Soil Tolerance for  
Hospital, Institutional and Industrial Use

Active Ingredient

Didecyl dimethyl ammonium chloride 4.25%

Inert Ingredients

95.75%  
100.00%

KEEP OUT OF REACH OF CHILDREN

**WARNING**

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.

SEE LEFT PANEL FOR  
ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration No.

6836-22

EPA Establishment No.

6836-IL-1

Net Contents

MANUFACTURED BY:  
LONZA INC., 17-17 Route 208, Fair Lawn, NJ 07410

For Sale For Use and Storage  
By Maintenance Personnel Only

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

JUN 21 1995

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

6836-22

**DIRECTIONS FOR USE**  
**GENERAL CLASSIFICATION**

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

LONZA DISINFECTANT CLEANER 30-3 is a proven "one-step" cleaner-disinfectant-sanitizer-fungicide-virucide-mildewstat in the presence of moderate amounts of organic soil.

Apply LONZA DISINFECTANT CLEANER 30-3 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 becomes visibly dirty.

**Disinfection** - to disinfect hard, non-porous surfaces, add 2.5 oz. per gallon of water. Treated surfaces must remain wet for 10 minutes. At this use-level, LONZA DISINFECTANT CLEANER 30-3 is also virucidal, fungicidal and mildewstatic.

**Sanitizing** - To sanitize porous and non-porous non-food contact surfaces, add 0.5 oz. per gallon of water. Treated surfaces must remain wet for 60 seconds.

**2.5 oz. per gallon use-level.**

The broad spectrum activity of LONZA DISINFECTANT CLEANER 30-3 has been evaluated in the presence of 5% serum and found to be effective against the following organisms by the AOAC Use-Dilution test.

- Pseudomonas aeruginosa
- Staphylococcus aureus
- Salmonella choleraesuis
- Escherichia coli
- Streptococcus pyogenes
- Proteus mirabilis
- Klebsiella pneumoniae
- Enterobacter aerogenes
- Streptococcus faecalis
- Shigella dysenteriae
- B: vibacterium ammoniagenes

**AOAC Fungicidal Test**

LONZA DISINFECTANT CLEANER 30-3 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, etc.

**Mold and Mildew Control:** At 2.5 oz. per gallon, LONZA DISINFECTANT CLEANER 30-3 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 2 oz. per gallon use-level, LONZA DISINFECTANT CLEANER 30-3 was evaluated in the presence of 10% serum and found to be effective against the following viruses: Herpes Simplex (a member of the virus family that causes infectious mononucleosis), Vaccinia (representative of the pox viruses), Adenovirus Type 5 (a causative virus in respiratory diseases), and Influenza A<sub>2</sub> as represented by the strains commonly called the Hong Kong Flu and the London Flu Virus, on inanimate environmental surfaces.

**Sanitizing-Non-Food Contact Surfaces (such as floor, walls, tables, etc.)** At 1/2 oz. per gallon use-level, LONZA DISINFECTANT CLEANER 30-3 is an effective sanitizer in waters up to 1000 ppm hardness against Staphylococcus aureus and Klebsiella pneumoniae in the presence of 5% serum on hard 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.