

6836-193

9-10-2001

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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SEP 10 2001

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

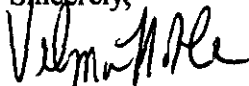
Subject: Lonza Formulation RTU
EPA Registration No. 6836-193
Notification Date: August 20, 2001
EPA Receive Date: August 21, 2001

Attention: Ms. Patricia Moriarty

This letter acknowledges receipt of your notification to delete "whirlpool bathtubs" from the label as per PR Notice 98-10. Based on a review of the submitted materials, the notification is acceptable and apart of the records on file.

If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



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

CONCURRENCES

SYMBOL							
SURNAME							
DATE							



Read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 2-28-95

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United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number
256905

Application for Pesticide - Section I

1. Company/Product Number 6836-193	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Lonza Formulation RTU	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Lonza Inc. 17-17 Route 208 Fair Lawn, NJ 07410 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification: Revised label to remove "Whirlpool bathtubs" and therefore, Directions for use on whirlpool bathtubs are no longer required as indicated in EPA approval letter dated 8/13/01.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	


Section - IV

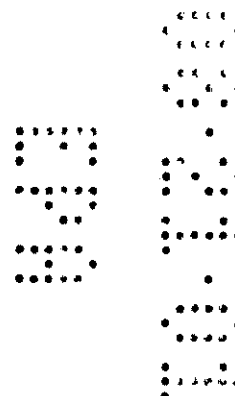
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Patricia A. Moriarty		Title Sr. Regulatory Associate		Telephone No. (Include Area Code) 201-794-2701	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.				6. Date Application Received (Stamped)	
2. Signature <i>Patricia A. Moriarty</i>		3. Title Sr. Regulatory Associate			
4. Typed Name Patricia A. Moriarty		5. Date August 20, 2001			

NOTIFICATION FOR: LONZA FORMULATION RTU
EPA REG. NO. 6836-193
AUGUST 20, 2001

CERTIFICATION STATEMENT

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR §152.46 and no other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 USC §1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR notice 98-10 and 40 CFR §152.46, this product may be in violation of FIFRA and I may be subject to enforcement actions and penalties under § 12 and 14 of FIFRA.


Patricia A. Moriarty
SR. Regulatory Associate
August 20, 2001



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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

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 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.

Storage and Disposal

Store only in tightly closed, original container in a secure area inaccessible to children and away from food or feed. Do not reuse empty container. Rinse thoroughly before discarding in trash.

LONZA FORMULATION RTU

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

Bactericidal against *Pseudomonas aeruginosa*,
Staphylococcus aureus and *Salmonella choleraesuis*

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

(Citrus)(Floral)(Pine)(Fresh)(Mint) Scent / Fragrance /
Odor

Active ingredient:

Alkyl (C₁₂, 40%; C₁₄, 50%; C₁₆, 10%)
dimethyl benzyl ammonium chloride..... 0.3%
Other ingredients:..... 99.7%
Total 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

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

EPA Reg. No. 6836-193

EPA Est. No. (as indicated on container.)

Net Contents (as indicated on container)

LONZA Inc.
Fair Lawn, NJ 07410

(Note to reviewer: the following is all optional marketing language:)

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) germs
- 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
 - Contains Eucalyptus and 67 exotic wild flower oils.
 - Eucalyptus Fragrance
-

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 (in 10 minutes).
- 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 harmful germs
- helps prevent the spread of food-borne contamination on kitchen and household surfaces.
- helps prevent the spread of harmful germs 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.

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(Note to reviewer: the following is all optional marketing language:)

Use **Lonza Formulation RTU** to clean and disinfect kitchen surfaces.

Use **Lonza Formulation RTU** to clean and disinfect bathroom surfaces.

Use **Lonza Formulation RTU** to clean and disinfect household surfaces.

Use **Lonza Formulation RTU** for non-scratch cleaning of showers and tubs, shower doors and vinyl shower curtains, fixtures, and toilet bowls.

Use **Lonza Formulation RTU** to clean and disinfect nonporous salon (barber) tools and instruments: combs, brushes, scissors, blades, and manicure instruments.

Use **Lonza Formulation RTU** in homes, hospitals, medical and dental offices, nursing homes, day care centers, nurseries, restaurants, bars, cafeterias, institutional kitchens, convenience stores, institutional facilities, public rest rooms, institutions, schools and colleges, athletic facilities, locker rooms, dressing rooms, shower and bath areas, exercise facilities, barber shops, salons, 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, airplanes and ultrasonic baths.

Use **Lonza Formulation RTU** 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, doorknobs, garbage cans, shower stalls, bathtubs, tubs and glazed tiles, sinks, urinals, toilets, toilet bowls, toilet bowl surfaces, other bathroom fixtures, exhaust fans, and hard nonporous surfaces made of metal, stainless steel, glazed porcelain, glazed ceramic, sealed stone, fiberglass, plastic (such as polystyrene, polypropylene), enameled surfaces, finished woodwork, Formica®, vinyl, and plastic upholstery.

Use **Lonza Formulation RTU** on diaper pails, plastic laundry hampers (baskets) and baby furniture (cribs, changing tables).

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.

Use in the kitchen, bathroom and nursery for a deep down clean.

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.

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 against:

(*Bacteria*):

Pseudomonas aeruginosa (*Pseudomonas*)

Staphylococcus aureus (*Staph*)

Salmonella choleraesuis (*Salmonella*)

(*Viruses*):

*Herpes Simplex Type 2 (*Herpes*)

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

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

(*Fungi*):

Trichophyton mentagrophytes (*The Athlete's Foot Fungus*)

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*)

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.

PELIGRO:

Si no sabe 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 / *VIRUCIDAL / DIRECTIONS:

Preclean prior to disinfection. Apply **Lonza Formulation RTU** until surfaces are thoroughly wet. Treated surfaces must remain wet for 10 minutes. Food contact surfaces must be rinsed with potable water after disinfection. Wipe dry with a clean cloth, sponge or tissue (wiper).

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

DISINFECTION / *VIRUCIDAL / 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 10 minutes. Food contact surfaces must be rinsed with potable water after disinfection. Wipe dry with a clean cloth, sponge or tissue (wiper).

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 in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities, health clubs and spas. Follow disinfection directions.

(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.

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 10 minutes, 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 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 Formulation RTU**.

CONTACT TIME: Leave surface wet for 30 seconds. Use a 10 minute contact time for disinfection against all other bacteria, viruses and fungi 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.

SANITIZER DIRECTIONS FOR NON-FOOD CONTACT SURFACES:

Treated surfaces must remain wet for 30 seconds. Prepare a fresh solution daily or when use solution becomes visibly dirty.

TO SANITIZE AND DEODORIZE NON-FOOD CONTACT SURFACES: Spray until thoroughly wet. Let stand 30 seconds. Then wipe. For heavily soiled areas, a precleaning is required.

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