

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

JAN - 4 2001

Subject: Bio-Guard L-15
EPA Registration No. 6836-164
Amendment Date: 10/16/00
EPA Receive Date: 10/18/00

Attention: Ms. Christina Swick,
Agent for Lonza

The amendment, referenced above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A) to add additional organisms, change the signal word, and primary brand name is acceptable provided the following label changes are addressed before this product is released for shipment.

1. Lonza Formulation L-15 is acceptable as this product's new primary brand name.
2. Lonza Formulation L-15 is substantially similar to Lonza Formulation L-7,6836-165, which is categorized as I for primary eye irritation based on the May 15, 2000 acute toxicology data evaluation. According to PR Notice 2000-3, "A Note to Physician" section is required on products that are considered corrosive or toxicity category I for eye or skin. This section must be added to the label appearing below the "First Aid" statements.
3. The surface, "tiles," must be qualified as hard, non-porous by stating "glazed tiles." This change needs to occur on page 2: left and right columns, 5th paragraphs and on page 3: left column, 1st paragraph. Also, the surface, "stone", must be deleted because it is considered to be a porous surface.
4. The heading, "Instruments and Tools," must be revised to state "Barber and Beauty Instruments and Tools."

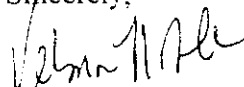
CONCURRENCES

SYMBOL	780C						
SURNAME	Campbell						
DATE	1/03/01						

- 5. Under the Veterinary Practice/Animal Care/Animal Laboratory, the following statement must be added as the last sentence in this section, "Thoroughly scrub all feeding and watering equipment with soap or detergent, and rinse with potable water before reuse."

A stamped label is enclosed for your records. Please submit two (2) copies of the final printed label before you release this product for shipment. If you have any questions regarding this letter, please contact Jacqueline Campbell at (703) 308-6416.

Sincerely,



Velma Noble

Product Manager (31)

Regulatory Management Branch I

Antimicrobials Division (7510C)

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 rubber gloves when handling. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

FIRST AID

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention
IF ON SKIN: Wash with plenty of soap and water. Get medical attention if skin irritation persists.
IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger, or if available by administering syrup of ipecac. If person is unconscious, do not give anything by mouth and do not induce vomiting.
Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

(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.

(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.

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%
Inert Ingredients	96.00%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

ADVERTENCIA:

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

SEE LEFT / SIDE / RIGHT / BACK PANEL FOR PRECAUTIONARY STATEMENTS

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

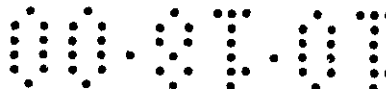
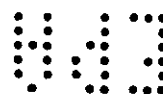
with COMMENTS

in EPA Letter Dated:

JAN 4 - 2001

Under the Federal Insecticide, Fungicide, and Rodenticide Act as

amended, for the pesticide, registered under EPA Reg. No. 6836-164



This product contains no phosphorous.

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, 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 recoat.

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.

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 kills household germs; effective against harmful *Pseudomonas aeruginosa* (pseudomonas), *Staphylococcus aureus* (staph) 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, 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.

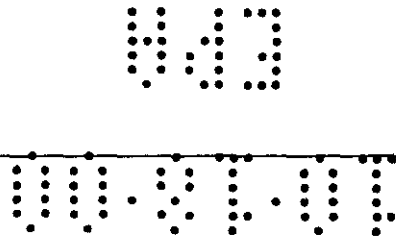
Lonza Formulation L-15 is recommended for use on conductive flooring. For other specialized cleaning and disinfecting operations, consult your local (Company) representative.

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.

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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 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, stone 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 precleaned surfaces at 2-1/2 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:

- Pseudomonas aeruginosa
- Salmonella choleraesuis
- Staphylococcus aureus
- Enterobacter aerogenes
- Escherichia coli
- Shigella sonnei
- Streptococcus pyogenes

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

- Aspergillus niger
- Candida albicans

DIRECTIONS FOR USE

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.

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DISINFECTION/VIRUCIDAL/MOLD AND MILDEW CONTROL DIRECTIONS:

PREPARATION OF USE-SOLUTION:

Hospitals, Nursing Homes, Veterinary clinics, and other Medical facilities: Use 5 oz. of Lonza Formulation L-15 per 1-1/2 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 2-1/2 oz. Lonza Formulation L-15 per gallon of water (1 part Lonza Formulation L-15 to 50 parts water).

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.

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

For precleaned surfaces, use 2 oz. of Lonza Formulation L-15 per 1-1/3 gallons of water (1 part Lonza Formulation L-15 to 87 parts water).

To clean and disinfect in one operation use 5 oz. of Lonza Formulation L-15 per 1-1/2 gallons of water (1 part Lonza Formulation L-15 to 39 parts water).

TO DISINFECT:

Apply the use-solution to 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.

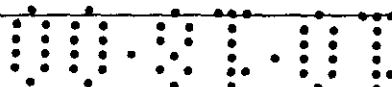
Treated surfaces must remain wet for 10 minutes. Wipe dry with a clean cloth or sponge or let air dry.

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.

FOR DEODORIZING GARBAGE CANS, GARBAGE TRUCKS INDUSTRIAL WASTE RECEPTACLES AND GARBAGE HANDLING EQUIPMENT: It is especially important to preclean 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.



***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.

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.

Instrument and Tool Directions:
 Use 2 1/2 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.

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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.

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. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

