



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 28, 2019

Jennifer DePietro
Regulatory Affairs Associate
Lonza Inc.
412 Mount Kemble Ave., Suite 200S
Morristown, NJ 07960

Subject: Notification per PRN 98-10 – Minor label modifications
Product Name: Lonza Formulation DC-103
EPA Registration Number: 6836-152
Application Date: November 16, 2018
Decision Number: 546489

Dear Ms. DePietro:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you have any questions, you may contact Tara Flint via email at flint.tara@epa.gov or Eric Miederhoff at Miederhoff.eric@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "E. Miederhoff".

Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Note to Reviewer:

[Items in brackets [AAA] are optional and may/may not be included on final label]

{Items in braces {AAA} are for information purposes and will not appear on final label}

LONZA FORMULATION DC-103

NOTIFICATION

6836-152

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

01/28/2019

One-Step Disinfectant

Cleaner – Fungicide – Mildewstat – Virucide* – Deodorizer
For Homes, Restaurants, Hospitals, Institutional and Industrial Use

Effective in the presence of 5% serum contamination

Fresh / Clean / Mild / Lemon / Pine / Mint / Floral / Citrus [scent] [fragrance] [scented] [odor]

- Formulated for Effective Farm Premise Sanitation
- Formulated for Effective Poultry Premise Sanitation
- Formulated for Effective Swine Premise Sanitation
- Formulated for Effective Mushroom Farm Sanitation
- Formulated for Veterinary Practice / Animal Care / Animal Laboratory Disinfection
- For use in federally inspected meat and poultry plants

• Staphylocidal • Pseudomonacidal • Bactericidal • Salmonellacidal • Fungicidal • Virucidal*

Active Ingredients:

Octyl decyl dimethyl ammonium chloride.....	0.025%
Dioctyl dimethyl ammonium chloride.....	0.010%
Didecyl dimethyl ammonium chloride.....	0.015%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride.....	0.034%
Other Ingredients	99.916%
Total	100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION [PRECAUCIÓN]

See [left] [side] [right] [back] panel for Precautionary Statements and First Aid

EPA Reg. No. 6836-152

EPA Establishment No. *(insert EPA Est. No. here)*

Net Contents *(insert container size here)*

[DOT Symbols]

[Country of origin *(insert country)*]

[Manufactured in *(insert country)*]

[Barcode]

[\$X.XX] [XX¢]

Manufactured by:

LONZA INC.

412 Mount Kemble Avenue

Suite 200S

Morristown, NJ 07960

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Caution. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

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.

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

{Note to reviewer: If container size is 5 gallons or larger, the following Environmental Hazards statements will be used:}

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.

{Note to reviewer: Pages 3-8 are considered optional marketing language.}

- Citrus Scent
- Cleans [Cleaner]
- [Convenient] Ready To Use formula.
- Deodorizes [Deodorant]
- Disinfects [Disinfectant]
- [Economical] [Spray & Wipe] formula.
- Fresh Mild Scent
- Kitchen, Bathroom, Household Disinfectant Cleaner.
- Ready-to-Use
- This product contains no [phosphates] [or] [phosphorous] [compounds].
- [Trigger] [Pump] spray[er]

Lonza Formulation DC-103

- can be used with a mop and bucket, trigger sprayers, sponge or by soaking.
- cleans, disinfects and deodorizes in one labor saving step.
- Cuts [through] [tough] grease and grime.
- delivers non-acid disinfectant and cleaning performance.
- deodorizes by killing microorganisms that cause offensive odors.
- [improves labor results by] effectively controls [controlling] malodors.
- Inhibits [the growth of] [mold] [and] [mildew]
- is a complete, chemically balanced disinfectant.
- is a versatile disinfectant for hard, nonporous nonfood contact surfaces in Veterinarian, Animal care and Farm Premise applications.
- is a [versatile] cleaner and broad spectrum disinfectant formulated for use only on non-critical instruments in Ultrasonic Baths [Ultrasonic cleaning units].
- is a mildewstat and will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard nonporous surfaces.
- is a [one-step] [Hospital Use] disinfectant cleaner that is effective against a broad spectrum of bacteria, is virucidal* [including HIV-1, the AIDS Virus and Hepatitis B Virus and Hepatitis C virus], fungicidal, and inhibits the growth of mold and mildew, and their odors, when used as directed.
- is effective yet economical.
- is effective at controlling mold and mildew odor on mattresses, pillows and shower curtains. **{Not for use in California}**
- is formulated for use in daily maintenance programs with a balance of detergents and malodor counteractants that deliver effective cleaning, disinfecting and malodor control.
- meets AOAC testing standards for hospital disinfectants.
- [Kills] [Eliminates] [Removes] [Destroys] [is effective against] avian influenza A (H3N2) [and] (H5N1) on pre-cleaned environmental surfaces
- [Kills] [Eliminates] [Removes] [Destroys] [is effective against] (*Insert pathogen or pathogens from lists on pages 7-8*) on [pre-cleaned] environmental surfaces
- [Kills] [Eliminates] [Removes] [Destroys] [is effective against] [Germs] [Bacteria] [Viruses*] [on [pre-cleaned] environmental surfaces]
- kills household germs; effective against *Pseudomonas aeruginosa* [Pseudomonas], *Staphylococcus aureus* [Staph] and *Streptococcus pyogenes* [Strep], Influenza A / Brazil [influenza] and Trichophyton mentagrophytes [Athlete's foot fungus] [A cause of Ringworm].
- Kills odor-causing bacteria.
- leaves [your house with] a [clean] [fresh] scent.
- provides long lasting freshness against tough [pet] odors such as odors from litter boxes and pet accidents.
- Removes soap scum
- will disinfect, clean and deodorize hard, non-porous surfaces in rest rooms and toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause malodors.
- will not leave grit or soap scum.

- Formulated for effective farm, poultry, and swine premise and veterinary practice.
- Broad spectrum kill of bacteria.
- Effective against *Aspergillus fumigatus*
- Effective against [Carbapenem-resistant Enterobacteriaceae] [CRE], including:
 - *Enterobacter cloacae* NDM-1
 - *Escherichia coli* – NDM-1 positive
 - *Klebsiella pneumoniae* – NDM-1 positive

Soft Surface Claims

- (proven) (effective) soft surface sanitizer[†]
 - (proven) (effective) for use on soft surfaces[†]
 - (proven) (effective) on fabric surface(s)[†]
 - For use on (soft surfaces) such as [insert from soft surface use sites]
 - One step sanitizer for soft surfaces[†]
 - One step sanitizer for fabric surface(s)[†]
 - Sanitizes soft surfaces (in 5 minutes)[†]
 - Sanitizes fabric surfaces (in 5 minutes)[†]
 - Is a proven soft surface sanitizer against: [†]
 - *Staphylococcus aureus*
 - *Enterobacter aerogenes*
- † Spot treatment of soft surfaces

{Note to Reviewer: These statements for claims against large non-enveloped, and/or enveloped emerging viral pathogens shall not appear on marketed (final print) product labels.}

This product qualifies for emerging viral pathogen claims per the EPA's "Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels".

[Lonza Formulation S-103] has demonstrated effectiveness against viruses similar to **[Feline calicivirus (surrogate for Norwalk virus)]** on hard, nonporous surfaces. Therefore, **[Lonza Formulation S-103]** can be used against **[name of large, non-enveloped or enveloped emerging viral pathogen]** when used in accordance with the directions for use against **[Feline calicivirus (surrogate for Norwalk virus)]** on hard, non-porous surfaces. Refer to the **CDC or OIE** website at **[pathogen-specific website address]** for additional information.

[Name of illness/outbreak] is caused by **[name of large, non-enveloped or enveloped emerging viral pathogen]**. **[Lonza Formulation S-103]** kills similar viruses and therefore can be used against **[name of emerging viral pathogen]** when used in accordance with the directions for use against **[Feline calicivirus (surrogate for Norwalk virus)]** on hard, non-porous surfaces. Refer to the **[CDC or OIE]** website at **[website address]** for additional information.

Use Lonza Formulation DC-103

- as a disinfectant on hard, nonporous surfaces.
- for Poultry Premise Sanitation [Hatcheries] of hard nonporous surfaces in: Egg Receiving Area, Egg Holding Area; Setter Room, Tray Dumping Area, Trays, Buggies, Racks, Egg Flats, Chick Holding Room, Hatchery Room, Chick Processing Area, Chick Loading Area, Poultry Buildings, Ceilings, Sidewalls and Floors, Drinkers and other Poultry House related equipment, and all other hard nonporous surfaces in the Hatchery environment.
- for Swine Premise Sanitation of hard nonporous surfaces: Waterers and Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns and areas, Nursery blocks, Creep area, Chutes.
- for Farm Premise Sanitation of hard nonporous surfaces: floors, walls, feed racks, mangers, troughs, automatic feeders, fountains and waterers, forks, shovels, scrapers and other nonporous surfaces in barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals.
- in federally inspected Meat & Poultry Plants as a disinfectant on all surfaces in inedible product processing areas, nonprocessing areas and / or exterior areas. This product was authorized by USDA as category D1 under the prior authorization program and its formula has not been changed.
- in kitchens, bathrooms and other household areas.
- in the laundry to control odors on musty bedding and linens. Test on a small inconspicuous area before using. **{Not for use in California}**
- in work areas such as tool rooms and garages for odor control and light duty cleaning.
- for disinfecting of ultrasound transducers, probes, mammography compressor plates and other hard nonporous surfaces.
- for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures and toilet bowls.
- on coils and drain pans of air conditioning and refrigeration equipment and heat pumps. Follow the directions for disinfection.
- [on] [to clean and disinfect] nonporous personal protective safety equipment, wrestling headgear, boxing headgear, protective headgear, athletic helmets, hard hats, half mask respirators, full face breathing apparatus, gas masks, goggles, spectacles, face shields, hearing protectors, and ear muffs. Rinse all equipment that comes in prolonged contact with skin with warm water and allow to air dry before reuse. [Precaution: Cleaning at 120°F temperature will avoid overheating and distortion of the personal safety equipment that would necessitate replacement.]
- [on] [to clean and disinfect] nonporous athletic mats, wrestling mats, gymnastic mats, exercise equipment and training tables.
- on mildew stains in damp areas such as bathrooms, showers, kitchens, basements and laundry rooms.
- to clean and disinfect finished floors, sinks and tubs.
- to clean and disinfect finished floors. Can be applied with damp mop or autoscrubber. Cleans and disinfects without dulling gloss.
- to clean and disinfect nonporous salon / barber tools and instruments: combs, brushes, scissors, blades and manicure instruments.
- to clean and disinfect nonporous fire fighting bunker / turnout gear; trousers; overcoats, gloves, boots, hoods, helmets, air masks.
- to clean and disinfect tables, chairs, and countertops
- to remove odors caused by flooding and smoke from fires.
- with a mop and bucket, trigger sprayer, sponge or by soaking.

Cross-contamination is of major housekeeping concern. **Lonza Formulation DC-103** has been formulated to aid in the reduction of cross-contamination on treated surfaces in not only in hospitals, but in schools, institutions and industry.

Lonza Formulation DC-103 is a phosphate free, germicidal detergent effective in the presence of a moderate amount of organic soil on hard nonporous surfaces found at mushroom farms. **Lonza Formulation DC-103** has been designed for use between mushroom crops. Areas of intended use include breezeways and track alleys before spawning, inside and outside walls of mushroom houses, lofts, floors, storage sheds and casing rings. Use of **Lonza Formulation DC-103** must be limited to areas where compost and mushrooms are not present.

Cleaning claims:

- Clean[s] to a [virtually streak free] shine
- [Clear drying] [formula] for multiple surfaces
- [Dissolves] [Cleans] [Removes] [Eliminates] dirt and soils
- Eliminates dirt [and][soils]
- Fast drying, leaves no [dull][or][sticky] residue
- [Tested] for [use on] automotive surfaces
- Use on hard, nonporous surfaces: [plastic], [vinyl], [metal], [glass], [painted surfaces]
- Won't leave [a] [greasy] residue

Disinfecting claims:

- As [a] [the] leader in [automotive] [car] care, (*insert company name*) delivers this Disinfecting [Spray] [Cleaner] [Product] to give you the power of cleaning and disinfecting [in one easy step]
- Cleans and disinfects [in one easy step]
- Disinfecting Auto [Spray][Cleaner]
- Kills 99.9% of bacteria and viruses*
- Kills 99.9% of germs and bacteria, including the Flu Virus*, while cleaning [your] [dash], [steering wheel], [vinyl], [glass] [and more] to a virtually streak free finish
- Kills the Flu Virus¹ (¹On hard, nonporous surfaces)
- The interior of your vehicle is not only susceptible to dirt and dust, but can also harbor germs, [especially during Flu season]

Scent Names

<i>{Note to reviewer: each block below also represents a graphic depicting the corresponding scent with the exception of citrus, apple, and berries, which will be submitted to the Agency for review.}</i>	
• Cool Mist [Scent]	• New Car [Scent]
• Eucalyptus Pine [Scent]	• Orange [Scent]
• Fresh Lavender [Scent]	• Pure Linen [Scent]
• Fresh Outdoors [Scent]	• Vanilla [Scent]
• Fresh Scent	• Warm Apple Spice [Scent]
• Island Retreat [Scent]	• Wild Berry [Scent]
• Mountain Air [Scent]	

Odor Controlling Claims

- Mold Odor Destroyer
- Continuous Odor Removal
- Destroys [mold] odors at the source.
- Doesn't just mask odors, it eliminates them.
- Eliminates smoke [pet] [mold] odors.

Other claims:

- XX% More than the YY[oz][mL] Size
- 100% satisfaction guaranteed or your money back. If you are unsatisfied for any reason, contact us for a full refund.
- As [a] [the] leader in quality car care, (*insert company name*) absolutely guarantees its products will meet or exceed your highest standards.
- Visit our website for additional products and product information.
- Questions [or Comments]? [Please][Visit] (*insert website*) [or] [Call] (*insert phone #*)
- Made in U.S.A.
- Value [Pack] [Size]
- Bonus [Pack] [Size]

[AREAS OF USE:]

Use **Lonza Formulation DC-103** in:

{Note to reviewer: Each entry below also represents a graphic depicting the corresponding area of use. The graphics will only represent individual objects or outsides or insides of buildings as described below. No people, animal or food will be depicted in graphics.}

Bathrooms
Homes [Households]
Kitchens

Clinics
Dental offices
Health Care Facilities
Hospitals
Medical Offices
Medical Related facilities
Nursing homes
Sick Rooms

Day care centers
Nurseries

Bars
Cafeterias
Convenience stores
Food processing plants
Food storage areas
Institutional kitchens
Restaurants [Front of House]
USDA inspected food processing facilities

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,
Schools
Shower and bath areas
Salons [Beauty] [Tanning]

Camp grounds
Play ground equipment

Animal laboratories
Dairy farms
Farms
Hog farms
Kennels
Mushroom Farms
Poultry farms
Pet animal quarters
Pet shops
Turkey farms
Zoos

Airplanes
Airports
Ambulances
Boats
Buses
Campers
Cars
Emergency [Police] [EMS] [Fire] [Rescue] vehicles

Mobile homes
Ships
Taxis
Trailers
Trains
Transportation terminals

[TYPES OF SURFACES:]

Use **Lonza Formulation DC-103** on washable hard, nonporous surfaces of:

{Note to reviewer: Each entry below also represents a graphic depicting the corresponding type of surface. No people, animal or food will be depicted in graphics. Only exteriors of microwaves and refrigerators will be depicted. Toy graphics will be submitted to Agency for review.}

Appliances, exteriors	Urinals
Bathroom fixtures	Walls
Bathtubs [fiberglass]	Whirlpool [bathtubs] [tubs] [units]
Cabinets	
Cages	Non-critical medical device surfaces:
Chairs	Beds [Medical] [Hospital]
Coils and drain pans of air conditioning and refrigeration equipment and heat pumps	Bed frames
Conductive flooring	Bed rails
Counters [Countertops]	Crutches
Countertop laminates	Defibrillators
Desks	Gurneys
Doorknobs	Non-critical [hospital] [medical] equipment surfaces:
Floors	[Medical] Examining tables
Garbage cans	[Medical] [Hospital] Lamps
Highchairs	Rescue tools
Kennel runs	Resuscitators
Microwave ovens, exteriors	[Medical] [Hospital] Scales
Outdoor [patio] furniture except cushions and wood frames	Stands
Refrigerators, exteriors	Stretchers
Refrigerated storage and display equipment	Stethoscopes
Showers	Walkers
Shower stalls	Wheel chairs
[Fiberglass] Shower stalls	Other hard nonporous surfaces made of:
[Fiberglass] Sinks [bathroom] [kitchen]	Glazed ceramic
Sinks [bathroom] [kitchen]	Glazed enameled surfaces
Stoves [stovetops]	Glazed porcelain
Tables, [Non-wooden picnic tables]	Laminated surfaces
Telephones	Metal
Toilets	Plastic [such as polystyrene or polypropylene]
Toilet bowls	Sealed stone
Toilet bowl surfaces	Stainless steel
Tubs [Fiberglass]	Upholstery, vinyl and plastic
Tiles, glazed	Woodwork, finished
Ultrasonic baths	

Use on [washable] hard, non-porous surfaces of:

[interior] [dashboard]	[seats]	side view mirror[s]
[instrument panel]	[painted surfaces]	seat belt buckle[s]
[gauges]	[stick][gear] shift	carbon fiber
[steering wheel]	[car][center] console cup holder[s]	fiberglass
[window[s]]	turn signal	change holder
[doors]	switch gear	window crank[s]
[door handles]	rear view mirror[s]	dashboard
Soft (household) surfaces		
Upholstery	(upholstered) furniture	(Fabric) Hamper(s)
Fabric	(fabric) Window treatment(s),	(Fabric) (Dog) (Pet) Bedding,
(upholstered) Couches(es),	Curtain(s), Draperies, Shower	Blankets
Sofa(es) Chair(s), seat cushion(s)	curtain(s)	(fabric) (upholstered) (car) seat(s)
(upholstered) cushions(s),	(fabric) (Gym) (Laundry) (diaper)	(fabric) stuffed animal(s), toy(s)
pillow(s)	Bags, back pack(s)	

{Note to reviewer: ATCC numbers are listed on the data matrix.}

Lonza Formulation DC-103 is a [one-step] [Hospital use] disinfectant, Bactericidal according to the current AOAC Use-Dilution Test Method, Fungicidal according to the AOAC Fungicidal Test and Virucidal* according to the virucidal qualification modified in the presence of 5% organic serum against:

{or}

As a disinfectant, **Lonza Formulation DC-103** [kills] [is effective against]:

[Bacteria:]

Pseudomonas aeruginosa [Pseudomonas]

Salmonella enterica [Salmonella]

Staphylococcus aureus [Staph]

Acinetobacter baumannii [Acinetobacter]

Burkholderia cepacia

Campylobacter jejuni [Campylobacter]

Corynebacterium ammoniagenes

Enterobacter aerogenes

Enterobacter cloacae NDM-1

Enterococcus faecalis [Enterococcus]

Enterococcus faecalis - Vancomycin resistant [VRE]

Escherichia coli [E. coli]

Escherichia coli, New Delhi Metallo-Beta Lactamase (NDM-1)

ESBL Escherichia coli [Extended spectrum beta-lactamase producing E. coli]

Klebsiella pneumoniae [Klebsiella]

Klebsiella pneumoniae – NDM-1 positive

Legionella pneumophila

Listeria monocytogenes [Listeria]

Salmonella schottmuelleri [Salmonella]

Salmonella typhi [Salmonella]

Serratia marcescens

Shigella dysenteriae [Shigella]

Staphylococcus aureus - Community Associated Methicillin-Resistant [CA-MRSA] [NRS384] [USA300]

Staphylococcus aureus - Community Associated Methicillin-Resistant [CA-MRSA] [NRS123] [USA400]

Staphylococcus aureus - Methicillin-Resistant [MRSA]

Staphylococcus aureus Multi-Drug Resistant [resistant to tetracycline [Tc], penicillin [Pc], streptomycin [Sm] and erythromycin [Em] and susceptible to chloramphenicol [Cm] *in vitro*]

Staphylococcus aureus - Vancomycin Intermediate Resistant – [VISA]

Streptococcus pyogenes [Strep] [a cause of scarlet fever]

Vibrio cholerae

[Viruses:]

*Hepatitis B Virus [HBV]

*Hepatitis C Virus [HCV]

*Herpes Simplex Virus Type 1

*Herpes Simplex Virus Type 2

*HIV-1 [AIDS Virus]

*Human Coronavirus

*Influenza Virus Type A / Brazil [Influenza]

*Influenza Virus Type A / Hong Kong [Influenza]

*2013 Influenza A Virus (H7N9)

*Respiratory Syncytial Virus [RSV]

*SARS Associated Coronavirus [SARS] [cause of Severe Acute Respiratory Syndrome]

*Vaccinia [Pox Virus]

{Note to reviewer: the following are non-enveloped viruses :}

*Norwalk Virus [Feline Calicivirus] [Norovirus]

*Rotavirus

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. This product [*Product Name*] is a broad-spectrum hard surface disinfectant that has been shown to be effective against (*influenza A virus tested and listed on the label*) and is expected to inactivate influenza A viruses including Pandemic 2009 H1N1 [formerly called swine flu].
- This product has demonstrated effectiveness against influenza A virus and is expected to inactivate influenza A viruses including Pandemic 2009 H1N1 influenza A virus.
- This product has demonstrated effectiveness against (*influenza A virus tested and listed on the label*) and is expected to inactivate influenza A viruses including Pandemic 2009 H1N1 [formerly called swine flu].
- Kills Pandemic 2009 H1N1 influenza A virus [formerly called swine flu].
- Kills Pandemic 2009 H1N1 influenza A virus.

Lonza Formulation DC-103 [kills] [is effective against] [the following animal viruses:]

Avian Infectious Bronchitis Virus

Avian Influenza [virus] (H3N2)

Avian Influenza [virus] (H5N1)

Canine Distemper Virus

Feline Calicivirus

Murine Norovirus

Newcastle's Disease Virus

Pseudorabies Virus

[Fungi:]

Aspergillus niger

Aspergillus fumigatus

Trichophyton mentagrophytes [the Athlete's Foot Fungus] [A Cause of Ringworm] [A Cause of Ringworm of the foot]

*{If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.}
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. [If you do not understand the label, find someone to explain it to you in detail.]*

DIRECTIONS FOR USE

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

Before use in federally inspected meat and poultry food processing plants and dairies, food products and packaging materials must be removed from the room or carefully protected.

DISINFECTION / VIRUCIDAL* / FUNGICIDAL / MOLD & MILDEW CONTROL DIRECTIONS:

Apply **Lonza Formulation DC-103** undiluted to hard, nonporous surfaces, thoroughly wetting the surfaces with a cloth, mop, sponge, sprayer or by immersion. Treated surfaces must remain wet for 10 minutes. *{Note to reviewer: if using reduced contact time for Influenza Virus Type A and/or Human Coronavirus, the following sentence will be required:}* **[For [Influenza Virus Type A] [and] [Human Coronavirus]**, treated surfaces must remain wet for 1 minute.] Wipe dry with a cloth, sponge or mop or allow to air dry. For heavily soiled areas, a preliminary cleaning is required.

For sprayer applications, use a coarse spray device. Spray 6 - 8 inches from surface; rub with brush, sponge or cloth. Avoid breathing spray.

Rinse all surfaces that come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes.

For fungicidal activity: Lonza Formulation DC-103 is an effective one-step fungicide against Trichophyton mentagrophytes when used on hard nonporous surfaces in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities. Allow surface to remain wet for 10 minutes.

For mold and mildew: Repeat treatment every 7 days or more often if new growth appears.

{Note to reviewer: Alternate directions for products sold in spray bottles:}

DISINFECTION / *VIRUCIDAL / FUNGICIDAL / MOLD & MILDEW CONTROL DIRECTIONS:

Spray 6 - 8 inches from hard, nonporous surface, until surfaces are thoroughly wet. Do not breathe spray. Treated surfaces must remain wet for 10 minutes. *{Note to reviewer: if using reduced contact time for Influenza Virus Type A and/or Human Coronavirus, the following sentence will be required:}* **[For [Influenza Virus Type A] [and] [Human Coronavirus]**, treated surfaces must remain wet for 1 minute.] Wipe dry with a clean cloth, sponge, or mop or allow to air dry. For heavily soiled areas, a pre-cleaning is required.

or

[To Disinfect:] Spray 6-8 inches from the hard, nonporous surface, until surface is thoroughly wet. [Do not breathe] [Avoid breathing] spray. Let stand 10 minutes. *{Note to reviewer: if using reduced contact time for Influenza Virus Type A and/or Human Coronavirus, the following sentence will be required:}* **[For [Influenza Virus Type A] [and] [Human Coronavirus]**, treated surfaces must remain wet for 1 minute.] Wipe dry with a clean cloth or sponge or allow to air dry. For heavily soiled areas, a pre-cleaning is required.

Rinse all surfaces that come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes.

For fungicidal activity: Lonza Formulation DC-103 is an effective one-step fungicide against Trichophyton mentagrophytes when used on hard nonporous surfaces in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities. Allow surface to remain wet for 10 minutes.

For mold and mildew: Repeat treatment every 7 days or more often if new growth appears.

{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 pre-clean 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-1 AND HBV AND HCV 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] or Hepatitis B Virus [HBV] or Hepatitis C Virus [HCV].

Special Instructions for Cleaning and Decontamination against HIV-1 or HBV or HCV on Surfaces / Objects Soiled With Blood / Body Fluids.

Personal Protection: Clean-up **should must** always be done wearing protective gloves, gowns, masks and eye protection.

Cleaning Procedure: Blood and other body fluids containing HIV or HBV or HCV must be thoroughly cleaned from surfaces and objects before application of **Lonza Formulation DC-103**.

Contact Time: Leave surface wet for 1 minute [60 seconds] for HIV-1 and 10 minutes for HBV and HCV. 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 must** be autoclaved and disposed of according to local regulations for infectious waste disposal.

NON-ACID TOILET BOWL AND URINAL DISINFECTANT / CLEANER DIRECTIONS:

Remove gross filth prior to disinfection.

Empty toilet or urinal and apply **Lonza Formulation DC-103** to exposed surfaces and under the rim with a cloth, mop, sponge, or sprayer. Brush or swab thoroughly, allow to stand for 10 minutes, and flush.

SALON [BARBER] INSTRUMENTS AND TOOLS DISINFECTION [BACTERICIDE] / [VIRUCIDE*] / [FUNGICIDE] DIRECTIONS:

Use **Lonza Formulation DC-103** undiluted to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, plastic rollers, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Use fresh product daily or more often if product becomes 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.

ULTRASONIC BATH DISINFECTANT [/ VIRUCIDAL*] DIRECTIONS:

Use **Lonza Formulation DC-103** to disinfect hard nonporous non-critical objects compatible with Ultrasonic cleaning units. Pour **Lonza Formulation DC-103** directly into bath chamber. Pre-clean heavily soiled objects. 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. Use fresh product for each use.

DISINFECTION OF WHIRLPOOL UNITS: After using the whirlpool unit, drain, and fill with **Lonza Formulation DC-103** to just cover the intake valve. 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 cleaned, drain the solution from the unit and rinse cleaned surfaces with fresh water. Repeat for heavily soiled units.

FOR USE ON FINISHED FLOORS: Apply with a damp mop or autoscrubber. Allow surface to remain wet for 10 minutes. Wipe or allow to air dry.

["SPECIAL INSTRUCTIONS FOR INACTIVATING AVIAN INFLUENZA"; ~~EMERGING VIRAL PATHOGENS~~ AND OTHER ANIMAL VIRUSES LISTED ON THIS LABEL]

{or}

[VETERINARY [PRACTICE]] [FACILITIES] / [ANIMAL CARE] [FACILITIES] / [ANIMAL LABORATORY] [FACILITIES] / [ZOOS] / [PET SHOPS] / [KENNELS] DISINFECTION [/ VIRUCIDAL*] DIRECTIONS:

For cleaning and disinfecting hard nonporous surfaces: equipment used for feeding or watering animals, utensils, instruments, cages, kennels, stables, catteries, pens, stalls and etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, pens, stalls and etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with **Lonza Formulation DC-103** for a period of 10 minutes. Wipe or allow to air dry. 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. Thoroughly scrub all treated surfaces, then rinse all surfaces that come in contact with food, including equipment used for feeding or watering, with potable water before reuse. Ventilate buildings, animal enclosures, [vehicles] and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

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 **Lonza Formulation DC-103** 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, trucks, 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.

SMALL ANIMAL [HOUSING] [CAGE], [KENNEL] [AND CRATE] DISINFECTION / VIRUCIDAL* DIRECTIONS:

1. Remove all animals and feeds from kennel, crate, cage, carryalls.
2. Remove all litter and animal droppings. Thoroughly clean all hard, nonporous surfaces with soap or detergent and rinse with water. Empty all feeding and watering appliances.
3. [Apply **Lonza Formulation DC-103** to surfaces with a cloth, mop, sponge or coarse sprayer until thoroughly wet.] [Spray **Lonza Formulation DC-103** onto surfaces until thoroughly wet.] Immerse animal handling and cleaning equipment; such as leashes, muzzles and scrapers. Treated surfaces must remain wet for 10 minutes, then wipe or allow to air dry.
4. Rinse all surfaces that come in contact with food including animal feeding devices, bowls or dishes with potable water prior to reuse.
5. Do not re-introduce or house animals until treatment has been absorbed, set or dried.

REPTILE TANK CLEANING AND DISINFECTION DIRECTIONS:

Remove all reptiles from the enclosure [tank] prior to cleaning and disinfecting. Remove all litter or droppings from surfaces. Empty all equipment used for feeding or watering reptiles. Thoroughly clean all hard, nonporous surfaces with soap or detergent and rinse with water. Apply **Lonza Formulation DC-103** to the surfaces of the enclosure [tank] until thoroughly wet. Allow surfaces to remain wet for 10 minutes. Wipe dry using a clean cloth or sponge or paper towel. Rinse all surfaces that come in contact with food, including equipment used for feeding or watering, with potable water before reuse. Allow the [enclosure] [tank] to ventilate for a minimum of 10 - 15 minutes before replacing the reptiles.

DO NOT apply **Lonza Formulation DC-103** directly onto the reptile. If **Lonza Formulation DC-103** comes into contact with the reptile's skin, then immediately wash the material off of the animal with lukewarm water. If the reptile ingests **Lonza Formulation DC-103**, contact your veterinarian immediately.

POULTRY AND SWINE PREMISE DISINFECTION [/ VIRUCIDAL*] DIRECTIONS:

Remove all animals and feeds from premises, vehicles, and enclosures such as coops and crates. Remove all litter, droppings 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 surfaces with **Lonza Formulation DC-103** for 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, trucks, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

Hatcheries: Use **Lonza Formulation DC-103** undiluted to treat the following hard nonporous surfaces: hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces wet for 10 minutes or more. Then allow to air dry.

Vehicles: Treat all vehicles including mats, crates, cabs and wheels with water and **Lonza Formulation DC-103**. Use **Lonza Formulation DC-103** undiluted to treat all vehicles. Leave all treated surfaces wet for 10 minutes or more. Wipe dry with a clean cloth or sponge or allow to air dry.

Shoe Bath Disinfectant Directions: To prevent cross contamination into animal areas, shoe baths containing one inch of product must be placed at all entrances to buildings and hatcheries. Scrape waterproof work boots and place in bath for 10 minutes prior to entering area. Change the bath daily or more often if solution appears diluted or soiled.

Dressing Plant Disinfectant Directions: Disinfect equipment, utensils, walls and floors in poultry and animal dressing plants. Disinfect offal rooms, exterior walls and loading platforms of dressing plants. Cover or remove all food and packaging materials. Remove all heavy soils prior to application. Saturate all surfaces with **Lonza Formulation DC-103**. Scrub to loosen all soils. Surfaces must remain wet for 10 minutes, and then thoroughly rinsed with potable water before operations are resumed. Allow to air dry.

MUSHROOM FARM PREMISE USE:

Site Preparation: The first step in any on-going sanitation program must be the removal of gross contamination and debris. This may be accomplished by using a shovel, broom, or vacuum, depending on the area to be disinfected.

Cleaning and Disinfection: For general cleaning and disinfection, apply **Lonza Formulation DC-103** with a cloth, mop, sponge, sprayer or by immersion to thoroughly wet the surfaces. Treated surfaces must be allowed to remain wet for 10 minutes. Wipe or allow to air dry. For heavily soiled areas, pre-clean first. Use fresh product for each use or more often if product becomes visibly diluted, clouded or soiled.

DO NOT APPLY USE-SOLUTION TO THE MUSHROOM CROP, COMPOST OR CASING. Rinse treated surfaces with potable water before they contact the crop, compost or casing.

TO CLEAN AND DEODORIZE: Apply undiluted to surfaces with a cloth, mop, sponge or sprayer. Wipe or allow to air dry.

{or}

Spray directly on surface to be cleaned. Wipe or allow to air dry.

TO SANITIZE SOFT SURFACES†:

Hold bottle 6" – 8" from surface and spray until fabric is wet. Fabric must remain wet for 5 minutes. Allow fabric to air dry [reapply as necessary]. (Highly)(Heavily) soiled areas must be cleaned prior to sanitizing.

† Spot treatment of soft surfaces

WATER DAMAGE RESTORATION AGAINST ODOR-CAUSING BACTERIA AND FUNGI FOR HOME, INSTITUTIONAL, INDUSTRIAL AND HOSPITAL USE: {Not for use in California}

This product is particularly suitable for use in water damage restoration situations against odor causing bacteria on the following porous and semi-porous materials: carpets, carpet cushions, subfloors, drywall, trim and frame lumber, tackless strip and paneling. Saturate the affected materials with enough product to remain wet for at least 10 minutes.

Sewer Backup and River Flooding: During mitigation procedures, remove gross filth or heavy soil along with non-salvageable materials. Saturate all affected areas with a coarse spray device before and after cleaning and extraction.

Carpets, Carpet Cushions and Other Porous Materials such as Subfloors, Drywall, Trim and Frame Lumber, Tackless Strip and Paneling: For water damage from a clean source, extract excess water. Test hidden area for colorfastness. Remove gross filth or heavy soil. Saturate all affected areas with a coarse spray device. Roll, brush or agitate into the materials and allow materials to remain wet for 10 minutes. Follow with a thorough extraction. Dry rapidly and thoroughly.

Special instructions For Cleaning Carpet Against Odor Causing Bacteria: Use this product in industrial and institutional areas such as homes, motels, hotels, nursing homes, schools, and hospitals. Use on wet-cleanable synthetic fibers. Do not use on wool. Vacuum carpet thoroughly prior to cleaning. Test fabric for colorfastness. Do not mix this product with other cleaning products. Follow the cleaning procedures specified by the manufacturer of the cleaning equipment. After using the product, set the carpet pile and protect the carpet from furniture legs and bases while drying. Do not over-wet. If applied to stain resistant nylon carpet, apply a fabric protector according to the manufacturer's directions.

{Refill Alternate 1:}

To Refill: Refill (*container size*) oz. sprayer size [pump] from this convenient refill container. Use only in [*product name*] spray [pump] bottle [container]. Do not dilute.

{Refill Alternate 2:}

To Refill this bottle [container]: REMOVE [trigger spray] [pump] [cap] from empty [bottle] [container]. POUR: Unscrew cap on refill and pour directly into empty bottle [container]. USE: Replace [trigger sprayer] [pump] and use as you normally would.

{Refill Alternate 3:}

This product can also be used [straight] [undiluted] from this refill. Unscrew cap and transfer trigger [pump] to this [bottle] [container].

{Refill Alternate 4:}

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.

OPTIONAL TRIGGER INSTRUCTIONS

[Open flip cap and firmly insert [red] [white] hose tip. After each use turn sprayer nozzle to 'OFF' position and snap back into bottle to avoid leaks. Once trigger is connected store and transport in upright position [to avoid leakage through breather hole].]

[Optional instructions on cap: [Shake well.] [Remove sticker. Open flip cap. Firmly insert [red] [white] hose tip.]]

{Note to reviewer: For Nonrefillable Containers, Ready to Use Household/Residential Use Products. The phrase "except as described in the directions for use" will only be used when refill directions are used on the final label.}

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Nonrefillable container. Do not reuse or refill this container [except as described in the directions for use]. Wrap [container] and put in trash or offer for recycling if available.

{or}

Store in original container in areas inaccessible to children. Nonrefillable container. Do not reuse or refill this container [except as described in the directions for use]. Wrap [container] and put in trash or offer for reconditioning if appropriate.

{Note to reviewer: Nonrefillable Containers, Ready-To-Use Products for Commercial/Institutional/Industrial Uses— no new container rinsing directions, not a dilutable per PRN 2007-4. The phrase "except as described in the directions for use" will only be used when refill directions are used on the final label.}

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Open dumping is prohibited. Store in original container in areas inaccessible to children.

Container Disposal:

[Plastic Containers:] Nonrefillable container. Do not reuse or refill this container [except as described in the directions for use]. Triple rinse [or equivalent]. 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.

[Metal Containers:] Nonrefillable container. Do not reuse or refill this container [except as described in the directions for use]. Triple rinse [or equivalent]. Offer for recycling if available or puncture and dispose of in sanitary landfill or by other procedures approved by state and local authorities.

[Bag in Box Containers:] Nonrefillable container. Do not reuse or refill this container [except as described in the directions for use]. Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

{Note to reviewer: For Nonrefillable Sealed Containers: Several packaging options are designed in such a way that they cannot be opened (such as a molded plastic bottle with a small opening for dispensing the product). None of these can be triple rinsed because they are essentially closed sealed containers. The following text will be used on these sealed container types:}

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Open dumping is prohibited. Store in original container in areas inaccessible to children.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash.

{Note to reviewer: The following is considered optional graphics and marketing language.}

{Note to reviewer. The following may be used only if the supplemental registrant has obtained a Kosher Certification.}



{Any Kosher Symbol such as:}

[Kosher]

{Note to reviewer: The following is an optional graphic that will be used to illustrate the scent.}



{Note to reviewer: The following may be used for products used for animal/veterinary practice disinfection}



**THE FOLLOWING SECTIONS CONTAIN PROPRIETARY
LANGUAGE AND GRAPHICS.**

**THESE SECTIONS ARE ONLY AVAILABLE FOR
SUPPLEMENTAL REGISTRANTS APPROVED FOR ITS USE.**

{Note to reviewer: The following are proprietary optional graphics that will be used to illustrate possible use sites.}

{Section 1}



garbage area
área de basura



toilet
baño

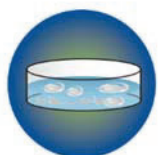


mold damage
alimentos



shower
ducha

{Note to reviewer: The following are proprietary optional graphics that will be used to illustrate odors to be controlled.}



mold & mildew
moho y hongos



smoke
humo



pet carrier
portador del
animal doméstico