

6836-27

03-01-2004

14

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 47-5**
EPA Registration Number 6836-27
Application / letter Dated December 29, 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							

2/4

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. CORROSIVE. Causes irreversible eye and damage and skin burns. Do not get in eyes, on skin or on clothing. Wear chemical goggles, protective clothing and rubber gloves. Harmful if swallowed or absorbed through the skin. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. 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 greater, 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 (47-5)**

Disinfectant - Cleaner - Sanitizer -
Fungicide - Mildewstat - Virucide* - Deodorizer
with Organic Soil Tolerance for
Schools, Industry and Non-Medical Institutions

Active Ingredients:	
Didecyl dimethyl ammonium chloride.....	2.5%
Other Ingredients:.....	97.5%
Total	100.0%

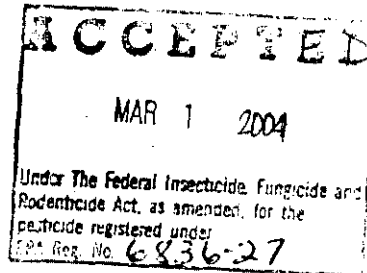
KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Reg. No. 6836-27
EPA Est. No. *(insert EPA Establishment No. here)*
Net Contents: *(insert container size here)*

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



LONZA DISINFECTANT CLEANER 47-5 is a disinfectant / cleaner that is especially designed for schools, homes, non-medical institutions and industry. A single application removes moderate amounts of dirt and grime, disinfects and is virucidal. When used as directed, the hard nonporous surface disinfecting action of LONZA DISINFECTANT CLEANER 47-5 will reduce the hazard of cross-contamination.

LONZA DISINFECTANT CLEANER 47-5 is an effective one-step sanitizer for non-food contact surfaces. It cleans and sanitizes in waters up to 550 ppm hardness. This hard water tolerance is in excess of most potable waters and will insure complete sanitizing action when used as directed.

LONZA DISINFECTANT CLEANER 47-5 cleans, deodorizes, disinfects, kills common household germs such as Staphylococcus aureus, Salmonella choleraesuis, kills Trichophyton mentagrophytes, (the fungus causing athlete's foot), and is virucidal* against Herpes Simplex Type I, Vaccinia Virus, Influenza A₂ (the Hong Kong Flu and the London Flu viruses) on inanimate, environmental surfaces. Prevents the growth of odor causing bacteria.

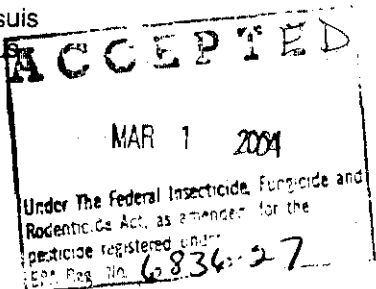
When used as directed LONZA DISINFECTANT CLEANER 47-5 will deodorize surfaces in toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause mal odors.

This product will inhibit the growth of mold and mildew and their odors when used as directed.

LONZA DISINFECTANT CLEANER 47-5 is a proven one-step cleaner-disinfectant-sanitizer-fungicide-virucide-mildewstat in the presence of moderate amounts of organic soil.

The broad spectrum of LONZA DISINFECTANT CLEANER 47-5 has been evaluated at 2 1/2 oz. (1/3 cup) per gallon use-level in the presence of 5% serum and found to effective against the following organisms by the AOAC Use-Dilution Test:

- Escherichia coli
- Salmonella choleraesuis
- Staphylococcus aureus



LONZA DISINFECTANT CLEANER (47-5)
EPA REG. NO. 6836-27
EPA DRAFT LABEL 12-29-03

VIRUCIDAL PERFORMANCE*

At 2 oz. (1/4 cup) per gallon use-level, LONZA DISINFECTANT CLEANER 47-5 was evaluated in the presence of 10% serum and found to be effective on inanimate, environmental surfaces against the following viruses:

- Herpes Simplex (a member of the virus family that causes infectious mononucleosis),
- Influenza A₂ (the Hong Kong Flu and the London Flu Viruses)
- Vaccinia (representative of the pox viruses),

AOAC FUNGICIDAL TEST

LONZA DISINFECTANT CLEANER 47-5 is effective against Trichophyton mentagrophytes (the athlete's foot fungus) when used on surfaces in areas such as locker rooms, shower and bath areas, exercise areas, dressing rooms, etc.

DIRECTIONS FOR USE

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

Apply LONZA DISINFECTANT CLEANER 47-5 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. For heavily soiled areas, a preliminary cleaning is required.

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.

Prepare a fresh solution daily or when use-solution becomes diluted or soiled.

DISINFECTION / VIRUCIDAL / FUNGICIDAL DIRECTIONS:

To disinfect hard, nonporous surfaces, add 2 1/2 oz. (1/3 cup) per gallon of water. Treated surfaces must remain wet for 10 minutes. Wipe dry with a clean cloth or sponge or allow to air dry. At this use-level, LONZA DISINFECTANT CLEANER 47-5 is also virucidal and fungicidal.

FLOORS, WALLS

To clean and disinfect floors, walls, and other hard surfaces, use 2 1/2 oz. (1/3 cup) to a gallon of water. Mop or wipe thoroughly. Allow surfaces to remain wet for 10 minutes. Allow to air dry or wipe excess liquid with cloth or sponge.

KITCHEN AREAS

Use 2½ oz. (1/3 cup) to a gallon of water to clean glazed porcelain surfaces, sinks, drain boards, stoves and refrigerator exteriors. Allow surfaces to remain wet for 10 minutes. Allow to air dry or wipe excess liquid with cloth or sponge. Rinse all food contact surfaces thoroughly with potable water before reuse. Pour 4 oz. (½ cup) down sink to cut grease and deodorize.

Do not use on glasses, utensils or dishes.

BATHROOM

To deodorize tub and glazed tiles and behind sinks and storage areas, use 2½ oz. (1/3 cup) per gallon of water. Use 2½ oz. (1/3 cup) per gallon of water to disinfect exterior bowl surfaces. Allow surfaces to remain wet for 10 minutes. Allow to air dry or wipe excess liquid with cloth or sponge.

EXTRA TOUGH JOBS

Use full strength. Wear rubber gloves to protect skin.

MOLD AND MILDEW CONTROL

At 2½ oz. (1/3 cup) per gallon, LONZA DISINFECTANT CLEANER 47-5 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 every 7 days or more often if mildew growth returns.

SANITIZING NON-FOOD CONTACT SURFACES

(such as floors, walls, tables)

At ¾ oz. per gallon of water, LONZA DISINFECTANT CLEANER 47-5 is an effective sanitizing agent against *Staphylococcus aureus* and *Klebsiella pneumoniae* in the presence of 5% serum on hard, porous and non-porous non-food contact, environmental surfaces. Apply with a mop, cloth or coarse mechanical sprayer so as to thoroughly wet surfaces. Treated surfaces must remain wet for 30 seconds. Wipe dry with cloth, sponge or mop or allow surfaces 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.

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.

