

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 19-A
EPA Registration No. 6836-28
MOU Compliance Amendment dated January 25, 1995

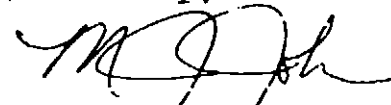
The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, will be acceptable provided that you make the labeling changes listed below before you release the product for shipment bearing the amended label.

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)

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CONCURRENCES

SYMBOL								
SURNAME								
DATE								

Cross contamination is of major housekeeping concern not only in hospitals, but in schools, institutions and industry. LONZA DISINFECTANT-CLEANER 19-a 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.

LONZA DISINFECTANT-CLEANER 19-a is an extremely effective one-step sanitizer for non-food contact surfaces. It cleans and sanitizes in waters up to 850 ppm hardness. This hard water tolerance is in excess of most potable waters and will insure complete sanitizing action when used as directed.

Two ounces of LONZA DISINFECTANT-CLEANER 19-a per gallon of water will deodorize surfaces in bathrooms, garbage storage areas, and other areas where bacterial growth can cause mal odors. This product will inhibit the growth of mold and mildew and their odors.

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

THIS PRODUCT MUST BE KEPT UNDER LOCKED STORAGE SUFFICIENT TO MAKE IT INACCESSIBLE TO CHILDREN OR PERSONS UNFAMILIAR WITH ITS PROPER USE.

- DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL
- OPEN DUMPING IS PROHIBITED
- DO NOT REUSE EMPTY CONTAINER

PESTICIDE DISPOSAL

PESTICIDE, SPRAY MIXTURE 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.

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 28

LONZA DISINFECTANT CLEANER (19-a)

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

Active Ingredient

Didecyl dimethyl ammonium chloride 4.5%

Inert Ingredients

95.5%
100.0%

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.

6836-28

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

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 19-a is a proven "one-step" cleaner-disinfectant-sanitizer-fungicide-virucide-mildewstat in the presence of moderate amounts of organic soil.

Apply LONZA DISINFECTANT CLEANER 19-a 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 hospital surfaces, 2 1/2 oz. per gallon of water. Treated surfaces must remain wet for 10 minutes. At this use-level, LONZA DISINFECTANT CLEANER 19-a is also virucidal and fungicidal. At 1 1/4 oz. per gallon, LONZA DISINFECTANT CLEANER 19-a will disinfect hard non-porous surfaces in schools, industry and non-medical institutions.

Sanitizing - To sanitize porous and non-porous, non-food contact surfaces, add 1 oz. per 2 1/4 gallon of water. Treated surfaces must remain wet for 30 seconds.

Hospitals and nursing homes, add 2.5 oz. per gallon of water. The broad spectrum activity of LONZA DISINFECTANT CLEANER 19-a 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
- Brevibacterium ammoniagenes

AOAC Fungicidal Test

LONZA DISINFECTANT CLEANER 19-a is an effective fungicide against phyton 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 1 1/4 oz. per gallon, LONZA DISINFECTANT CLEANER 19-a 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 19-a 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 A₂ as represented by the strains commonly called the Hong Kong Flu and the London Flu Virus, on inanimate environmental surfaces.

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For schools, non-medical institutional and industrial areas: At 1/4 oz. per gallon of water, LONZA DISINFECTANT CLEANER 19-a delivers excellent cleaning and germicidal effectiveness. It is effective against Staphylococcus aureus, Salmonella choleraesuis and Escherichia coli. The same AOAC tests used above to confirm suitable performance for hospitals were used.

Sanitizing-Non-Food Contact Surfaces (such as floor, walls, tables, etc.). At 1 oz./2 1/4 gallon use-level, LONZA DISINFECTANT CLEANER 19-a is an effective sanitizer in waters up to 850 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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