

6836-193

7-24-2003

1/8

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

JUL 24 2003

SUBJECT: Lonza Formulation RTU
EPA Registration Number: 6836-193
Application Dated: April 25, 2003
Receipt Date: April 26, 2003

Dear Mr. Sloan:

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

- revise label language

Conditions

Revise the label as follows:

1. Make the following revision to page one:

On pages two and four you have identified that this product will be used in commercial settings. Thus revise the second section following the name of the product to state: "For Hospitals, Household, Institutional, *Commercial* and Industrial Use"

2. Make the following revisions to page four:

Upon reexamining our previous comment, to aid in clarifying the label revise to read "Exterior Surfaces of Microwave Ovens" deleting the word which follows: (microwaves)". The term **CONCURRENCES** Microwaves is not to be used alone without the clarifier "exterior surfaces of."

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|---------|----------|--|--|--|--|--|--|
| SYMBOL | | | | | | | |
| SURNAME | J. Sloan | | | | | | |
| DATE | 7/24/03 | | | | | | |

2/8

Your label includes the surface "fiberglass" which is a porous material. There are fiberglass surfaces which are treated to render them water tight or non-porous. Thus revise your label to identify these types of non-porous surfaces: "Fiberglass, sinks, tubs, and showers"

3. Make the following revisions to page five:

Revise both sets of "Disinfection Directions" by deleting the parenthesis () which surround the phrase "Follow virucidal or Fungicidal directions when using as a virucidal or fungicidal agent." This statement is not optional and thus is not to be surrounded by ().

Delete the following statement in the Disinfection Directions for spray bottles as this text appears twice in this section. Delete the statement "Treated surfaces must remain wet for 1 minute."

4. Make the following revision to page six:

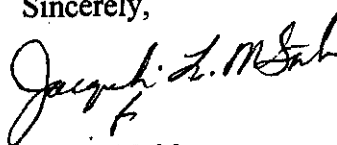
Revise the "To Sanitize and Deodorize Non-Food Contact Surfaces" directions to state: "Prepare a fresh solution *at least* daily or when use solution becomes visibly dirty."

General Comments

A stamped copy of the accepted 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 concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



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

Enclosure: Stamped Label

7510C.T.Lantz.7/24/03:6836-193a

CONCURRENCES

| SYMBOL | | | | | | | |
|---------|--|--|--|--|--|--|--|
| SURNAME | | | | | | | |
| DATE | | | | | | | |

**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.

STORAGE AND DISPOSAL

Store only in tightly closed, original container in a secure area inaccessible to children and away from food or feed. Refill empty container only with Lonza Formulation RTU. Rinse empty container thoroughly before discarding in trash or recycle.

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 (in one minute)

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 (C ₁₂ , 40%; C ₁₄ , 50%; C ₁₆ , 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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUL 24 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 6836-193

(Note to reviewer: the following is considered 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) 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
 - 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.
- 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.

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

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).

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.

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) (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) (the 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 O157: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

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

(AREAS OF USE:)

Use Lonza Formulation RTU in:

Bathrooms
Homes (households)
Kitchens

Dental offices
Hospitals
Medical Offices
Nursing homes

Day care centers
Nurseries

Bars
Cafeterias
Convenience stores
Institutional kitchens
Restaurants

Athletic facilities
Barber shops
Business and office buildings
Colleges
Correctional facilities
Dressing rooms
Exercise facilities
Factories
Hotels
Institutional facilities
Institutions
Locker rooms
Motels
Prisons
Public facilities
Public rest rooms
Salons
Schools
Shower and bath areas

Camp grounds
Play ground equipment

Airplanes
Boats
Buses
Campers
Cars
Emergency vehicles
Mobile homes
Ships
Taxis
Trailers
Trains
Transportation terminals

(TYPES OF SURFACES:)

Use Lonza Formulation RTU on washable hard, nonporous surfaces of:

Appliances
Bathroom fixtures
Bathtubs
Cabinets
Cages
Chairs
Conductive flooring
Counters (countertops)
Countertop laminates
Desks
Doorknobs
Exhaust fans
Floors
Garbage cans
Highchairs
Exterior Surfaces of Microwave ovens
(Microwaves)
Outdoor furniture

Exterior Surfaces of Refrigerators
Showers
Shower stalls
Sinks (bathroom, kitchen)
Stoves (stove tops)
Tables, (picnic tables)
Telephones
Toilets
Toilet bowls
Toilet bowl surfaces
Tubs
Tiles, glazed
Ultrasonic baths
Urinals
Walls

Other hard nonporous surfaces made of:

Fiberglass
Formica®
Glazed ceramic
Glazed enameled surfaces
Glazed porcelain
Metal
Plastic (such as polystyrene or polypropylene)
Sealed stone
Stainless steel
Upholstery, vinyl and plastic
Woodwork, finished

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 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.

(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. 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 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.

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 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 DISINFECTANT (/ 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 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 should be 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. Prepare a fresh solution daily or when use solution 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