

6836-276

08/12/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



Office of Pesticide Programs

Joanna Holcombe,  
Lonza Inc.  
90 Boroline Road  
Allendale, NJ 07401, USA

AUG 12 2011

**Subject:** Lonza DC-101 RTU  
**Registration No.:** 6836-276  
**Amendment Dated:** June 28, 2011  
**Submission #:** 898909

Dear Ms. Holcombe,

The following amendment submitted in connection with registration under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable as listed below:

**Proposed Amendment**

- Add "Virus" to Herpes Simplex Type 1 & 2 nomenclature;
- Make Spanish signal word optional;
- Add placeholder for Department of Transportation (DOT) symbols;
- Add optional "Country of Origin (insert country)" and Manufactured in (insert country)" Statements;
- Add placeholder for Barcode;
- Update company address;
- Add note to reviewer in footer that language in [ ] is optional or interchangeable;
- Add note to reviewer identifying optional marketing language;
- Add note to reviewer identifying optional graphics for types of surface;
- Change "should" to "must" and remove "recommended" as they appear in the label per PR Notice 2000-5;
- Change Salmonella choleraesuis to Salmonella enterica; and
- Revise Storage and Disposal language per PR Notice 2007-4

**General Comments:**

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies 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 Velma Noble PM Team 31 at (703) 308-6233 or Jamil Mixon at (703) 308-8032.

Sincerely,  
  
Velma Noble,  
Product Manager, Team 31  
Regulatory Management Branch  
Antimicrobials Division (7510P)

CONCURRENCES

SYMBOL	Enclosure:.....	Stamped Label.....						
SURNAME								
DATE								

# LONZA DC-101 RTU

One-Step Acid Cleaner, Disinfectant, Virucide\*, Sanitizer, Mildewstat, Deodorizer With Organic Soil tolerance For Hospital, Institutional, Industrial Use

Ready - To - Use

\*Virucidal against HIV-1 [AIDS Virus] and Herpes Simplex Virus 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.

Active Ingredients:

Octyl decyl dimethyl ammonium chloride.....	0.75%
Dioctyl 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%
Other Ingredients:.....	97.50%
	100.00%

**KEEP OUT OF REACH OF CHILDREN**

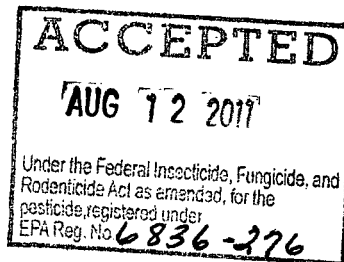
**DANGER [PELIGRO]**

See [left] [back] [right] [side] panel for Precautionary Statements and First Aid

EPA Reg. No. 6836-276  
EPA Est. No. (insert EPA Est. No. here)  
Net Contents (as indicated on container)

[DOT symbols]  
[Country of origin: (insert country)]  
[Manufactured in: (insert country)]  
[Barcode]

LONZA, INC.  
90 Boroline Road  
Allendale, NJ 07401



**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 if swallowed or inhaled. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash 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.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferable by mouth-to-mouth if possible. Call a poison control center or doctor for treatment advice.

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.

*{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.

*{Note to reviewer: The following is considered optional marketing language.}*

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

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

When used as directed, **Lonza DC-101 RTU** 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 RTU** will remove hard water deposits and limestone buildups when used as directed.

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

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

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

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

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

**Lonza DC-101 RTU** 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, glazed ceramic, and plastic).

**Lonza DC-101 RTU** 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 RTU** 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 RTU** 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 RTU** 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.

{Note to reviewer: The following is considered optional marketing language.}

**WHERE TO USE:**

{Note to reviewer: Each entry below also represents a graphic depicting the corresponding type of surface. No people or food will be depicted in graphics.}

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 RTU**. 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®.

**Lonza DC-101 RTU** is a Hospital Disinfectant, bactericidal according to the AOAC Use-Dilution Test method, modified in the presence of 5% organic serum against:

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

**Lonza DC-101 RTU** is virucidal\* according to the virucidal qualification, modified in the presence of 5% organic serum against:

- HIV-1 [AIDS virus]
- Herpes Simplex Virus Type 1
- Herpes Simplex Virus Type 2

**Lonza DC-101 RTU** is a sanitizer for hard nonporous non-food contact surfaces against:

- Klebsiella pneumoniae
- Staphylococcus aureus

~~{If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.}~~

**PELIGRO:**

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

**DIRECTIONS FOR USE**

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

**DISINFECTION DIRECTIONS:**

Apply **Lonza DC-101 RTU** full strength 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, glazed ceramic, and plastic, thoroughly wetting surfaces.

**Lonza DC-101 RTU** 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.

Rinse all surfaces that come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse. This product must not be used to clean utensils, glassware and dishes.

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.

**\*Virucidal directions:**

Follow "Disinfection Directions". Treated surfaces must remain wet for 1 minute.

**Mold and Mildew Control directions:**

Thoroughly wet all treated surfaces completely with **Lonza DC-101 RTU**. Let air dry. Repeat application weekly or when growth or odors reappear.

**Toilet Bowl Disinfectant / Cleaner directions:**

Remove gross filth and heavy soil from toilet bowl. Remove toilet bowl water. Apply **Lonza DC-101 RTU** to exposed surfaces including under the rim with a brush swab, cloth, mop, sponge or coarse mist pump, or trigger sprayer. Brush or swab thoroughly, allow to stand for 10 minutes and flush.

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 Virus Types 1 & 2 treated surfaces must remain wet for 1 minute. For heavy soiled areas, a preliminary cleaning is required.

**\*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 must 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 RTU**.

**CONTACT TIME:** Leave surface wet for 1 minute. Use a 10 minute contact time for disinfection against all other bacteria claimed.

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

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

To sanitize hard porous and nonporous environmental surfaces, follow "Disinfection Directions". Treated surfaces must remain wet for 60 seconds.

**Directions for Food Processing Plants:** Use on non-food contact surfaces such as floors, walls, tables, garbage cans and disposal areas. Before using this product, food products and packaging materials must be removed or carefully protected. Then follow the "Disinfection Directions."

**Directions for Food Storage Areas:** Use on non-food contact surfaces such as shelves, floors, walls and tables. Before using this product, food products and packaging materials must be removed or carefully protected. Then follow the "Disinfection Directions."

**For cleaning and deodorizing shower stalls and shower fixtures:** starting at the bottom and working toward the top, simply apply **Lonza DC-101 RTU** to 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:** Apply **Lonza DC-101 RTU** to exposed surfaces including under the rim. Agitate thoroughly with brush, swab, sponge or cloth. Allow to soak for a few minutes then flush.

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{Note to reviewer: For Nonrefillable Containers; Ready to Use Household/Residential Use Products}

## **STORAGE AND DISPOSAL**

Store in original container in areas inaccessible to children.

Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for recycling if available.

{or}

Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for reconditioning if appropriate.

{Note to reviewer: Nonrefillable Containers, Ready-To-Use Products for Commercial/Institutional/Industrial Uses— no new container rinsing directions, not a dilutable per PRN 2007-4}

## **STORAGE AND DISPOSAL**

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

### **Pesticide Storage:**

Open dumping is prohibited. Store in original container in areas inaccessible to children.

### **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:**

Nonrefillable container. Do not reuse or refill this container.

**{Plastic Containers:}** Triple rinse (or equivalent). 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 smoke. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

**{Metal Containers:}** Triple rinse (or equivalent). Offer for recycling or reconditioning if available or puncture and dispose of in sanitary landfill or by other procedures approved by state and local authorities. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations. DO NOT cut or weld metal containers.

**{Bag in Box Containers:}** Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.