



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SURSTANCES

Georgia Anastasiou Agentc/o Lonza Inc. Lewis and Harrison 122 C Street, N.W., Suite 740 Washington, D.C. 20001

JAN 28 2008

Subject:

Lonza Formulation RTU

EPA Reg. No. 6836-193

Application Dated: October 29, 2007 Receipt Date: October 30, 2007

Dear Ms. Anastasiou,

The following amendment submitted in connection with registration under the section 3(c) (7) (a) of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended is acceptable with comments.

Proposed Amendment

Revising the label

Comments

Make the following changes to your labeling:

- 1) Page three, delete the 25th marketing claim "Super Strength Cleaner". The Agency does not allow terms or claims like this because it implies heightened efficacy. *Refer to the Chapter 12th of the Label Review Manual 3rd Edition*.
- 2) Page four, revise the 21^{st} and 23^{rd} claims by deleting the term "harmful" because it is misleading and implies heighten efficacy of your product.

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- 3) Page four, revise the 22^{nd} and 23^{rd} claims by deleting the phrases "prevent the spread of food-borne contamination" and "prevent the spread of harmful germs" and state "help prevent cross contamination on....surfaces" for the reason that your product is not approved for sanitization on food contact surfaces.
- 4) Page eleven, delete the word "solution" change to "this product" in the **DISINFECTION**DIRECTIONS for it indicates this product is to be diluted.

"Change this product at least daily or when this product becomes visibly dirty.

5) Page twelve, correct the Note section by revising the second statement located in the "SALON/BARBER INSTRUMENTS AND/BACTERICIDAL" directions for clarification.

"Note: Stainless steel shears and **metal** instruments must be removed after 10 minutes, rinsed, dried, and kept in a clean non-contaminated receptacle. Prolonged soaking may caused damage to metal instruments."

- 6) Page thirteen, revise the following statements in the "SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS" directions to reflect the Mandatory Language of PR Notice 2000-5.
 - **PERSONAL PROTECTION:** Clean-up **must** always be done wearing protective gloves, gowns, masks and eye protection.
 - **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.
- 7) Page fourteen, revise the following statement in the **TO SANITIZE AND DEODORIZE NON-FOOD CONTACT SURFACES** directions for it indicates that this product is effective when diluted:

"Change this product at least daily or when this product becomes visibly dirty"

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General Comments

A stamped copy of the acceptable with comments labeling 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 Velma Noble at (703) 308-6233.

Sincerely,

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Velma Noble Product Manager (31) Regulatory Management Branch1 Antimicrobial Division (7510P)

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LONZA FORMULATION RTU

Disinfectant - Cleaner - Fungicide - Mildewstat- Virucide* - Deodorizer for Hospitals, Household, Institutional, Commercial and Industrial Use

> Bactericidal against Pseudomonas aeruginosa, Staphylococcus aureus and Salmonella choleraesuis [in one minute]

> > Virucidal against HIV-1 (the AIDS Virus), Influenza A / Hong Kong, and Herpes Simplex Type 2

[Citrus] [Floral] [Pine] [Fresh] [Mint] [Clean] [Lemon] [Scent] [Fragrance] [Odor]

Active ingredient: Alkyl (C₁₂, 40%; C₁₄, 50%; C₁₆, 10%) dimethyl benzyl ammonium chloride 0.3% Total100.0%

KEEP OUT OF REACH OF CHILDREN CAUTION

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

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EPA Reg. No. 6836-193 EPA Est. No. (as indicated on container.) Net Contents (as indicated on container))

6836-193

LONZA Inc. 90 Boroline Road Allendale, NJ 07401

EPA Rea. No. 6836-193 EPA DRAFT 9-28-07

LONZA FORMULATION RTU (Note to reviewer: Language in () is considered optional or interchangeable)

PAGE 1 OF 17



PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes eye and skin irritation. Do not get in eyes, on skin or clothing. Wash thoroughly with soap and water after handling.

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.

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.

(If container size is 5 gallons or larger, 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.



- Ready-to-Use
- Citrus Scent
- Fresh Mild Scent
- Cleaner
- Deodorizer
- Disinfectant.
- Cleans
- Disinfects
- Deodorizes
- Removes soap scum
- [Convenient] Ready To Use formula.
- [Economical] [Spray & Wipe] formula.
- Cuts [through] [tough] grease and grime.
- Kills [odor causing] Mold and Mildew
- Kills odor-causing bacteria.
- Inhibits [the growth of] [mold] [and] [mildew]
- Kitchen, Bathroom, Household Disinfectant Cleaner.
- For Kitchens Too!
- For Bathrooms Too!
- Leaves [your house with] a [clean] [fresh] scent.
- Trigger spray[er]
- Pump spray[er]
- Contains no phosphates.
- Cleans and deodorizes pet spills.
- Cleans rodent soiled areas.
- (for formulation without dye only): Dye Free
- (for sub-registrations that only sell to commercial establishments): For commercial use only
- Removes soap scum
- Scrub Free
- Bleach Free



Lonza Formulation RTU:

- delivers non-acid cleaning performance in an economical Ready-to-Use package.
- applies the proper strength for the job with no dilution required.
- [removes) [cleans) [ground-in) dirt, [tough) grease, grime, food stains, soap scum, fingerprints, [tough] soils, crayon / pencil marks and heel marks [in] (and around] [the house], [kitchen] [and bathroom].
- cuts [tough] grease and grime [without scrubbing].
- improves labor results by effectively controlling odors [for a long lasting clean].
- Leaves the [whole] house smelling [clean] [and] [fresh].
- leaves [kitchens], [bathrooms] and [households] clean [and smelling fresh].
- [cleans], [deodorizes] and [disinfects] most washable [household] surfaces.
- can be used on most washable surfaces. [Test a small area first.]
- cleans and deodorizes in one labor-saving step.
- cleans with a fresh scent.
- eliminates odors.
- will not leave grit or soap scum.
- is a versatile multi-purpose cleaner and broad spectrum disinfectant formulated for use in Ultrasonic Baths [Ultrasonic cleaning units].
- is a multi-purpose cleaner, disinfectant and deodorizer.
- is a hospital disinfectant offering broad spectrum disinfectant activity against a wide range of microorganisms.
- kills household germs.
- Is effective against Pseudomonas aeruginosa [Pseudomonas], Staphylococcus aureus [Staph] and *Influenza A/Hong Kong, while effectively controlling mildew.
- is a [Ready-to-Use] [Hospital] disinfectant cleaner
- is effective against a broad spectrum of bacteria, is virucidal* [including HIV-1, the AIDS Virus], fungicidal, and inhibits the growth of mildew and their odors when used as directed.
- kills germs
- helps help
- helps present the spread of harmony on kitchen, bathroom, and other household surfaces.
- is formulated for use in daily maintenance programs with a balance of detergents, disinfectants, and malodor counteractants that deliver effective cleaning, disinfecting, and malodor control.



Use Lonza Formulation RTU:

- to clean and disinfect kitchen surfaces.
- to clean and disinfect bathroom surfaces.
- to clean and disinfect household surfaces.
- for non-scratch cleaning of showers and tubs, shower doors and vinyl shower curtains, fixtures, and toilet bowls.
- to clean and disinfect nonporous salon [barber] tools and instruments: combs, brushes, scissors, blades, and manicure instruments.
- Use in the kitchen, bathroom and nursery for a deep down clean.

Use Lonza Formulation RTU on diaper pails, plastic laundry hampers [baskets] and baby furniture [cribs, changing tables].

This odor destroyer is effective at neutralizing odors caused by mildew, pets, smoke, urine, cooking, vomit, garbage, restrooms, etc. This is not a masking agent

When used as directed, Lonza Formulation RTU will clean and deodorize surfaces in rest room and toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause malodors.

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

(Note to reviewer. The following may be used only if the supplemental registrant has obtained a Kosher Certification.)



(Any Kosher Symbol such as:)

(Kosher)



Lonza Formulation RTU is a Hospital Disinfectant, Bactericidal according to the current AOAC Use-Dilution Test method and Virucidal* according to the virucidal qualification on inanimate surfaces.

Lonza Formulation RTU is effective as a disinfectant against:

(Bacteria):

Pseudomonas aeruginosa [Pseudomonas] (in one minute)

Staphylococcus aureus [Staph] (in one minute)

Salmonella choleraesuis [Salmonella] (in one minute)

(Viruses:)

*Herpes Simplex Type 2 [Herpes] (in 10 minutes)

*HIV-1 (AIDS Virus) (in 30 seconds)

*Influenza A/Hong Kong [Influenza] (in 60 seconds)

(Fungi:)

Trichophyton mentagrophytes [The Athlete's Foot Fungus] [A Cause of Ringworm] [in 10 minutes)

Lonza Formulation RTU is a sanitizer for hard, nonporous (kitchen, bathroom and household) non-food contact surfaces according to the method for Sanitizers - Non Food Contact Surfaces, modified in the presence of 5% organic serum, in 30 seconds by killing 99.9% of:

Enterobacter aerogenes

Enterococcus (Streptococcus) faecalis [Vancomycin-resistant] [VREF]

Escherichia coli [E. coli]

Escherichia coli 0157:H7 [pathogenic E. coli

Salmonella choleraesuis [Salmonella]

Staphylococcus aureus [Staph]

Streptococcus pyogenes [Strep]



(AREAS OF USE:)			
Use Lonza Formulation RTU in:			
Bathrooms	Athletic facilities		
Homes (households)	Barber shops		
Kitchens	Business and office buildings		
	Camp grounds		
Clinics	Colleges		
Dental offices	Correctional facilities		
Health Care Facilities	Dressing rooms		
Hospitals	Exercise facilities		
Medical Offices	Factories		
Medical Related Facilities	Hotels		
Nursing homes	Institutional facilities		
Sick Rooms	Institutions		
	Locker rooms		
Day care centers	Motels		
Nurseries	Playground Equipment		
	Prisons		
Bars	Public facilities		
Cafeterias	Public rest rooms		
Convenience stores	Schools		
Institutional kitchens	Shower and bath areas		
Restaurants	Salons (Beauty)		

(AREAS OF USE:) Use Formulation HWS-256 in:				
Airplanes	Mobile homes			
Airports	Railcars			
Ambulances	Taxis			
Boats	Trailers			
Buses	Trains			
Campers	Transportation terminals			
Cars	Trucks (Box Trucks)			
Emergency (Police) (EMS) (Fire) (Rescue) vehicles	Ships			



(TYPES OF SURFACES:)			
Use Lonza Formulation RTU on washable hard, nonporous surfaces of:			
Appliances, exteriors of	Telephones		
Bathroom fixtures	Toilets		
Bathtubs (Fiberglass)	Toilet Bowls		
Cabinets	Toilet bowl surfaces		
Cages	Tubs		
Chairs	Tiles, glazed		
Coils and drain pans of air	Ultrasonic baths		
conditioning and refrigeration	Urinals		
equipment and heat pumps	Walls		
Conductive flooring	Non-critical [hospital] [medical] equipment surfaces		
Counters (countertops)			
Countertop laminates	Beds [Medical] [Hospital]		
Desks	Bed frames		
Doorknobs	Bed rails		
Exhaust Fans	Crutches		
Fiberglass Sinks, Tubs and Showers	Defibrillators		
Floors	Gurneys		
Garbage cans	[Medical] Examining tables		
Highchairs	[Medical] [Hospital] Lamps		
Microwave ovens, exteriors of	Rescue tools		
Outdoor furniture	Resuscitators		
Refrigerators, exteriors of	[Medical] [Hospital] Scales		
Showers	Stands		
Shower Stalls	Stretchers		
Sinks (bathroom, kitchen)	Stethoscopes		
Stoves (Stovetops)	Walkers		
Tables (picnic tables)	Wheel chairs		
,			



(TYPES OF SURFACES:)
Use Lonza Formulation RTU on washable hard, nonporous surfaces of:
Other hard nonporous surfaces made of:
Glazed ceramic
Glazed enameled surfaces
Glazed porcelain
Laminated Surfaces
Metal
Plastic (such as polystyrene or polypropylene)
Sealed granite
Sealed limestone
Sealed marble
Sealed slate
Sealed stone
Sealed terra cotta
Sealed terrazzo
Stainless steel
Upholstery, vinyl and plastic
Woodwork, finished



PELIGRO:

Si no sable el inglés, solicite instrucciones a su supervisor antes de esto producto.

DIRECTIONS FOR USE

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

GENERAL CLEANING / DEODORIZING DIRECTIONS:

(Spray) (Apply to) soiled area then wipe clean. Repeat for heavily soiled areas.

DISINFECTION DIRECTIONS:

Preclean prior to disinfection. Apply Lonza Formulation RTU until surfaces are thoroughly wet. Treated surfaces must remain wet for 1 minute for disinfection against bacteria. Follow virucidal or Fungicidal directions when using as a virucidal or fungicidal agent. Wipe dry with a clean cloth, sponge, mop or [tissue] [wiper] or allow to air dry.

Food contact surfaces must be rinsed with potable water after disinfection. Do not use to disinfect utensils, glassware and dishes.

Use a fresh solution at least daily or when salation becomes visibly dirty.

(Note to reviewer: Alternate directions for products sold in spray bottles:)

DISINFECTION DIRECTIONS:

Preclean prior to disinfection. Spray 6 - 8 inches from surface, until surfaces are thoroughly wet. Do not breathe spray. Treated surfaces must remain wet for 1 minute for disinfection against bacteria. Follow virucidal or Fungicidal directions when using as a virucidal or fungicidal agent. Wipe dry with a clean cloth, sponge, mop or [tissue] [wiper] or allow to air dry.

Food contact surfaces must be rinsed with potable water after disinfection. Do not use on utensils, glassware and dishes.

VIRUCIDAL DIRECTIONS:

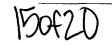
Follow disinfection directions for application instructions. Treated surfaces must remain wet for 10 minutes for Herpes Simplex Type 2 and 60 seconds [1 minute] for Influenza A / Hong Kong.

MOLD AND MILDEW CONTROL DIRECTIONS:

LONZA FORMULATION RTU effectively inhibits the growth of mold and mildew and the odors caused by them when applied to hard, nonporous surfaces. Follow disinfection instructions. Allow to air dry on surface. Repeat when mildew growth returns.

FUNGICIDAL DIRECTIONS:

LONZA FORMULATION RTU is an effective fungicide against Trichophyton mentagrophytes [the Athlete's Foot Fungus] [A Cause of Ringworm] in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities, health clubs and spas. Follow disinfection directions for application instructions. Treated surfaces must remain wet for 10 minutes.



(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.)

This product is not for use on medical device surfaces.

NON-ACID TOILET BOWL AND URINAL DISINFECTANT / CLEANER DIRECTIONS:

Empty toilet bowl or urinal and apply Lonza Formulation RTU to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer. Repeat and allow to stand for 1 minute, then flush.

ULTRASONIC BATH DISINFECTANT / CLEANER DIRECTIONS:

Use Lonza Formulation RTU to clean and disinfect hard nonporous noncritical objects compatible with Ultrasonic cleaning units.

Pour Lonza Formulation RTU directly into bath chamber. Preclean soiled objects. Place objects into unit and operate for a minimum of 10 minutes, according to manufacturers use directions.

Remove objects and rinse with sterile water (sterile water for injection), or allow to air dry. Replace product daily or when liquid becomes visibly dirty or discolored.

SALON / BARBER INSTRUMENTS AND TOOLS DISINFECTION [/ VIRUCIDAL / FUNGICIDAL / BACTERICIDAL] DIRECTIONS:

Preclean soiled instruments and tools. Completely immerse water safe nonporous salon instruments and tools in Lonza Formulation RTU for 10 minutes. Rinse thoroughly and dry before use. Use fresh product daily or more often if product becomes cloudy or soiled.

NOTE: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried, and kept in a clean non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

*KILLS HIV ON PRE-CLEANED 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 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 Formulation RTU.

CONTACT TIME: Leave surface wet for 30 seconds. Use a 1 minute contact time for disinfection against [Influenza A/Hong Kong [Influenza] and] bacteria and a 10 minute contact time against all other viruses and fungi claimed.

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

TO SANITIZE AND DEODORIZE NON-FOOD CONTACT SURFACES: [Spray] [Apply] Lonza Formulation RTU until thoroughly wet. Treated surfaces must remain wet for 30 seconds. Then wipe. For heavily soiled areas, a precleaning is required.

(Note for reviewer: If product is <u>not</u> sold in a spray bottle:)
Use a fresh solution at least daily or when salation becomes visibly dirty.

DEODORIZER DIRECTIONS:

Air Freshener, porous surfaces: Apply a light spray onto surfaces such as upholstery, drapes, bedding, carpet, A/C filters, etc.

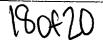
Pet Odors: Saturate precleaned area with enough Lonza Formulation RTU to remain damp for at least 8 minutes, then blot with clean cloth. Repeat if necessary. Effective on bedding and litter boxes. Allow to dry.

Laundry: 3 ounces during the final rinse will deodorize offensive odors.

Potpourri: Easy to use. Just pour into pot or small pan and simmer.

Automobile/RV: Spraying liberally onto seats, carpets, headliner and ashtray or into the trunk will eliminate odors from tobacco, beverage spills and musty carpet.

Hard Surfaces: Apply directly to odor source such as diaper or garbage pails, fishing gear, bed pans, hampers, toilets, shower curtains, fireplace, athletic or work shoes, etc. Use in sick rooms, closets, basements or anywhere there are odors.



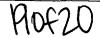
Refill Directions:

Remove top from empty spray bottle.

Unscrew cap on refill and pour contents directly into empty bottle until full. Replace trigger sprayer. If liquid remains in refill bottle, replace cap. Store for future use. Use product according to label directions.

To operate: Turn nozzle to on position and spray.

REFILL 50% More Free! 33 oz. at 22 oz. Price



(Note to reviewer: If the container size is one 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 store on side. Avoid creasing or impacting of side walls. Offer for recycling if available or discard in trash.

(Note to Reviewer: For Nonrefillable Containers.)
Nonrefillable container

(Note to reviewer. One of the following statements must be used for Nonrefillable Containers.)

Do not reuse or refill this container

OR

(Only if the label does not include household/residential use)

Do not reuse this container to hold materials other than pesticides (this product) or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state.

(Note to reviewer. One of the following statements must be used for Refillable Containers.) Refillable Container. Refill this container with pesticide (this product) only. Do not reuse this container for any other purpose.

OR

Refillable Container. Refill this container with [this product] only. Do not reuse this container for any other purpose."

(If container is greater than one gallon, use the following storage and disposal statements:)

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

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal

[Insert Statements from below]

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

(Note to Reviewer: For Nonrefillable Containers.)
Nonrefillable container

(Note to reviewer. One of the following statements must be used for Nonrefillable Containers.)

Do not reuse or refill this container

OR

(Only if the label does not include household/residential use)

Do not reuse this container to hold materials other than pesticides (this product) or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state.

(Note to reviewer. One of the following statements must be used for <u>Refillable Containers</u>.) Refillable Container. Refill this container with pesticide (this product) only. Do not reuse this container for any other purpose.

OR

Refillable Container. Refill this container with [this product] only. Do not reuse this container for any other purpose."