

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC - 8 2003

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

Subject: Lonza Formulation L-15
EPA Registration No. 6836-164
Amendment Date: September 8, 2003
EPA Receipt Date: September 10, 2003

Dear Mr. Sloan,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

- Update First Aid and Precautionary Statements

Conditions

Revise the label as follows:

1. Revise the "Precautionary Statements" by addressing the category I labeling for primary skin irritation. The 1st three statements must read "Causes irreversible eye damage and skin burns. Do not get in eyes, *on skin*, or on clothing. Wear protective eyewear, *protective clothing*, and protective gloves."
2. Page 2, right column, 5th claim: Delete "harmful" from the claim.
3. Page 2, right column, 9th claim: Delete "organic" from the claim.
4. Page 3, right column: Qualify woodwork and fiberglass as hard nonporous surfaces by stating "finished" woodwork and specifying what object is made of fiberglass.
5. Page 2 and 3: Since this product is used in homes, you must state "*exterior surfaces*" of the refrigerator.
6. Page 3, left column, 4th claim: Delete EPA and state "according to Mildewstat guidelines."

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

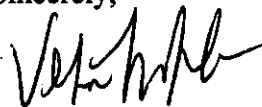
- 7. Under the "Disinfection" directions, revise the potable rinse statement to read "Do not use on utensils, glassware, or dishes."
- 8. Since the Efficacy data, submitted to support this product as a disinfectant, was conducted without a soil load, you must state that whirlpool units must be precleaned. Also, delete the statement, repeat for heavily soiled units.

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies 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 Jacqueline McFarlane at (703) 308-6416.

Sincerely,



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

Enclosure: Stamped Label

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage. Do not get in eyes, on skin or on clothing. Avoid contact with skin. Wear protective eyewear (goggles, face shield or safety glasses) and protective gloves (rubber, chemical resistant) when handling. Harmful if swallowed. 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 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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.

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

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

(If container size is 5 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.

LONZA FORMULATION L-15

Disinfectant – Deodorant - Cleaner

Multi-Purpose Odor Counteractant Cleaner

Kills Pseudomonas, Salmonella and Staphylococcus

Virucidal*

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

Active Ingredient:

Alkyl (C ₁₄ 58%, C ₁₆ 28%, C ₁₂ 14%) dimethyl benzyl ammonium chloride.....	4.00%
Other Ingredients	96.00%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

PELIGRO:

Si no sabe inglés, pida instrucciones a su supervisor antes de usar este producto.

SEE LEFT / SIDE / RIGHT / BACK PANEL FOR PRECAUTIONARY STATEMENTS AND FIRST AID

EPA Reg. No. 6836-164

EPA Est. No. (as indicated on container)

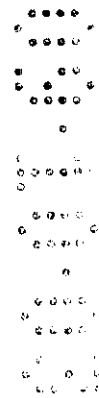
Net Contents (as indicated on container)

LONZA, INC.

17-17 Route 208, Fair Lawn, NJ 07410

ACCEPTED
with COMMENTS
in EPA Letter Dated:
DEC 8 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 6836-164



For use in households.
 For residential use. For use in homes.
 For use all around the house. Easy to Use!
 Cleans (Cleaner)
 Deodorizes (Deodorizer)
 Disinfects (Disinfectant)
 Concentrate (Concentrated)
 Kills many household germs
 Removes Ugly Mildew Stains!
 Eliminates odors.
 Eliminates pet odors.
 Destroys odors!
 This product contains no (phosphates) (or) phosphorous (compounds).

Cross-contamination is of major housekeeping concern not only in hospitals, but also in schools, institutions, and industry. **Lonza Formulation L-15** has been formulated to aid in the reduction of cross-contamination from treated surfaces in these areas.

When used as directed, **Lonza Formulation L-15** 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 malodors.

Lonza Formulation L-15 reduces the surface tension of water, improving its wettability. Microbes are capable of mass reproduction in sub-visible pores and cracks of surfaces. The excellent wettability of **Lonza Formulation L-15** improves the penetration of the use solution into areas that otherwise might not be reached.

Lonza Formulation L-15 is effective against a wide variety of gram positive and gram-negative bacteria. It is also an excellent deodorant and is especially effective in controlling odors that are bacterial in origin and has a pleasant lemon (mint) odor.

Lonza Formulation L-15 mixes with water to form clear, stable use solutions. Use solutions are non-corrosive and non-staining to plastic, vinyl, synthetics, enamel, glazed tile and most common metals.

Lonza Formulation L-15 can be used with a mop and bucket, trigger sprayers, sponge, or by soaking.

Lonza Formulation L-15 provides effective cleaning strength that will not dull most metal-interlock floor finishes, and does not require a rinse prior to re-coat.

Lonza Formulation L-15 improves labor results by effectively controlling odors.

Lonza Formulation L-15 cleans, shines, deodorizes and disinfects all pre-cleaned nonporous household surfaces, inhibits the growth of mold and mildew, leaving surfaces in the house including bathrooms & kitchens clean and smelling fresh.

ACCEPTED
 with COMMENTS
 in EPA Letter Dated:
 DEC 8 2003

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, and pesticide,
 registered under EPA Reg. No. 6836-164

Lonza Formulation L-15
 EPA Reg. No. 6836-164
 EPA Draft Label 9-8-03

Lonza Formulation L-15 is recommended for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures, and toilet bowls.

Lonza Formulation L-15 is for use in kitchens, bathrooms and other household areas.

Lonza Formulation L-15 is for use in Ultrasonic baths.

Lonza Formulation L-15 is for use in Whirlpool bathtubs

Lonza Formulation L-15 kills household germs; effective against harmful *Pseudomonas aeruginosa* (pseudomonas), *Staphylococcus aureus* (strep), and *Streptococcus pyogenes* (strep), and Influenza A/Brazil.

Lonza Formulation L-15 is a neutral pH multi-surface cleaner, and deodorizer.

Use **Lonza Formulation L-15** on the multi-touch surfaces responsible for cross-contamination.

Use **Lonza Formulation L-15** on finished floors, high speed burnished floors, conductive flooring, tables, chairs, bathroom bowls, basins, counter tops, bed rails, door knobs and handles, glass surfaces including windows and mirrors.

Lonza Formulation L-15 is a balanced formulation combining Lonza's true odor counteractants, a non-ionic synthetic detergent, a quaternary ammonium compound, organic chelating agents and synergizing builders...for effective cleaning, and deodorizing when used as directed.

Lonza Formulation L-15 is intended primarily as a premium cleaner where disinfection and true odor counteraction are also indicated. It is excellent for washing hard nonporous surfaces such as glazed porcelain, glazed tile, glass, stainless steel, chrome, rubber, plastic, metal, and does not damage washable painted, varnished or lacquered surfaces. It can be used on nonporous surfaces such as walls, tables, floors, chairs, countertops, bathroom fixtures, sinks, shelves, racks, carts, refrigerators, and other similar surfaces. Because **Lonza Formulation L-15** rinses spot-free, it is particularly suitable for linoleum, rubber sealed cork, vinyl and asphalt tile floors. It has outstanding rinsing qualities and is an excellent cleaner for marble or terrazzo.

Lonza Formulation L-15 is recommended for use on conductive flooring.



Lonza Formulation L-15 may be used in (Areas of Use): hospitals, homes, medical and dental offices, nursing homes, day care centers, nurseries, restaurants, restaurants and bars, cafeterias, institutional kitchens, food storage areas, institutional facilities, public rest rooms, institutions, offices, schools, athletic facilities, beauty salons, camp grounds, play grounds, public facilities, farms, food processing plants, transportation terminals, hotels and motels, factories, business and office buildings, boats, ships, campers, trailers, mobile homes, cars, buses, trains, taxis, airplanes, health care facilities, colleges, veterinary clinics, animal life science laboratories, industrial facilities, recreational facilities, retail and wholesale establishments.

Lonza Formulation L-15 may be used on the following washable hard nonporous surfaces: countertops, stovetops, exhaust fans, sinks, appliances, refrigerators, tables, picnic tables, outdoor furniture, chairs, desks, telephones, highchairs, washable walls, cabinets, doorknobs, telephones, garbage cans, walls, floors enameled surfaces, woodwork, Formica®, vinyl and plastic upholstery, shower stalls, tubs and glazed tiles, toilets, glazed porcelain tiling, bathtubs, bathroom sinks, urinals, toilet bowls, toilet bowl surfaces, bathroom fixtures, and hard nonporous surfaces made of metal, stainless steel, glazed porcelain, glazed ceramic, fiberglass, and plastic.

Lonza Formulation L-15 kills common germs such as Escherichia coli (E. coli), Staphylococcus aureus (Staph), Salmonella choleraesuis (Salmonella), Streptococcus pyogenes (Strep) and Influenza A / Brazil (Influenza) on hard nonporous surfaces. Prevents the growth of odor causing bacteria.

Lonza Formulation L-15 is a Hospital Disinfectant for pre-cleaned surfaces at 2-½ oz. per gallon of water; is Bactericidal according to the AOAC Use-Dilution Test method, Virucidal* according to the virucidal qualification, a Mildewstat according to the EPA Mildewstat guidelines, against:

(Bacteria:)

- Pseudomonas aeruginosa (Pseudomonas)
- Salmonella choleraesuis (Salmonella)
- Staphylococcus aureus (Staph)

- Enterobacter aerogenes
- Escherichia coli (E. coli)
- Shigella sonnei
- Streptococcus pyogenes

(Viruses:)

- *Herpes Simplex Type 2
- *HIV-1 (AIDS Virus)
- *Influenza A/Brazil (Influenza)

(Fungi:)

- Aspergillus niger
- Candida albicans

ACCEPTED
 WITH COMMENTS
 in EPA Label Draft
 DEC 8 2008
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. 6836-164

Lonza Formulation L-15
EPA Reg. No. 6836-164
EPA Draft Label 9-8-03

DIRECTIONS FOR USE

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

To Clean and Deodorize or to Preclean Prior to Disinfection: Depending on the soil level of the area to be cleaned, use 5 - 10 oz. of **Lonza Formulation L-15** per gallon of water (1 part **Lonza Formulation L-15** to 31 - 63 parts water). Rub with brush, sponge or cloth. Wipe dry with a clean cloth or sponge or let air dry.

DISINFECTION/VIRUCIDAL/MOLD AND MILDEW CONTROL DIRECTIONS:

PREPARATION OF USE-SOLUTION:

Hospitals, Nursing Homes, and other Medical facilities: Use 5 oz. of **Lonza Formulation L-15** per 1- ½ gallons of water (1 part **Lonza Formulation L-15** to 39 parts water) for one step cleaning and disinfection of areas with light to medium soil loads. For heavily soiled areas, preclean and disinfect with 2-½ oz. **Lonza Formulation L-15** per gallon of water.

Industrial Areas, Barber Shops, Restrooms, Restaurants, Food and Meat Processing Plants (non-food processing areas) and other Non-Medical Uses:

For pre-cleaned surfaces, use 2 oz. of **Lonza Formulation L-15** per 1-1/3 gallons of water (3 oz. of **Lonza Formulation L-15** per 2 gallons of water).

TO DISINFECT:

Apply the use-solution to precleaned hard nonporous surfaces, thoroughly wetting surfaces with a clean cloth, mop, sponge, squeegee, mechanical scrubber, mechanical spraying device or (trigger) sprayer. For sprayer applications, use a coarse spray device. Spray 6-8 inches from surface, rub with brush, sponge or cloth. Avoid breathing spray. Treated surfaces must remain wet for 10 minutes. Wipe dry with a clean cloth or sponge or let air dry. Rinse all surfaces that come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse. This product should not be used to clean utensils, glassware and dishes. Prepare a fresh solution daily or more often if solution becomes visibly diluted or soiled.

(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.

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 L-15.

CONTACT TIME: Leave surface wet for 1 minute (60 seconds) Use a 10 minute contact time for disinfection against all other viruses, bacteria and fungi claimed.

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

ULTRASONIC BATH DISINFECTANT DIRECTIONS:

Use LONZA FORMULATION L-15 to disinfect hard nonporous, non-critical objects compatible with Ultrasonic cleaning units.

Pre-clean soiled objects. Pour fresh use-solution of 2 ½ oz. per gallon of water directly into bath chamber. Place objects into unit and operate for a minimum of 10 minutes, according to the manufacturer's directions.

Remove objects and wash with sterile water (sterile water for injection) or allow to air dry. Prepare fresh solution for each use.

DISINFECTION OF WHIRLPOOL UNITS:

After using the whirlpool unit, drain and refill with fresh water to just cover the intake valve. Add 2 ½ oz. of Lonza Formulation L-15 for each gallon of fresh water added. Start the pump to circulate the solution. Wash down the unit sides, seat of the chair lift and any related equipment with a clean swab, brush or sponge. Treated surfaces must remain wet for 10 minutes. After the unit has been thoroughly disinfected, drain the solution from the unit and rinse the disinfected surfaces with fresh water. Repeat for heavily soiled units.

Non-Acid Toilet Bowl Disinfectant/Cleanser Directions:

Remove gross filth prior to disinfection.

From concentrate:

Add 5 oz. to the toilet bowl and mix. Brush thoroughly over exposed surfaces and under the rim and flush. Repeat for disinfection and allow to stand for 10 minutes and flush.

From use-solution:

Empty toilet bowl or urinal and apply a 5 oz./gal. use-solution to exposed surfaces including under the rim with a cloth, mop, sponge, or sprayer. Brush thoroughly over exposed surfaces including under the rim and flush. Repeat for disinfection and allow to stand for 10 minutes and flush.

FOR DEODORIZING GARBAGE CANS, GARBAGE TRUCKS, INDUSTRIAL WASTE RECEPTACLES AND GARBAGE HANDLING EQUIPMENT: It is especially important to pre-clean for the product to perform properly. Then, apply a wetting concentration of 8 oz. of Lonza Formulation L-15 per gallon of water (1 part Lonza Formulation L-15 to 15 parts water).

MOLD AND MILDEW CONTROL: Follow directions for hospital disinfection. Repeat treatment every 7 days or when new growth appears.

Barber and Beauty Instrument and Tool Directions:

Use 2 ½ oz. of Lonza Formulation L-15 per gallon of water. Completely immerse pre-cleaned brushes, combs, scissors, clipper blades, razors, manicure implements, and other nonporous instruments so those surfaces remain wet for 10 minutes. Rinse thoroughly and dry before use. Change solution daily or more often if solution becomes visibly diluted 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.

Directions for Food Processing Plants: Use on non-food contact surfaces such as floors, walls, tables, garbage cans and disposal areas. Before using this product, food products and packaging materials must be removed or carefully protected. Then follow the "Disinfection Directions".

Directions for Food Storage Areas: Use on non-food contact surfaces such as shelves, floors, walls and tables. Before using this product, food products and packaging materials must be removed or carefully protected. Then follow the "Disinfection Directions".

Farm Premise Use:

Remove all animals and feed from premises, vehicles and enclosures. 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. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with a use-solution of 5 oz. of LONZA FORMULATION L-15 per gallon of water (or equivalent dilution) for a period of 10 minutes. 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. Ventilate buildings, cars, boats and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

DEC 8 2003

Registered under EPA Reg. No. 6836-164

Veterinary Practice / Animal Care / Animal Laboratory / Zoos / Pet Shop / Kennels Disinfection Directions: For cleaning and disinfecting hard nonporous surfaces including equipment, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 5 oz. of **LONZA FORMULATION L-15** per gallon of water (or equivalent dilution) for a period of 10 minutes. 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. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all feeding and watering equipment with soap or detergent and rinse with potable water before reuse.

(If container size is one gallon or less, use the following Storage and Disposal statements:)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not reuse empty container. Wrap and discard in trash or recycle.

(If container size 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

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls.

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 of 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 of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

DEC 8 2003

6836-164

