

6836-28

03-01-2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR - 1 2004

Mr. Robert Sloan
Sr. Regulatory Services Associate
Lonza Inc.
17-17 Route 208
Fair Lawn, NJ 07410

Subject: **Lonza Disinfectant Cleaner (19a)**
EPA Registration Number 6836-28
Application / letter Dated December 30, 2003
EPA Received Date December 30, 2003

Dear Mr. Sloan:

The following amendment, submitted in connection with registration the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

Proposed Amendment:

- revise labeling per EPA letter dated 11/14/03

General Comments:

A stamped copy of the labeling accepted with conditions is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland on (703) 308-6224.

Sincerely,


Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosure Stamped Label

		CONCURRENCES						
SYMBOL								
SURNAME								
DATE								

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, safety glasses or face shield), protective clothing and protective gloves (rubber or chemical resistant). Harmful if swallowed or absorbed through the skin. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

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

(Note to reviewer: If container size is 5 gallons or larger, the following Environmental Hazards statements will be used.)

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.

**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%
Other Ingredients.....	95.5%
Total:.....	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

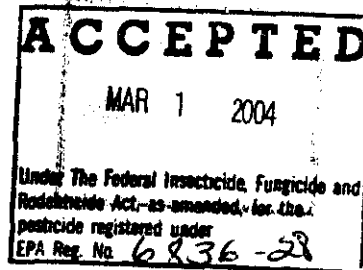
See (left) (right) (back) (side) panel for Precautionary Statements and First Aid.

EPA Registration No.6836-28

EPA Est. No. *(insert EPA Establishment number here)*

Net Contents *(insert container size here)*

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



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 nonporous surface disinfecting action will reduce the hazard of cross-contamination.

LONZA DISINFECTANT-CLEANER 19-a is an 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 malodors.

This product will inhibit the growth of mold and mildew and their odors.

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.

At 2½ 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. The same AOAC tests confirm suitable performance for hospitals.

- 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

At 2½ oz. per gallon, **LONZA DISINFECTANT CLEANER 19-a** 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. Follow Hospital disinfection directions.

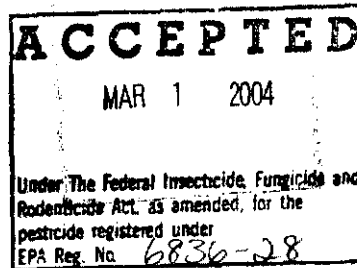
Virucidal Performance*

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:

- Adenovirus Type 5 (a causative virus in respiratory diseases)
- Herpes Simplex Type 1 (a member of the virus family that causes infectious mononucleosis)
- Vaccinia (representative of the pox viruses)
- Influenza A₂ (as represented by the strains commonly called the Hong Kong Flu and the London Flu Virus)

At 1¼ oz. per gallon, **LONZA DISINFECTANT CLEANER 19-a** will disinfect hard nonporous surfaces in schools, industry and non-medical institutions.

At 1¼ oz. per gallon of water, **LONZA DISINFECTANT CLEANER 19-a** delivers excellent cleaning and germicidal effectiveness. It is effective against Escherichia coli, Salmonella choleraesuis, Staphylococcus aureus



DIRECTIONS FOR USE

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

For Disinfection in hospitals, nursing homes, and other medical institutions: Use 2½ oz. per gallon of water. At this use-level, **LONZA DISINFECTANT CLEANER 19-a** is also virucidal and fungicidal.

For Disinfection in schools, offices, and non-medical, commercial and industrial areas: Use 1¼ oz. per gallon of water,

Apply **LONZA DISINFECTANT CLEANER 19-a** to walls, floors and other hard nonporous surfaces such as tables, chairs, countertops, sinks and bed frames with a cloth, mop or coarse (mechanical) spray device so as to thoroughly wet surfaces. Treated surfaces must remain wet for 10 minutes. Wipe dry with a clean cloth or sponge or allow to air dry.

Rinse all surfaces that come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes as a disinfectant.

For heavily soiled areas, a preliminary cleaning is required.

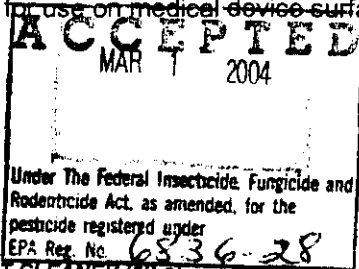
Prepare a fresh solution daily or when use becomes visibly dirty.

(Note to reviewer: For products used on medical devices, only one of the following two statements will be used:)

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. (Optional sentence: This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.)

or

This product is not for use on medical device surfaces.



LONZA DISINFECTANT CLEANER (19-a)
EPA REG. NO. 6836-028
EPA DRAFT LABEL 12-30-03

Mold and Mildew Control: At 1¼ 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, nonporous surfaces. Follow Disinfection Directions. Allow to dry on surface and repeat weekly (every 7 days) or more often if mildew growth returns.

Sanitizing-Non-Food Contact Surfaces (such as floor, walls, tables, etc.).

At 1 oz. per 2¼ gallon use-level, **LONZA DISINFECTANT CLEANER 19-a** is an effective sanitizer in waters up to 850 ppm hardness surfaces, against *Staphylococcus aureus* and *Klebsiella pneumoniae* in the presence of 5% serum on hard porous and non-porous non-food contact environmental surfaces. Apply use solution with a cloth, mop or coarse (mechanical) spray device so as to thoroughly wet surfaces. Treated surfaces must remain wet for 30 seconds. Wipe dry with a clean cloth or sponge or allow to air dry.

(If container size is 1 gallon or less, the following storage and disposal statements will be used:)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not reuse empty container. Discard in trash or recycle.

(If container size is greater than gallon, the following storage and disposal statements will be used:)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage

Do not store on side. Avoid creasing or impacting of side walls. Open dumping is prohibited.

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

(Plastic containers): 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 way of smoke.

(Metal Containers:) 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.