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MAR 10 1995

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

Attention: Mr. Eliot I. Harrison, Agent

Subject: Lonza Formulation RTU
EPA Registration Number 6836-193
Letters Dated February 13, 1995,
February 14, 1995 and February 15, 1995

) The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, will be acceptable provided that you make the labeling changes listed below before you release the product for shipment bearing the amended label.

1. On the second page of your label, delete the uses for cutting boards, in refrigerators and freezers.
2. On the third page, delete the uses for food storage areas, food processing plants, food preparation areas, cutting boards, coolers, ice chests, refrigerator meat and vegetable and egg bins, tupperware, kitchen equipment like food processors, blenders, cutlery and other utensils.
3. The above uses will be permitted only when documentation from the Food and Drug Administration has been submitted that this product is cleared for use on sanitizing food contact surfaces.
4. Revise the precautionary statements to read:

Precautionary Statements

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

CONCURRENCES

SYMBOL							
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DATE							

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5. The revised updated Confidential Statements of Formula (Alternate #15 and Alternate #17) are in compliance with PR Notice 91-2, agree with the label and both are acceptable.

6. All proposed perfumes and the dye are acceptable for use in this formulation.

A stamped copy of your labeling is enclosed for your records. Submit one (1) copy of the final printed label prior to release of the product for shipment.

If you have any questions concerning this letter, please contact Martha Terry at (703) 305-6982.

Sincerely,

WF

Walter C. Francis
Acting Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

Enclosure

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Precautionary Statements
Hazards to Humans and
Domestic Animals

CAUTION

Causes eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling. Avoid contact with foods.

Statement of Practical Treatment:
For eye contact, flush eyes with water for 15 minutes. If irritation occurs, contact physician immediately.

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.

Contains no phosphates.
Contains biodegradable active ingredients.

LONZA
Formulation
RTU

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Disinfectant-Cleaner-Fungicide-Mildewstat-Virucide*-
Deodorizer
for Hospitals, 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)

Active ingredients

Alkyl (C ₁₂ , 40%; C ₁₄ , 50%; C ₁₆ , 10%) dimethyl benzyl	0.3%
ammonium chloride
Inert Ingredients	99.7%
Total Ingredients	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

EYE IRRITANT
AVOID EYE AND SKIN CONTACT

See (back) (side) (right) (left) panel
For additional precautionary statements

EPA Registration No.	6836-193
EPA Establishment No.	6836-IL-1
Net Contents	

Manufactured by:
LONZA Inc., Fair Lawn, NJ 07410

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 10 1995

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

6836-183

Citrus Scent
New!
Cleaner, Deodorizer, Disinfectant.
Fresh mild scent.
Convenient Ready To Use formula.
Economical spray & wipe formula.
Kills odor causing bacteria.
Cuts through tough grease and grime.
Kills odor causing germs and bacteria.
Inhibits growth of mildew.
Cleans and deodorizes pet spills.
Cleans rodent soiled areas.
Kitchen, Bathroom, Household Disinfectant Cleaner.
Cleans Dirt, Grease and Food Stains
Cleans, disinfects and deodorizes most hard non-porous surfaces and leaves your house with a clean fresh scent.
Contains Eucalyptus and 67 exotic wild flower oils.
Trigger spray.
Pump spray.

Lonza Formulation RTU delivers unsurpassed non-acid cleaning performance in an economical Ready-to-Use package.
Effective, yet economical, Lonza Formulation RTU always applies the proper strength for the job with no dilution required.
Lonza Formulation RTU Ready-to-Use strength minimizes labor costs by eliminating the need for dilution.
Lonza Formulation RTU removes dirt, grease, grime, food stains, soap scum, fingerprints, tough soils, crayon/pencil marks and heel marks in and around the house, kitchen, bathroom.
Lonza Formulation RTU cuts grease and grime without scrubbing.
[REDACTED]
will [REDACTED].
Lonza Formulation RTU removes tough grease, food stains, soap scum, and ground-in dirt and grime throughout the house.
Lonza Formulation RTU is recommended for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures, and toilet bowls.
Lonza Formulation RTU maximizes labor results by effectively controlling odors for a long lasting clean.
Multi-Purpose Lonza Formulation RTU eliminates odors. This odor destroyer is effective neutralizing odors caused by mildew, pets, smoke, urine, cooking, vomit, garbage, restrooms, etc. This is not a masking agent.

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Lonza Formulation RTU multi-purpose cleaner, disinfectant and deodorizer that leaves the whole house smelling clean and fresh.
Multi-Purpose Lonza Formulation RTU cleans, deodorizes and disinfects most washable surfaces.
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.
Lonza Formulation RTU cleans, disinfects and deodorizes in one labor-saving step.
Use Lonza Formulation RTU to clean, and disinfect kitchen surfaces. Use on [REDACTED], counters, sinks, tables, stoves and microwave ovens, [REDACTED]
[REDACTED]
Lonza Formulation RTU cleans, deodorizes and disinfects all non-porous household surfaces. Use in the Kitchen, Bathroom and Nursery for a deep down clean.
Lonza Formulation RTU Cleans, shines, deodorizes and disinfects all non-porous household surfaces. Inhibits the growth of mildew, leaving kitchens, bathrooms, households clean and smelling fresh.
Lonza Formulation RTU 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.
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 kills germs and cleans with a fresh scent.
Lonza Formulation RTU Kills [REDACTED] germs and helps prevent the spread of food-borne contamination on all hard Kitchen, Bathroom, Household surfaces.
Lonza Formulation RTU helps prevent the spread of harmful germs on all hard Kitchen, Bathroom, Household surfaces.
Lonza Formulation RTU is for use on most washable surfaces. Test a small area first.

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in EPA Letter Dated:

MAR 10 1995

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Lonza Formulation RTU is recommended for use on exhaust fans, metal ducts and filters, coils and drain pans of air conditioning and refrigeration equipment and heat pumps.

Lonza Formulation RTU is recommended for cleaning and disinfecting of ultrasound transducers, probes, mammography compressor plates and other inanimate hard surfaces.

Lonza Formulation RTU will not leave grit or soap scum. Will not cause swelling of transducer membrane or harm compressor plates.

Lonza Formulation RTU is a versatile multi-purpose cleaner and broad spectrum disinfectant formulated for use in Ultrasonic Baths (Ultrasonic cleaning units).

Lonza Formulation RTU is formulated to effectively clean and disinfect ear molds and all other equipment, and is registered as a hospital disinfectant offering broad spectrum disinfectant activity against a wide range of microorganisms.

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

Lonza Formulation RTU may be used in hospitals, homes, medical and dental offices, nursing homes, day care centers, nurseries, restaurants, restaurants and bars, cafeterias, institutional kitchens, [REDACTED] institutional facilities, public rest rooms, institutions, schools, athletic facilities, camp grounds, play grounds, public facilities, [REDACTED] transportation terminals, hotels and motels, factories, business and office buildings, boats, ships, campers, trailers, mobile homes, cars, buses, trains, taxis, airplanes.

Lonza Formulation RTU may be used on washable hard non-porous surfaces including [REDACTED] and storage areas. [REDACTED]

[REDACTED] countertops, stovetops, exhaust fans, sinks, appliances, refrigerators, tables, picnic tables, outdoor furniture, chairs, desks, telephones, highchairs, bed frames, washable walls, cabinets, doorknobs, baby toys, telephones, shower stalls, tubs and tiles, toilets, portable toilets, porcelain tiling, garbage cans, stainless steel, enameled surfaces, woodwork, formica, vinyl, leather and plastic upholstery, bathtubs, shower stalls, sinks, urinals, toilet bowls, toilet bowl surfaces, related fixtures, walls, floors and other hard non-porous surfaces (such as metal, stainless steel, glazed porcelain, ceramic, fiberglass and stone).

Lonza Formulation RTU kills household germs in 10 minutes; effective against harmful pseudomonas, staph and influenza, while effectively controlling mildew.

Lonza Formulation RTU is a Ready-to-Use Hospital Disinfectant Cleaner that 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.

Lonza Formulation RTU is a disinfectant cleaner that is effective against a broad spectrum of bacteria, is virucidal* (including HIV-1, the AIDS Virus), fungicidal, and will prevent the growth of mildew and their odors when used as directed.

Lonza Formulation RTU is an effective fungicide against Trichophyton mentagrophytes (the athlete's foot fungus) when used on surfaces in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities, health clubs and spas.

Lonza Formulation RTU kills *Pseudomonas aeruginosa* (*Pseudomonas*), *Staphylococcus aureus* (*Staph*), *Salmonella choleraesuis* (*Salmonella*), *Herpes Simplex* Type 2 Virus (*Herpes*), HIV-1 virus (AIDS virus), Influenza Type A/Hong Kong (Influenza), *Trichophyton* *mentagrophytes* (the Athlete's Foot Fungus).

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

Pseudomonas aeruginosa (Pseudomonas)
Staphylococcus aureus (Staph)
Salmonella choleraesuis (Salmonella)
Trichophyton mentagrophytes (The Athlete's Foot Fungus)

*Herpes Simplex Type 2 (Herpes)
Influenza A/Hong Kong (Influenza) in 60 seconds
HIV-1 (AIDS Virus) in 30 seconds

Lonza Formulation RTU is a mildewstat and will effectively inhibit the growth of mildew and the odors caused by them when applied to hard, non-porous surfaces.

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with COMMENTS
in EPA Letter Dated

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Under the Federal Insecticide, Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
6536-193

To operate: Turn nozzle to on position and spray.

PELIGRO:

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

Directions for Use

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

(Instrucciones de uso)

El empleo de este producto de manera contraria a lo indicado en su etiqueta constituye una violación de la Ley Federal.)

Apply Lonza Formulation RTU to hard (inanimate) non-porous surfaces thoroughly wetting surfaces as recommended and required
(Aplicar la solución utilizable a superficies duras (inanimadas) no porosas mojando completamente las superficies según lo recomendado y requerido.)

For heavily soiled areas, a preliminary cleaning is required.
(Remove coupling gel from transducer.)
(Para áreas muy manchadas, se requiere una limpieza preliminar.)

Rinse food contact surfaces with potable water.
(Enjuague con agua potable las superficies que contactan alimentos.)

(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.)

(Este producto no debe usarse como esterilizante/desinfectante de alto nivel en ninguna superficie o instrumento que: (1) haya de introducirse directamente en el organismo humano, ya sea en la circulación sanguínea o en contacto con ésta o con zonas orgánicas normalmente estériles, o (2) haya de entrar en contacto con mucosas intactas aunque habitualmente no atraviese la barrera hematológica o no penetre de alguna otra manera en zonas normalmente estériles del organismo. Este producto no se puede usar para la limpieza preliminar o para la descontaminación de dispositivos médicos de importancia crítica o semicrítica antes de proceder a la esterilización o la desinfección de alto nivel)

General Cleaning: Spray soiled area then wipe clean. Repeat for heavily soiled areas. A rinse is recommended for surfaces in direct contact with food.

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Disinfection/*Virucidal/Mildew Control directions:
(Instrucciones de desinfección/control de
*virucidad/enmohoecimiento:)

Preclean prior to disinfection.
(Limpieza preliminar antes de proceder a la desinfección).

Trigger spray 6-8 inches from surface, rub with brush,
sponge or cloth. Do not breathe spray mist.

(Rociar 6 a 8 pulgadas desde la superficie, frotar con cepillo, esponja o trapo. No respirar el vapor/del rociador.)

Treated surfaces must remain wet for 10 minutes. MAP
(Las superficies tratadas deben mantenerse mojadas durante 10 minutos.)

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
(Limpieza con un trapo o papel de seda.)
Approved under EPA Reg. No.

Non-Acid Toilet Bowl Disinfectant/Cleaner directions:

Empty toilet bowl or urinal and apply to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer. Repeat and allow to stand for 10 minutes and flush.

(Instrucciones para el desinfectante/limiador no ácido de inodoro:

Vaciar la taza del inodoro o orinal y aplicar a las superficies expuestas, inclusive debajo del reborde, con un trapo, estropajo, esponja o rociador. Repetir y dejar estar por 10 minutos y correr el agua.)

To Disinfect and Deodorize: Pre-clean first. Spray until thoroughly wet. Let stand 10 minutes. Then wipe. A rinse is recommended for surfaces in direct contact with food.

Ultrasonic Bath Disinfectant/Cleaner directions:

Use Lonza Formulation RTU to clean and disinfect hard (inanimate) non-porous objects compatible with Ultrasonic cleaning units.

Pour fresh solution directly into bath chamber. Preclean soiled objects. Place objects into unit and operate for a minimum of 10 minutes, according to manufacturer's use directions.

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

Earmold and ITE Cleaner Directions: Spray solution onto earmold. Wipe dry. For In The Ear (ITE) Hearing Aids, spray solution on tissue and wipe down. For disinfecting, clean as directed above, then allow solution to remain on earmold or ITE for 10 minutes before wiping, or allow to air dry. DO NOT IMMERSE HEARING AID IN SOLUTION.

• 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 virus, bacteria, 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.

("MATA EL VIH EN SUPERFICIES/OBJECTOS EXPUESTOS AL MEDIO AMBIENTE PREVIAMENTE CONTAMINADOS CON SANGRE/LIQUIDOS CORPORALES, CUANDO SE LOS HA LIMPIADO PREVIAMENTE, en lugares destinados al cuidado de la salud u otros lugares donde se prevea la posibilidad de contaminación de superficies/objectos inanimados con sangre o líquidos corporales y en los que dichas superficies/objectos pueden estar relacionados con el portento de transmisión del virus de la inmunodeficiencia humana tipo (VIH-1) (asociado con el SIDA).

"INSTRUCCIONES ESPECIALES PARA LA LIMPIEZA Y DESCONTAMINACION CONTRA EL VIH-1 SOBRE SUPERFICIES/OBJECTOS CONTAMINADOS CON SANGRE/LIQUIDOS CORPORALES."

PROTECCION PERSONAL: La limpieza deberá hacerse siempre usando guantes de látex protectores, batas, máscaras y protección de la vista.

PROCEDIMIENTO DE LIMPIEZA: La sangre y otros líquidos corporales que contienen el VIH deben limpiarse completamente de las superficies y los objetos antes de aplicar **Lonza Formulation RTU**.

TIEMPO DE CONTACTO: Dejar la superficie mojada durante 30 segundos. Dejar 10 minutos de tiempo contacto para la disinfección contra todos los otros virus, bacterias y hongos declarados.

ELIMINACION DE MATERIALES INFECCIOSOS: La sangre, los líquidos corporales, materiales de limpieza y ropa deben someterse al autoclave y eliminarse de acuerdo con la reglamentaciones locales sobre eliminación de desechos infecciosos.)

Ventilation and Air Conditioning Duct Work Sanitizing directions:

Preparation: Duct work should be mechanically cleaned, vacuumed or blown free of dirt, dust, mold and debris, using a commercially available duct cleaning system or service.

Application: Spray or fog **Lonza Formulation RTU** solution into duct work using a suitable spraying or fogging device. Make sure that the surfaces are thoroughly wet for at least 60 seconds. During application, area must be closed as tightly as possible and sealed. After spraying or fogging, the area should be opened and aired for one (1) hour before repopulating. Do not breathe spray mist. Use an applicable NIOSH/MSHA approved respirator

appropriate for fogging or spraying this product. After application, allow to air dry. Treat as required. **FOGGING**

IS TO BE USED AS AN ADJUNCT TO MAR 10 1995 ACCEPTABLE MANUAL CLEANING AND DISINFECTING OF SURFACES.

Salon (Barber) Instruments and Tools Disinfection

Directions:

Preclean soiled instruments and tools. Completely immerse non-porous salon instruments and tools for 10 minutes. Rinse thoroughly and dry before use. Fresh solution should be prepared daily or more often if solution becomes cloudy or soiled.

NOTE: 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.

Deodorizer Directions:

Air Freshener, porous surfaces: Apply a light spray into the air, or 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 and all vents will eliminate odors for tobacco, beverage spills and musty carpet.

Hard Surfaces: Apply directly to odor source such as diaper or garbage pails, fishing gear, bed pans, hairnets, 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.