

PM 31

6836-86

8-31-99

1 of 6

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 31 1999

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

Subject: Lonza DC-101  
EPA Registration No. 6836-86  
Your Amendment Dated: 6/3/99  
EPA Received Date: 6/8/99

Attention: Ms. Ruth Trager

The amendment referenced above, submitted in connection with registration under FIFRA, as amended, to update your label will be acceptable provided you address the following label recommendations before you release the product for shipment.

Page 2:

1. If you want to support a disinfection claim for food contact surfaces in restaurants and food service establishments, you must recommend using a potable rinse on specific food contact surfaces such as "countertops, tables, picnic tables, appliances, and/or stovetops." Also, a disclaimer statement should be added to the label: "This product must not be used to clean the following food contact surfaces: utensils, glassware, and dishes."
2. The surface, "ceramic", needs to be qualified as hard, non-porous by stating "glazed ceramic".
3. According to the 2<sup>nd</sup> paragraph, this product is fungicidal; however, there are no other references on this label as to the specific fungi mitigated. If this product is supporting fungicidal claims, the label should include the appropriate areas of disinfection as well as the fungi scientific name according to Labeling Guidelines for Pesticide Use Directions for Antimicrobial Products, section 101-3 p.28. Alternatively, you can delete the reference to this product being "fungicidal".

CONCURRENCES

SYMBOL	Campbell						
SURNAME	7500						
DATE	AUG 31 1999						

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The "Directions for Use" for sanitizing non-food contact surfaces should be revised to "incorporate the sites and surfaces where this product is to used." Also, directions must indicate if and how the product is to be removed from the surfaces(s) after the recommended contact time. (See Attachment - DSS-TSS 15).

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- 1. The heading, "Cleaner/Deodorizer directions", should be placed on the label preceding its directions (3<sup>rd</sup> paragraph).
- 2. Under the HIV direction's Contact Time, you will need to clarify if the contact time is different for the 4 oz per gallon use-solution than the 3 oz per gallon. If it is not, you do not to specify the use-solution.

If your label changes are handled through word processing, you should go ahead and address the following comments in addition to the above comments. Please submit a revised label for the Agency's review. However, if you are in the process of printing labels, you will need to submit a label amendment addressing these comments prior to your next label printing.

- 1. The use sites, industry and institutions, needs to either be clarified or deleted.
- 2. Specific use directions will need to be developed for food processing plants. You must list specific non-food contact sites and surfaces for disinfection. You will also need to add the disclaimer statement: Do not use on food contact/processing surfaces or state "Before using this product, food products and packaging materials must be removed from the room or carefully protected. After use, all surfaces in the area must be thoroughly rinsed with potable water."

A stamped copy of the label is enclosed for your records. You should submit one (1) copy of the final printed label prior to the release of the product for shipment. If you have any questions regarding this letter, please contact Jacqueline Campbell at (703) 308-6416.

Sincerely,



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

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

AUG 31 1999

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 6836-86

**LONZA DC-101**

**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 goggles or face shield and rubber gloves when handling. Do not breathe spray mist. Harmful or fatal if swallowed. Avoid contamination of food. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

**STATEMENT OF PRACTICAL TREATMENT (FIRST AID)**

**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention.

**IF SWALLOWED:** Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

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

*(If container size is five gallons or greater, use the following Environmental Hazards statements):*

**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.

*(If container size is one gallon or less, use the following Storage and Disposal statements):*

**STORAGE AND DISPOSAL**

Store in original container in areas inaccessible to children. Do not reuse empty container. Securely wrap original container in several layers of newspaper and discard in trash or recycle.

*(If container size is greater than one gallon, use the following Storage and Disposal statements):*

**STORAGE AND DISPOSAL**

**PESTICIDE STORAGE:** Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Store in original container in areas inaccessible to children. Do not reuse empty container.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or 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:**

*(Metal containers)* Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose in a sanitary landfill, or by other procedures approved by state and local authorities.

*(Plastic containers)* Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

One-Step Acid Cleaner, Disinfectant, Virucide\*, Sanitizer, Mildewstat,  
Deodorizer With Organic Soil tolerance  
Plus Disinfectant Hard Water Tolerance  
at 3 oz. per gallon (250 ppm calculated as CaCO<sub>3</sub>)  
and  
at 4 oz. per gallon (400 ppm calculated as CaCO<sub>3</sub>)  
for Hospital, Institutional, Industrial Use

\*Virucidal against HIV-1 (AIDS Virus) and Herpes Simplex Types 1&2

Effective against Pseudomonas aeruginosa (Pseudomonas),  
Staphylococcus aureus (Staph) and Streptococcus pyogenes (Strep)

Removes Hard Water Deposits and Lime Soap Buildups  
Heavy Duty Bathroom Cleaner, Mildewstat, and Deodorizer  
Quickly removes soap scum from shower tile, fiberglass, chrome and  
glass, toilet bowls, sinks, tubs & spas.

**Active Ingredients:**

Octyl decyl dimethyl ammonium chloride.....	0.75%
Diocetyl dimethyl ammonium chloride .....	0.30%
Didecyl dimethyl ammonium chloride.....	0.45%
Alkyl (C <sub>14</sub> 50%, C <sub>12</sub> 40%, C <sub>16</sub> 10%) dimethyl benzyl ammonium chloride.....	1.00%
Inert Ingredients.....	97.50%
Total .....	100.00%

**KEEP OUT OF REACH OF CHILDREN  
DANGER PELIGRO**

See (left)(back)(right)(side) panel for additional  
precautionary statements

EPA Reg. No. 6836-86

EPA Est. No. (insert EPA Est. No. here)

Net Contents (as indicated on container)

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

3046

Cross-contamination is of major housekeeping concern not only in hospitals, but in schools, institutions, and industry. **LONZA DC-101** has been formulated to aid in the reduction of cross-contamination in these areas.

**LONZA DC-101** is a one-step disinfectant cleaner that is effective against a broad spectrum of bacteria, is virucidal\* (including HIV-1), fungicidal, and inhibits the growth of mold and mildew and their odors when used as directed.

**LONZA DC-101** is an effective one-step sanitizer-cleaner for use on non-food contact surfaces.

When used as directed, **LONZA DC-101** 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.

**LONZA DC-101** will remove hard water deposits and limestone buildups when used as directed.

**LONZA DC-101** is recommended for use in hospitals, medical and dental offices, nursing homes, public rest rooms, institutions, schools, athletic facilities, food processing plants, food storage areas, kitchens, restaurants and bars, transportation terminals, hotels and motels. For use in households.

**LONZA DC-101** is a mild acid pH disinfectant cleaner that disinfects, cleans and deodorizes in one labor-saving step. **LONZA DC-101** is a concentrate that can be used with a mop and bucket, trigger sprayers, sponge, or by soaking.

**LONZA DC-101** provides effective cleaning strength in removing difficult to clean soap scum, and hard water deposits.

**LONZA DC-101** improves labor results by effectively controlling odors.

**LONZA DC-101** Cleans, shines, deodorizes and disinfects all nonporous household surfaces. Inhibits the growth of mold and mildew, leaving bathrooms & kitchens clean and smelling fresh.

**LONZA DC-101** is recommended for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures, and toilet bowls.

**LONZA DC-101** is for use in kitchens, bathrooms and other household areas.

**LONZA DC-101** may be applied to bathtubs, shower stalls, sinks, urinals, toilet bowls, toilet bowl surfaces, related fixtures, walls, floors and other hard (inanimate) nonporous surfaces (such as metal, stainless steel, glazed porcelain, ceramic, and plastic).

**LONZA DC-101** kills household germs in ten minutes; effective against harmful *Pseudomonas aeruginosa* (pseudomonas), *Staphylococcus aureus* (staph) and *Streptococcus pyogenes* (strep), while effectively controlling mold and mildew.

**LONZA DC-101** is formulated to dissolve soap scum, corrosion and hard water deposits without scouring. Spray on - it clings and works on shower walls, glass doors, chrome, stainless steel and fiberglass, while you enjoy the fresh clean deodorizing fragrance.

**LONZA DC-101** has been used to clean hard, nonporous inanimate surfaces for over 10 years. Proven effective on all of the toughest bathroom problems.

**LONZA DC-101** penetrates and dissolves soap scum, ground-in dirt and grime, mineral deposits, and hard water stains, and kills household germs. Cleans and shines without abrasive scouring action. Deodorizes too! Leaving your bathroom smelling minty fresh.

**WHERE TO USE:** All bathroom tile, fiberglass, shower walls and doors, tubs and sinks, chrome fixtures and toilet bowls.

Note: Some older tubs or sinks may be etched or discolored by **LONZA DC-101**. Test on a small hidden area first. Do not use on decorative brass fixtures, polished aluminum, natural or synthetic marble. Do not place container on Formica®.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
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4016

**LONZA DC-101** is a Hospital Disinfectant, bactericidal at 1:32 dilution (4 ounces per gallon) according to the AOAC Use-Dilution Test method, modified in the presence of 400 ppm hard water plus 5% organic serum against:

*Pseudomonas aeruginosa*                      *Salmonella choleraesuis*  
*Staphylococcus aureus*

**LONZA DC-101** is a Hospital Disinfectant, bactericidal at 1:43 dilution (3 ounce per gallon) according to the AOAC Use-Dilution Test method, modified in the presence of 250 ppm hard water plus 5% organic serum against:

*Pseudomonas aeruginosa*                      *Klebsiella pneumoniae*  
*Staphylococcus aureus*                      *Proteus mirabilis*  
*Salmonella choleraesuis*                      *Salmonella typhi*  
*Brevibacterium ammoniagenes*                      *Serratia marcescens*  
*Enterobacter aerogenes*                      *Shigella dysenteriae*  
*Escherichia coli*                      *Streptococcus pyogenes*

**LONZA DC-101** is virucidal\* at 1:43 dilution (3 ounce per gallon) according to the virucidal qualification, modified in the presence of 400 ppm hard water plus 5% organic serum against:

HIV-1 (AIDS virus)                      Herpes Simplex Type 1  
Herpes Simplex Type 2

**LONZA DC-101** is a sanitizer for hard porous and nonporous non-food contact surfaces at 0.75 ounce per 1 gallon dilution against:

*Klebsiella pneumoniae*                      *Staphylococcus aureus*

#### DIRECTIONS FOR USE

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

#### **Disinfection directions:**

Add 3 oz. per gallon of water (250 ppm hardness)  
Add 4 oz. per gallon of water (400 ppm hardness).

Apply **LONZA DC-101** to bathtubs, shower stalls, sinks, urinals, toilet bowls, toilet bowl surfaces, related fixtures, walls, floors and other hard (inanimate) nonporous surfaces (such as metal, stainless steel, glazed porcelain, ceramic, and plastic), thoroughly wetting surfaces.

**LONZA DC-101** can be applied with a cloth, mop, sponge, or soaked or sprayed. For heavily soiled areas, a preliminary cleaning is required. For sprayer applications, use a coarse spray device. Spray with quick full strokes 6-8 inches from surface, rub with brush, sponge or cloth. Do not breathe spray. After use, close nozzle.

Treated surfaces must remain wet for 10 minutes. Wipe dry with a clean cloth or sponge or let air dry. Prepare a fresh solution daily or when use solution becomes diluted or soiled.

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.

#### **\*Virucidal directions:**

Add 3 oz. per gallon of water, for disinfection against all viruses claimed. Treated surfaces must remain wet for 1 minute. Prepare a fresh solution daily or when use solution becomes diluted or soiled.

#### **Mold and Mildew Control directions:**

Add 3 oz. per gallon of water, to inhibit the growth of mold and mildew and their odors on hard, nonporous surfaces. Thoroughly wet all treated surfaces completely. Let air dry. Repeat application weekly or when growth or odor reappear.

#### **Sanitizing Non-Food Contact Surface directions:**

Add 0.75 oz. per 1 gallon of water, to sanitize hard porous and nonporous environmental surfaces. Treated surfaces must remain wet for 60 seconds.

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7/25

**Toilet Bowl Disinfectant / Cleaner directions:**

From concentrate: Add 3 oz. to the toilet bowl and mix. Brush thoroughly over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.

From use-solution: Empty toilet bowl or urinal and apply a 4 oz./gal. use-solution to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer, allow to stand for 10 minutes and flush.

**Heavy Duty Cleaner / Disinfectant directions:**

To disinfect and control the growth of mold and mildew, treated surfaces must remain wet for 10 minutes; for HIV-1 (AIDS Virus) and Herpes Simplex Types 1 & 2 treated surfaces must remain wet for 1 minute. For heavy soiled areas, a preliminary cleaning is required.

To clean and deodorize (use from 1:10 dilution up to full strength)(use full strength).

For cleaning and deodorizing shower stalls and shower fixtures: starting at the bottom and working toward the top, simply foam on the surface and spread with a brush, sponge or cloth. Let set for a minute, agitate to loosen stubborn accumulations and then rinse with water. For cleaning and deodorizing toilet bowls, squirt foam on exposed surfaces including under the rim. Agitate thoroughly with brush, swab, sponge or cloth. Allow to soak for a few minutes then flush.

**\*KILLS HIV-1 ON PRECLEANED 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.**

**PERSONAL PROTECTION:** Clean-up should always be done wearing protective latex gloves, gowns, masks and eye protection.

**CLEANING PROCEDURE:** Blood and other body fluids containing HIV must be thoroughly cleaned from surfaces and objects before application of **LONZA DC-101**.

**CONTACT TIME:** Leave surface wet for 1 minute with 3 oz. per gallon use-solution. Use a 10 minute contact time for disinfection against all other bacteria claimed.

**DISPOSAL OF INFECTIOUS MATERIALS:** Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

**PELIGRO:**

Si no sabe el ingles, solicite instrucciones a su supervisor antes de usar este producto.

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