

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 19 2005

Mr. Eliot Harrison
Agent for Lonza
Lewis & Harrison
122 C Street, NW Ste. 740
Washington, DC 20001

Subject: Lonza DC-101
EPA Registration No. 6836-86
Amendment Date: April 4, 2005
EPA Receipt Date: April 5, 2005

Dear Mr. Harrison,

The amendment submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable with the conditions listed below.

- Response to Agency letter dated August 20, 2004

Conditions

Revise the label as follows:

1. Page 1: This product is category I for primary skin irritation. Under "Precautionary Statements," the 3rd sentence must be revised to include "protective clothing."
2. Page 1: Under "First Aid," Bold the subheadings, "IF IN EYES, IF ON SKIN OR CLOTHING, and "IF SWALLOWED."
3. Page 2: Under "Where to Use": The Agency classifies microwave ovens and refrigerators as food contact surfaces. We are particularly concerned about the use of this product in residential setting where we believe that the user will not conduct a potable water rinse on interior surfaces of refrigerators. If you desire that all surfaces of refrigerators and microwave ovens be treated in a commercial setting and are willing to limit the use on these surfaces by homeowners, you must revise the label by stating microwave oven exteriors, refrigerator exteriors, commercial/institutional microwave ovens and refrigerators..

It is suggested that this label have separate surfaces and directions for use in commercial settings and residential settings. These directions would continue to indicate the necessity for a potable water rinse on food contact surfaces for commercial use and could include

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treatment of refrigerators. The residential directions would limit the product to use on exterior surfaces of refrigerators.

4. Page 2: Under "Where to Use," specify that the picnic tables and Outdoor (patio) furniture are hard nonporous surfaces by stating *Non-wooden picnic tables and "Outdoor (patio) furniture except cushions and wood frames*
5. Page 4: Revise the "Virucidal" directions by adding "*Use a 30 minute contact time against Foot and Mouth Disease. Allow surfaces to air dry.*"
6. Page 4: Under "HIV-1" directions, the shaded revision must read "on" not "of." Also, revise the "contact time" by adding the statement, *Use a 30 minute contact time against Foot and Mouth Disease.*
7. Page 4: Under "Toilet Bowl/Urinal" add the statement, "*Remove gross filth prior to disinfection.*" Also, revise the 2nd sentence "From concentrate" section to read "*Thoroughly brush or swab over exposed surfaces and under the rim with a cloth, mop, brush, or sponge. Allow to stand 10 minutes and flush.*"
8. Since this product may be used to clean and disinfect various vehicles, you must add the following directions to the label:

Vehicles: Clean all vehicles including mats, crates, cabs, and wheels with high pressure water and Lonza DC-101. Use 3 oz. per gallon of water to treat all hard non-porous surfaces. Leave treated surfaces wet for 10 minutes, allow to air dry.

9. Since this product may be used in food processing plants and food storage areas, the following directions must be added:

Food Processing Plants and Storage Areas: Before disinfecting hard, non-porous surface, food products and packaging materials must be removed from the room or carefully protected. Follow disinfection directions.

Acceptable Data

Data Requirement	Means of Support	Status
Virucidal Efficacy: Foot and Mouth Disease	Submitted study, MRID 462199-01	Acceptable, 1:32 dilution in 1% soil for 30 minutes

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

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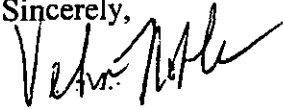
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Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

Should you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



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

Enclosure: Stamped Label
Efficacy Data Evaluation

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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) and protective gloves (rubber or chemical resistant) when handling. Do not breathe spray. Harmful or fatal if swallowed. Avoid contamination of food. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash 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.

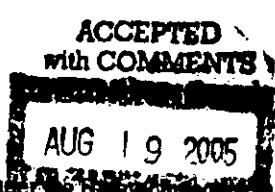
Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

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

(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.



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

LONZA DC-101

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 CaCO₃) and at 4 oz. per gallon (400 ppm calculated as CaCO₃) for Hospital, Institutional, Industrial Use

- *Virucidal against HIV-1 (AIDS Virus) and Herpes Simplex Types 1&2
- *Virucidal against Foot and Mouth Disease
- Effective as a disinfectant 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.
- Clean / Pine / Mint / Fresh [Scent] [Odor] [Fragrance]

Active Ingredients:

Octyl decyl dimethyl ammonium chloride	0.75%
Dioctyl dimethyl ammonium chloride	0.30%
Didecyl dimethyl ammonium chloride	0.45%
Alkyl (C ₁₄ 50%, C ₁₂ 40%, C ₁₆ 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 Precautionary Statements and First Aid

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

(Note to reviewer: The following is considered optional marketing language.)

- Cleans [Cleaner]
- Disinfects [Disinfectant]
- Deodorizes [Deodorizer]
- [Quickly] Removes soap-scum
- Cuts [through] [tough] grease and grime
- Contains no phosphates
- Concentrate [Concentrated] *(These words are to be used only by those products that are not sold as full strength)*

LONZA DC-101

- is a one-step disinfectant cleaner that is effective against a broad spectrum of bacteria,
- is virucidal* [including HIV-1].
- inhibits [the growth of] mold and mildew and their odors when used as directed.
- inhibits [the growth of] mold and mildew, leaving bathrooms & kitchens clean and smelling fresh.
- effectively controls mold and mildew.
- is an effective one-step sanitizer-cleaner for use on non-food contact surfaces.
- 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.
- will remove hard water deposits and limestone buildups when used as directed.
- is a mild acid pH disinfectant cleaner
- disinfects, cleans and deodorizes in one labor-saving step.
- is a concentrate that can be used with a mop and bucket, trigger sprayers, sponge, or by soaking.
- provides effective cleaning strength in removing difficult to clean soap scum, and hard water deposits.
- improves labor results by effectively controlling odors.
- cleans, shines, deodorizes and disinfects nonporous household surfaces.
- kills (household) germs (in ten minutes).

LONZA DC-101 is formulated to dissolve soap scum, corrosion and hard water deposits without scouring.

LONZA DC-101 has been used to clean hard, nonporous inanimate surfaces for over 10 years. Proven effective on tough 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.

Use **LONZA DC-101** in homes [households], hospitals, medical and dental offices, nursing homes, day care centers, nurseries, restaurants, bars, cafeterias, [institutional] kitchens, food processing plants, food storage areas, convenience stores, institutional facilities, public rest rooms, institutions, schools, colleges, athletic facilities, locker rooms, dressing rooms, shower and bath areas, exercise facilities, kitchens, bathrooms and other household areas, camp grounds, play grounds, public facilities, transportation terminals, hotels and motels, factories, business and office buildings, boats, ships, campers, trailers, mobile homes, cars, buses, trains, taxis and airplanes.

Use **LONZA DC-101 (WHERE TO USE:)** on washable hard nonporous surfaces: floors, walls, cabinets, counters [countertops], stoves [stovetops], sinks, appliances, microwave ovens, refrigerators, high chairs, tables, picnic tables, outdoor furniture, chairs, desks, telephones, door knobs, garbage cans, bathtubs, shower stalls, shower walls, glass shower doors tubs and glazed tiles, urinals, toilets, toilet bowls, toilet bowl surfaces, chrome fixtures, other bathroom fixtures, and hard nonporous surfaces made of metal, stainless steel, chrome, glazed porcelain, glazed ceramic, sealed stone, fiberglass and plastic (such as polystyrene, polypropylene) enameled surfaces, finished woodwork, vinyl and plastic upholstery,

[Test a small area first.]

[Do not use on PVD finished surfaces.]

Use **LONZA DC-101** for non-scratch cleaning of showers and tubs, shower doors and vinyl or plastic shower curtains, 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®.

(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 has been formulated to aid in the reduction of cross-contamination in these areas.

LONZA DC-101 is a [Hospital] disinfectant, bactericidal at 1:32 dilution [4 oz. per gallon of water] according to the AOAC Use-Dilution Test method, modified in the presence of 400 ppm hard water plus 5% organic serum against:
Pseudomonas aeruginosa [Pseudomonas]
Salmonella choleraesuis [Salmonella]
Staphylococcus aureus [Staph]

LONZA DC-101 is a [Hospital] disinfectant, bactericidal at 1:43 dilution [3 oz. per gallon of water] according to the AOAC Use-Dilution Test method, modified in the presence of 250 ppm hard water plus 5% organic serum against:
or:

LONZA DC-101 is a [Hospital] disinfectant, bactericidal at full strength according to the AOAC Use-Dilution Test method, modified in the presence of 5% organic serum against:

- Pseudomonas aeruginosa [Pseudomonas]
- Salmonella choleraesuis [Salmonella]
- Staphylococcus aureus [Staph]
- Brevibacterium ammoniagenes
- Enterobacter aerogenes
- Escherichia coli [E. coli]
- Klebsiella pneumoniae
- Proteus mirabilis
- Salmonella typhi
- Serratia marcescens
- Shigella dysenteriae
- Streptococcus pyogenes [Strep]

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

or
LONZA DC-101 is virucidal* at full strength according to the virucidal qualification against:

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

LONZA DC-101 is virucidal* at 1:32 dilution [4 oz. per gallon of water] [or equivalent dilution] according to the virucidal qualification, modified in the presence of 400 ppm hard water plus 5% organic serum against:

or
LONZA DC-101 is virucidal* at full strength according to the virucidal qualification against:

*Foot and Mouth Disease virus

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.

PREPARATION OF DISINFECTANT USE-SOLUTION:

Add 3 oz. per gallon of water (for 250-ppm water hardness)
Add 4 oz. per gallon of water (for 400-ppm water hardness).
Use full-strength

DISINFECTION DIRECTIONS:

Apply [recommended use-solution] (or) [full-strength] with a cloth, mop, sponge, or sprayer or by soaking until surfaces are thoroughly wet. Treated surfaces must remain wet for 10 minutes. Wipe dry with a clean cloth or sponge or let air dry. For sprayer applications, use a coarse spray device. Spray with quick full strokes 6 - 8 inches from surface. Rub with a brush, sponge or cloth. Do not breathe spray. After use, close nozzle. For heavily soiled areas, a preliminary cleaning is required.

Prepare a fresh solution daily or more often if use solution becomes diluted or soiled.

(Note to reviewer: The following sentence is for full-strength products that do not require dilution:)

Use fresh product daily or more often if product becomes diluted or soiled.

Rinse all surfaces that come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse.

(Note to reviewer: Alternate directions for products that are to be used full-strength and are sold in spray bottles)

Spray 6 - 8 inches from surface until surfaces are thoroughly wet. Do not breathe spray. Treated surfaces must remain wet for 10 minutes. Wipe dry with a clean cloth or sponge or let air dry. 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.

(Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must 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. [This product may be used to preclean 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.

***VIRUCIDAL DIRECTIONS:**

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

MOLD AND MILDEW CONTROL DIRECTIONS:

[Add 3 - 4 oz. per gallon of water] [Use full strength], 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 reappears.

DIRECTIONS FOR SANITIZING NON-FOOD CONTACT SURFACES:

LONZA DC-101 is a sanitizer for hard nonporous non-food contact surfaces at 3/4 oz. per gallon of water dilution against *Klebsiella pneumoniae* [and] *Staphylococcus aureus*. Treated surfaces must remain wet for 60 seconds. Wipe dry with a clean cloth or sponge or allow to air dry.

TOILET BOWL / URINAL DISINFECTANT AND CLEANER DIRECTIONS:

From concentrate: Add (3 - 4 oz.) to the toilet bowl or urinal 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 3 - 4 oz. per gallon 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 DIRECTIONS:

Use 8 oz. per gallon of water for heavy duty cleaning.

TO CLEAN AND DEODORIZE: [Use from 1:10 dilution up to full strength.] [Use full strength.] [Use 1:43 dilution.] [Use 1:32 dilution.]

Apply product to wet the surface[s] thoroughly. Let stand for at least one minute, rinse with water or allow to air dry.

(Note to reviewer: alternate cleaning and deodorizing directions:)

TO CLEAN AND DEODORIZE: [Use from 1:10 dilution up to full strength.] [Use full strength.] [Use 1:43 dilution.] [Use 1:32 dilution.]

For cleaning and deodorizing shower stalls and shower fixtures: starting at the bottom and working toward the top, [simply foam on] [apply 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, [squirt] [foam on] [apply to] exposed surfaces including under the rim. Agitate [Scrub] thoroughly with brush, swab, sponge or cloth. Allow to soak for a few minutes then flush.

(Note to reviewer: The following sentence is for full-strength products that do not require dilution)

Use fresh product daily or more often if product becomes diluted or soiled.

***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 OF SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS.

PERSONAL PROTECTION: Clean up should always be done wearing protective 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. 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.

FARM PREMISE DISINFECTION DIRECTIONS:

1. Remove all animals and feed from premises, vehicles and enclosures.
2. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals.
3. Empty all troughs, racks and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate all surfaces with a use-solution of 3 - 4 oz. of LONZA DC-101 per gallon of water (or equivalent dilution) for a period of 10 minutes.
6. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure.
7. Ventilate buildings, cars, boats and other closed spaces.
8. Do not house livestock or employ equipment until treatment has been absorbed, set or dried.
9. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

FOOT AND MOUTH DISEASE DIRECTIONS:

Add 4 oz. per gallon of water [or equivalent dilution] or use full strength. Follow Farm Premise Disinfection Directions, however, allow surface to remain wet for 30 minutes:

(Note to reviewer: If container size is one gallon or less, use the following Storage and Disposal directions):

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.

(Note to reviewer: If container size is greater than one gallon, use the following Storage and Disposal directions):

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. 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.