



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 13, 2023

Deanna Mansueto
Senior Regulatory Affairs Associate
Arxada, LLC
Electronic Transmittal: deanna.mansueto@arxada.com

Subject: PRIA Label Amendment – Add 90-day storage stability claim
Product Name: LONZA FORMULATION S-38
EPA Registration Number: 6836-73
Received Date: June 2, 2023
Action Case Number: 00452644

Dear Deanna Mansueto:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. Pursuant to 40 CFR 156.10(a)(6), you must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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 FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). 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) lists 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, FIFRA section 12(a)(1)(B). 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 Assurance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, you may contact Joe Daniels via email at Daniels.joseph@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Tara M. Flint Silva". The signature is written in a cursive, flowing style.

Tara Flint Silva, Acting Product Manager 31
Regulatory Management Branch I
Antimicrobials Division
Office of Pesticide Programs

Enclosure: Stamped Label

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 S-38

Active Ingredients:

Octyl decyl dimethyl ammonium chloride.....	1.140%
Dioctyl dimethyl ammonium chloride.....	0.456%
Didecyl dimethyl ammonium chloride.....	0.684%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride.....	1.520%
Inert [Other] Ingredients:.....	96.200%
Total:.....	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

{Note to Reviewer: In accordance with 40 CFR 156.68(d), all first aid statements, as prescribed, will appear on the front panel of the product label.}

(See [back], [side], [inner] [other] [fold-out] [booklet] [hang tag] [product container] [label(s)] [panel(s)] [container] for [complete] [additional] [information] [directions for use] [precautionary statements] [and] [storage and disposal])

(Please [refer to] [see] reference sheet for [additional] [directions for use] [information])

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 a poison control center or doctor, or going for treatment.

EPA Reg. No. 6836-73

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

Net Contents *(insert container size here)*

[DOT symbols]

[Country of origin (insert country)]

[Manufactured in (insert country)]

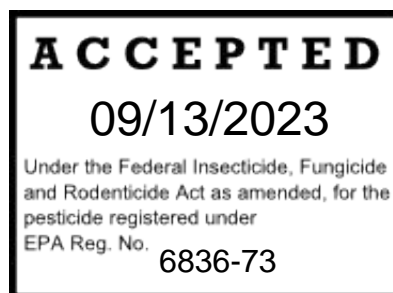
[Barcode]

Manufactured by:

Arxada, LLC

412 Mount Kemble Avenue, Suite 200S

Morristown, NJ 07960



PRECAUTIONARY STATEMENTS**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and protective (rubber or chemical resistant) gloves. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

{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. All designators (i.e. asterisks and numbers) used throughout the label may be interchanged as needed on final printed label.}

One-Step Disinfectant^{2,3}

Cleaner – Sanitizer – Fungicide – Mildewstat – Virucide* – Deodorizer
With Organic Soil Tolerance for Homes, Hospitals, Institutional, Commercial, Farm and Industrial Use

Citrus / Floral / Fresh / Clean / Pine / Mint / Lemon [Odor][Scent][Fragrance]

- 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

- Staphylocidal⁵ • Pseudomonacidal⁶ • Bactericidal • Fungicidal • Virucidal*

Lonza Formulation S-38

- Cleans and Disinfects in One Step^{2,3}
- Cleans, Disinfects, and Deodorizes
- Cleans, shines, deodorizes and disinfects nonporous household surfaces.
- Delivers cleaning performance in an economical concentrate.
- deodorizes by killing microorganisms that cause offensive odors.
- Disinfects surfaces by killing [99.9%] SARS-Related Coronavirus 2 [SARS-CoV-2] [USA-WA1/2020] [in one step^{2,3}]
- Effective against SARS-Related Coronavirus 2² [SARS-CoV-2] [USA-WA1/2020] [in 1 minute]
- [Effective against] [Disinfects] [Kills] [99.9%] SARS-CoV-2² [virus]
- [Effective against] [Disinfects] [Kills] [99.9%] SARS-CoV-2² [virus]
- [Effective against] [Disinfects] [Kills] [99.9%] SARS-CoV-2 virus², the cause of COVID-19
- [Eliminates] [Kills] 99.9% of [Household] Bacteria⁸
- [Eliminates] [Kills] 99.9% of [Household] Bacteria⁹
- [Eliminates] [Kills] 99.9% of Staphylococcus aureus and Klebsiella pneumoniae in 60 seconds²
- Inhibits the growth of odor [and stain] causing mold and mildew leaving bathrooms and kitchens clean and smelling fresh.
- is a complete sanitizer [that provides clear use solutions].
- is a [concentrated] [one-step^{2,3}] [Hospital Use] disinfectant that is effective against a broad spectrum of bacteria, is virucidal* [including HIV-1, the AIDS Virus], fungicidal, and inhibits the growth of odor [and stain] causing mold and mildew when used as directed.
- is a multi-surface² cleaner, deodorizer, and disinfectant. Use on windows, mirrors and other glass surfaces.
- is a proven "one-step" disinfectant^{2,3} - cleaner – sanitizer⁴ - fungicide - mildewstat - virucide* in the presence of moderate amounts of organic soil 5% serum contamination.
- is a [versatile] cleaner and broad spectrum disinfectant formulated for use only on non-critical instruments in Ultrasonic Baths [Ultrasonic cleaning units].
- is a [versatile] disinfectant and sanitizer for hard, nonporous nonfood contact surfaces in Veterinarian, Animal care and Farm Premise applications.
- is an economical concentrate [that can be diluted for use] [with a mop and bucket, trigger sprayers, sponge or by soaking].
- is an effective one-step sanitizer^{2,4}-cleaner for use on non-food contact surfaces.
- is effective yet economical.
- is formulated for use in daily maintenance programs with a balance of detergents and malodor counteractants that deliver effective cleaning, disinfecting and malodor control.
- [Kills] [Effective against] the virus^{1,2} that causes COVID-19
- [Kills] [Eliminates 99.9% of] SARS-Related Coronavirus² [SARS-CoV-2] [USA-WA1/2020] [causative agent of COVID-19] [the virus that causes COVID-19]
- Kills coronavirus^{1,2} that causes COVID-19

- Kills the virus^{1,2} that causes COVID-19
- Kills the coronavirus^{1,2} that causes COVID-19
- Kills [99.9% of] SARS-CoV-2², which causes COVID-19
- Kills [Eliminates 99.9% of] [household] germs
- [[Effective against] Pseudomonas aeruginosa [pseudomonas], Staphylococcus aureus [staph], Streptococcus faecalis [strep], Influenza Virus Type A [Influenza] and Trichophyton interdigitale [Athlete's foot fungus]².
- Kills Flu Virus [Influenza Virus Type A]
- Kills Influenza A Virus
- One Step [Cleaner and] Disinfectant^{2,3}
- [Proven to] kills[s] coronavirus^{1,2}
- [Proven to] kills[s] the virus^{1,2} that causes COVID-19
- Sanitizes² 99.9% of Staphylococcus aureus and Klebsiella pneumoniae in 60 seconds.
- tested using the AOAC Use-Dilution Method
- tested using the ASTM test method for non-food contact surface sanitizer
- will disinfect, clean and deodorize 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.

Cleans [Cleaner]
Concentrate [Concentrated]
Deodorizes [Deodorant]
Disinfects [Disinfectant]

{Note to reviewer: The following is based on a one gallon Net Contents package size. Proportional yields may be substituted for different container sizes or dilution rates:}

Concentrated product makes 64 gallons of use dilution.
at 2 fl. oz. per gallon
Concentrated product makes 128 gallons of use dilution.
at 1 fl. oz. per gallon
Concentrated product makes 256 gallons of use dilution.
at 1/2 fl.oz. per gallon

Use **Lonza Formulation S-38**

- as a disinfectant on hard, nonporous non-food surfaces.
- for non-scratch cleaning of sinks, showers and tubs, shower doors and curtains, glazed ceramic tiles, fiberglass, fixtures and toilet bowl exteriors.
- for sanitizing and disinfecting of ultrasound transducers, probes, mammography compressor plates and other hard nonporous surfaces.
- in inedible processing areas, non processing areas and or exterior areas in official establishments operating under the Federal meat, poultry, egg shell grading and egg products inspection programs
- in federally inspected Meat & Poultry Plants as a non-food contact sanitizer and / or disinfectant. 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.
- on coils and drain pans of air conditioning and refrigeration equipment and heat pumps. Follow the directions for sanitization of non-food contact surfaces⁷.
- on the multi-touch surfaces responsible for cross-contamination and infection.
- to clean and disinfect sealed finished floors, apply with damp mop or autoscrubber. Cleans and disinfects without dulling gloss.
- to clean and disinfect sealed finished floors, sinks and tubs.
- to clean and disinfect nonporous salon / barber tools and instruments: combs, brushes, scissors, blades and manicure instruments.
- with a mop and bucket, trigger sprayer, sponge or by soaking.

This product contains no [phosphates or] phosphorous [compounds].

Lonza Formulation S-38 is a phosphate free, germicidal detergent effective on visibly clean hard nonporous surfaces found at mushroom farms. **Lonza Formulation S-38** 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 S-38** must be limited to areas where compost and mushrooms are not present.

Cross-contamination is of major housekeeping concern. **Lonza Formulation S-38** has been formulated to aid in the reduction of cross-contamination between treated hard, non-porous surfaces not only in hospitals, but in schools, institutions and industry.

[AREAS OF USE:]

Use **Lonza Formulation S-38** 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 or food will be depicted in graphics.}

Bathrooms
Homes [households]
Kitchens

Clinics
Dental offices
Hospitals
Medical Offices
Medical related facilities
Nursing homes
Sick Rooms

Day care centers
Nurseries

Bars
Cafeterias
Convenience stores
Egg Processing plants
Federally inspected meat and poultry plants
Food processing plants
Food preparation areas
Food storage areas
Institutional kitchens
Restaurants
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
Salons [Beauty] [Tanning]
Schools
Shower and bath areas
Universities

Camp grounds
Play ground equipment

Animal laboratories
Dairy farms
Farms
Hog farms
Kennels
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
Railcars
Ships
Taxis
Trailers
Trains
Transportation terminals
Trucks [Box Trucks]

[TYPES OF SURFACES:]

Use **Lonza Formulation S-38** on washable hard, nonporous surfaces of:

{Note to reviewer: Each entry below also represents a graphic depicting the corresponding type of surface. No people 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
Basins	Walls
Bathroom fixtures	Whirlpool [bathtubs] [tubs] [units]
Bathtubs	Windows
Cabinets	
Cages	Non-critical medical device surfaces
Chairs	[Medical] [Hospital] Beds
Coils and drain pans of air conditioning and refrigeration equipment and heat pumps ⁷	Bed frames
Conductive flooring	Bed rails
Counters [countertops]	Crutches
Countertop laminates	Defibrillators
Desks	Gurneys
Doorknobs [and handles]	Non-critical [hospital] [medical] equipment surfaces
Fiberglass sinks, tubs, and showers	[Medical] Examining tables
Floors	[Medical] [Hospital] Lamps
Floors – high speed burnished	Rescue tools
Foot Spas	Resuscitators
Garbage cans	[Medical] [Hospital] Scales
Highchairs	Stands
Kennel runs	Stretchers
Microwave ovens, exterior surfaces of	Stethoscopes
Mirrors	Walkers
Outdoor [patio] furniture except cushions and wood frames	Wheel chairs
Refrigerators, exteriors	Other hard nonporous surfaces made of:
Refrigerated storage and display equipment ⁷	Fiberglass
Showers	Formica®
[Fiberglass] Shower stalls	Glass
[Fiberglass] Sinks [bathroom, kitchen]	Glazed ceramic
Stoves ⁷ [stovetops] ⁷	Glazed enameled surfaces
Tables [picnic tables]	Glazed porcelain
Telephones	Metal
Toilet exteriors	Plastic [such as polystyrene or polypropylene]
Toilet bowl exteriors	Sealed stone
Toilet bowl surfaces	Stainless steel
Tubs [Fiberglass]	Upholstery, vinyl and plastic
Tiles, glazed	Woodwork, finished
Ultrasonic baths	

For Poultry Premise Sanitation [Hatcheries]:

Buggies	Hatchery Room
Ceilings	Poultry Buildings
Chick Holding Room	Poultry House related equipment
Chick Loading Area	Racks
Chick Processing Area	Setter Room
Drinkers	Sidewalls
Egg Flats	Tray Dumping Area
Egg Holding Area	Trays
Egg Receiving Area	
Floors	

and other hard, nonporous surfaces in the Hatchery environment.

For Swine Premise Sanitation:

Chutes	Hauling Equipment
Creep area	Loading Equipment
Dressing Plants	Nursery blocks
Farrowing Barns and areas	Waterers and Feeders

For Farm Premise Sanitation:

Automatic feeders	Mangers
Feed racks	Scrapers
Floors	Shovels
Forks	Troughs
Fountains and waterers	Walls

and other nonporous surfaces in barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals.

For *Virucidal Effectiveness:

Lonza Formulation S-38 is an effective virucide in the presence of 5% serum against the following organisms:

- *Hepatitis B Virus [HBV]
- *Hepatitis C Virus [HCV]
- *Herpes Simplex Virus Type 1
- *Herpes Simplex Virus Type 2
- *HIV-1 [AIDS virus]
- *Influenza Virus Type A [Influenza]
- *Rotavirus
- *SARS-Related Coronavirus 2 [SARS-CoV-2] [cause of COVID-19]
- *Vaccinia Virus

For Hospitals, Medical and Dental Offices, Nursing Homes and other Medical Facilities:

According to AOAC Use Dilution Test, **Lonza Formulation S-38** is an effective hospital disinfectant in the presence of 5% organic serum against the following gram negative and gram positive organisms [*Bacteria*]:

Pseudomonas aeruginosa [*Pseudomonas*]
Salmonella enterica [*Salmonella*]
Staphylococcus aureus [*Staph*]

Acinetobacter baumannii [*Acinetobacter*]
Burkholderia cepacia [*Pseudomonas*]
Corynebacterium ammoniagenes
Klebsiella aerogenes
Enterococcus faecalis - Vancomycin resistant [VRE]
Escherichia coli [*E. coli*]
ESBL *Escherichia coli* – [Extended spectrum beta-lactamase producing *E. coli*]
Klebsiella pneumoniae [*Klebsiella*]
Salmonella schottmuelleri [*Salmonella*]
Serratia marcescens
Shigella dysenteriae [*Shigella*]
Staphylococcus aureus Methicillin-Resistant [MRSA]
Staphylococcus aureus - Vancomycin Intermediate Resistant – [VISA]
Streptococcus faecalis [*Strep*]

For Schools, Public Rest Rooms, Athletic Facilities, Food Processing Plants, Food Storage Areas, Kitchens, Restaurants, Bars, Transportation Terminals, Hotels, Motels and Other Non-Medical Institutional and Industrial Uses:

According to AOAC Use Dilution Test, **Lonza Formulation S-38** is an effective broad spectrum general disinfectant in the presence of 5% organic serum against the following organisms:

Corynebacterium ammoniagenes
Klebsiella aerogenes
Escherichia coli [*E. coli*]
Klebsiella pneumoniae [*Klebsiella*]
Salmonella enterica [*Salmonella*]
Salmonella schottmuelleri [*Salmonella*]
Serratia marcescens
Shigella dysenteriae [*Shigella*]
Staphylococcus aureus [*Staph*]
Streptococcus faecalis [*Strep*]

Lonza Formulation S-38 is a sanitizer for hard nonporous non-food contact surfaces tested according to the method for Sanitizers – Non-food Contact surfaces, modified in the presence of 300 ppm hard water plus 5% organic serum in 60 seconds against:

Klebsiella pneumoniae
Staphylococcus aureus

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

EMERGING VIRAL PATHOGENS

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’ when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

-Enveloped Viruses

For an emerging viral pathogen that is a/an...	...follow the directions for use for the following organisms on the label:
Enveloped virus	Human Rotavirus (ATCC VR-2018), Strain WA

[LONZA FORMULATION S-38] has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on **hard, non-porous surfaces**. Therefore, **[LONZA FORMULATION S-38]** can be used against **[name of emerging virus]** when used in accordance with the directions for use against **Rotavirus** on **hard, non-porous surfaces**. Refer to the **[CDC or OIE]** website at **[pathogen-specific website address]** for additional information.

OR

[Name of illness/outbreak] is caused by **[name of emerging virus]**. **[LONZA FORMULATION S-38]** kills similar viruses and therefore can be used against **[name of emerging virus]** when used in accordance with the directions for use against **Rotavirus** on **hard, non-porous surfaces**. Refer to the **[CDC or OIE]** website at **[website address]** for additional information.”

Preparation of Use-Solution:

Disinfection [- Medical][1:64].....	2 fl. oz. per gallon of water
Disinfection [- Non Medical][1:128].....	1 fl. oz. per gallon of water
Virucide [1:128].....	1 fl. oz. per gallon of water
Virucide [[Rotavirus] [HBV] [and] [HCV]] [1:64].....	2 fl. oz. per gallon of water
Sanitizer [1:256].....	1/2 fl. oz. per gallon of water [150 ppm active]
Mold and Mildew Control.....	1 fl. oz. per gallon of water
Heavy Duty Use.....	8 fl. oz. per gallon of water

For heavy duty use, add [mix] 8 fl. oz. of **Lonza Formulation S-38** per gallon of water.

For Bag – In – Box Containers:

How to use this package:

This package is designed to be used with dilution control systems only. Open package and connect to dispense according to directions on box top.

Trigger Sprayers:

Fill bottle from dispenser.

Apply to surfaces as specified in directions above.

Mop Buckets:

Fill bucket from dispenser.

Set up “Wet Floor” signs.

Mop floor surface as specified in directions above

[GENERAL DISPENSER INSTRUCTIONS] {These instructions may be substituted for any dispensing device to prepare the use solution}: [Remove cap and] insert cartridge [bottle] into dispenser. Note: See dispenser instructions for proper placement. Once cartridge [bottle] is properly inserted into dispenser, follow dispenser use instructions to dispense a [insert use dilution rate here] solution into a bucket, bottle, scrubber or other container.

[SEE SMARTDOSETM/MC DISPENSING SYSTEM OPERATING INSTRUCTIONS SHEET ENCLOSED IN EACH CASE]

BOTTLE FILL:



Bottle fill (enter dilution rate): Fill spray bottle half full with cold water. Select spray bottle icon on smartdose bottle, pull up on selector knob and completely push down on selector knob. Finish filling the spray bottle with water. Only one dose of concentrate (enter dose in fl. oz.) Per 32 fl. oz. of water.

5 GAL. BUCKET FILL:



Bucket fill (enter dilution rate): Fill bucket with 5 gallons of cold water. Select bucket icon on SmartDoseTM/MC bottle, pull up on selector knob and completely push down selector knob. One dose (enter dose in fl. oz.) of concentrate per 5 gallon of cold water.

5 GAL. AUTOSCRUBBER FILL:



Autoscrubber Fill (Enter Dilution Rate): Fill autoscrubber with desired amount of cold water. Select autoscrubber icon on SmartDoseTM/MC bottle, pull up on selector knob and completely push down selector knob. One dose (Enter Dose in fl. oz.) of concentrate per 5 gallon of cold water.

1 GAL. BUCKET FILL:



Bucket Fill (Enter Dilution Rate): Fill bucket with desired amount of cold water. Select bucket icon on SmartDose bottle, pull up on selector knob and completely push down selector knob. One dose of concentrate (Enter Dose in fl. oz.) per 1 gallon of water.

*{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 AND MILDEW CONTROL DIRECTIONS:

Apply use-solution to hard, nonporous surfaces, thoroughly wetting surfaces with a cloth, mop, sponge, sprayer or by immersion. Treated surfaces must remain visibly wet for 10 minutes. *{Note to reviewer: if using reduced contact time for SARS-CoV-2, the following sentence will be required:}* **[For SARS-CoV-2, treated surfaces must remain visibly wet for 1 minute.]** Wipe dry with a cloth, sponge or mop or allow to air dry. For visibly soiled areas, a preliminary 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 as a disinfectant.

For sprayer applications, use a coarse spray device. Spray 6 - 8 inches from the surface. Do not breathe spray.

{Note to reviewer: Only one of the following two statements will be used. Supplemental registrants will pick only one time frame for their label up to 3 months.}

90-DAY STORAGE STABILITY OF 1:64 USE-DILUTION: [Tests confirm that] the use solution of this product, when diluted with [200ppm unsoftened] tap water and stored in a sealed container, remains stable for *{Note to reviewer: one of the following timeframes must be selected:}* [up to 7 days] [for up to one week] [for up to one month] [for up to 2 months] [for up to 3 months]. If product becomes visibly dirty or contaminated, the use-dilution must be discarded and fresh product prepared. Always use clean, properly labeled containers when diluting this product. 90-day storage stability of the use-dilution does not apply to open containers such as buckets or pails.

{or}

Prepare a fresh solution daily or more often if the use solution becomes visibly diluted or soiled.

For fungicidal activity:

At 1 fl. oz. per gallon of water, **Lonza Formulation S-38** is an effective fungicide against *Trichophyton interdigitale* [the athlete's foot fungus] when used on surfaces in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities.

For mold and mildew control:

At 1 fl. oz. per gallon of water, **Lonza Formulation S-38** will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, non-porous surfaces. Allow to dry on surface. Repeat every seven 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 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 must always be done wearing protective gloves, gowns, masks and eye protection.

Cleaning Procedure: Blood and other body fluids containing HIV-1 or HBV or HCV must be thoroughly cleaned from surfaces and objects before application of **Lonza Formulation S-38**.

Contact Time: Leave surface visibly wet for 10 minutes

Disposal of Infectious Material: Blood, body fluids, cleaning materials and clothing must be autoclaved and disposed of according to local regulations for infectious waste disposal.

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

If surfaces are visibly dirty, preclean first.

From Concentrate:

Add 1 – 2 fl. oz. to the bowl water and mix. Thoroughly brush or swab over exposed surfaces including under the rim with a cloth, mop or sponge. Allow to stand for 10 minutes and flush.

From Use Solution:

Empty toilet bowl [or] [urinal] and apply a 1 – 2 fl. oz. per gallon use-solution 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.

For Heavy Duty Use:

Empty toilet bowl [or] [urinal] and apply an 8 fl. oz. per gallon use-solution to exposed surfaces including 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 [Mix] 1 - 2 fl. oz. of **Lonza Formulation S-38** per gallon of water [$\frac{1}{4}$ - $\frac{1}{2}$ fl. oz. per quart of water] [or equivalent dilution] to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, rollers, manicure and other salon instruments and tools for 10 minutes. For visibly soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Prepare fresh solution daily or more often if solution 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 DIRECTIONS:

Use **Lonza Formulation S-38** to disinfect hard nonporous non-critical objects compatible with Ultrasonic cleaning units. Pour fresh use-solution of 1 - 2 fl. oz. of **Lonza Formulation S-38** per gallon of water directly into bath chamber. Pre-clean visibly 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. Prepare fresh solution for each use.

DISINFECTION OF [WHIRLPOOL [BATH[S] [UNITS]]]:

After using the [whirlpool [bath] [unit]] drain and refill with fresh water to [just cover the intake valve] [cover the highest jet] [2 inches above the highest jet]. Add 1 – 2 fl. oz. of **Lonza Formulation S-38** for each gallon of fresh water added. Start the pump to circulate the solution. Wash down [the [deck] [seat of chair lift] [any related equipment]] any uncovered surfaces on the [bath] [unit] with a clean swab, brush or sponge with the solution. Treated surfaces must remain visibly wet for 10 minutes. After the [bath] [unit] has been thoroughly disinfected, drain and rinse surfaces with fresh water. Wipe dry with a clean sponge or cloth or allow to air dry. Repeat for visibly soiled units.

[WHIRLPOOL] FOOT SPA DISINFECTION DIRECTIONS:

After using [whirlpool] foot spa, drain the water and thoroughly clean all hard, non-porous surfaces with soap or detergent. Rinse with water. Saturate surfaces with 2 fl. oz. of product per gallon of water to exposed surfaces with cloth, sponge, or sprayer. Brush or swab thoroughly and allow solution to stand for 10 minutes. After unit has been thoroughly disinfected, rinse all cleaned surfaces with fresh water.

FOR USE ON SEALED FINISHED FLOORS: To limit gloss reduction use **Lonza Formulation S-38** at 1 – 2 fl. oz. per gallon. Apply with a damp mop or autoscrubber. Allow surface to remain visibly wet for 10 minutes. Wipe or allow to air dry.

VETERINARY PRACTICE / ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP / KENNELS DISINFECTION DIRECTIONS:

For cleaning and disinfecting hard nonporous surfaces: equipment used for animal food or water, utensils, instruments, cages, kennels, stables, catteries. 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. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 1 – 2 fl. oz. of **Lonza Formulation S-38** per gallon of water [or equivalent dilution] 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. Rinse all surfaces that come in contact with food, including equipment used for feeding or watering, with potable water before reuse. Ventilate buildings 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 a use-solution of 1 – 2 fl. oz. of **Lonza Formulation S-38** 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, 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.

POULTRY AND SWINE PREMISE DISINFECTION 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. Use 1 – 2 fl. oz. of **Lonza Formulation S-38** per gallon of water. Saturate surfaces with the disinfecting solution 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 1 – 2 fl. oz. of **Lonza Formulation S-38** per gallon of water to treat hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces visibly wet for 10 minutes or more. Wipe or allow to air dry.

Vehicles: Clean all vehicles including mats, crates, cabs and wheels with high pressure water and **Lonza Formulation S-38**. Use 1 - 2 fl. oz. of **Lonza Formulation S-38** per gallon of water to treat all vehicles. Leave all treated surfaces visibly wet for 10 minutes or more. Wipe or allow to air dry.

Shoe Bath Sanitizer Directions: To reduce the cross contamination of organisms between treated surfaces in animal areas, shoe baths containing one inch of freshly made solution must be placed at all

entrances to buildings and hatcheries. Scrape waterproof work boots and place in a ½ fl. oz. per gallon of water solution for 60 seconds prior to entering area. Change the solution in 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 visible soils prior to application. Saturate all surfaces with a 1 – 2 fl. oz. per gallon of water use solution of **Lonza Formulation S-38**. Scrub to loosen all soils. Surfaces must remain visibly wet for 10 minutes, then thoroughly rinsed with potable water before operations are resumed.

MUSHROOM FARM PREMISE USE:

Site Preparation: The first step in any on-going sanitation program must be the removal of visible 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, use 1 – 2 fl. oz. of **Lonza Formulation S-38** per gallon of water [or equivalent dilution]. Apply use solution with a cloth, mop, sponge, sprayer or by immersion to thoroughly wet the surfaces. Treated surfaces must be allowed to remain visibly wet for 10 minutes. Wipe or allow to air dry. For visibly soiled areas, preclean first. Prepare fresh solution for each use or more often if solution becomes visibly diluted, clouded or soiled.

For Heavy Duty Cleaning: When greater cleaning is desired, use 2 fl. oz. of **Lonza Formulation S-38** per gallon of water. Visibly soiled areas may require repeated cleaning before treatment.

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.

SANITIZING NON FOOD CONTACT SURFACES: [such as floors, walls, and tables]. Visible soil should be removed prior to sanitizing. Add ½ fl. oz. of **Lonza Formulation S-38** per gallon of water. **Lonza Formulation S-38** is an effective sanitizer against *Staphylococcus aureus* and *Klebsiella pneumoniae* in the presence of 5% serum on non-porous environmental surfaces. Treated surfaces must remain visibly wet for 60 seconds. Wipe dry with a sponge, mop, or cloth or allow to air dry.

TO SANITIZE BARBER / SALON INSTRUMENTS AND TOOLS: Preclean barber/beauty salon instruments. Immerse hard, nonporous barber / salon instruments and tools [such as combs, brushes, razors, scissors, blades and manicure instruments] in a use-solution of ½ fl. oz. of **Lonza Formulation S-38** per gallon of water [or equivalent dilution] for at least 60 seconds [one minute]. Rinse thoroughly and dry before use. Prepare a fresh solution daily or more often if solution becomes visibly diluted, cloudy or soiled.

NOTE: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried, and kept in a clean non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

TO CLEAN AND DEODORIZE: Mix 1 –2 fl. oz. of **Lonza Formulation S-38** per gallon of water to clean and deodorize hard non-porous, non-food surfaces. Apply using a cloth, mop, sponge or sprayer. Wipe or allow to air dry. Rinse all surfaces that come in contact with food such as countertops, exteriors of appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes.

GLASS CLEANING / DEODORIZING DIRECTIONS:

Add ½ - 2 fl. oz. of **Lonza Formulation S-38** per gallon of water to clean and deodorize windows, mirrors and glass surfaces. Use a coarse spray device. Spray 6 - 8 inches from surface. Rub with a sponge or cloth. Do not breathe spray. Rinse all surfaces that come in contact with food such as countertops, exteriors of appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes.

{Note to reviewer: For Nonrefillable Containers, Label has Household and Residential Uses}

STORAGE AND DISPOSAL

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

{Note to reviewer: For Nonrefillable Containers for commercial, industrial, and institutional uses – all sizes – No Reuse Rinsate Statement for Public Health Use products. Chapter 13, Table 6 of the Label Review Manual states that for “All products in containers that could be burned,” the registrant has the option to “Remain silent on burning;” therefore, no incineration language is provided for plastic containers.}

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.

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:

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.

[Plastic and Metal Containers:] Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

[Metal containers only:] DO NOT cut or weld metal containers.

[Bag in Box Containers:] 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: Packaging options can be in sealed containers or bottles designed for use dilution systems to reduce worker exposure to the concentrate. None of these can be triple rinsed because they are 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.

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

¹SARS-Related Coronavirus 2

²On hard, non-porous, non-food surfaces

³When used according to the disinfection directions.

⁴When used according to the sanitization directions.

⁵Staphylococcus aureus

⁶Pseudomonas aeruginosa

⁷Allow the surface to adjust to room temperature before disinfection.

⁸Staphylococcus aureus and Klebsiella pneumoniae

⁹Escherichia coli [E. coli], Staphylococcus aureus [staph], Streptococcus faecalis [strep]

{SECONDARY CONTAINER LABEL}

{Note to reviewer: This secondary container label will be used only when the product is diluted at 2 fl. oz. or less per gallon of water. Other dilutions must use concentrate signal word and precautionary statements from page 1 and 2.}

LONZA FORMULATION S-38

Active Ingredients:

Octyl decyl dimethyl ammonium chloride.....	1.140%
Diethyl dimethyl ammonium chloride.....	0.456%
Didecyl dimethyl ammonium chloride.....	0.684%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride.....	1.520%
Inert [Other] Ingredients:	96.200%
Total:.....	100.000%

The product in this container must be diluted at the use rate of 2 fl. oz. or less per gallon of water as directed on the pesticide product label.

KEEP OUT OF REACH OF CHILDREN

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

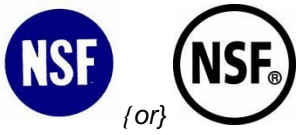
Follow the directions for use on the pesticide label when applying this product.

EPA Reg. No. 6836-73

Diluted product not for sale or distribution.

{Note to reviewer: The following are optional graphics and marketing language}

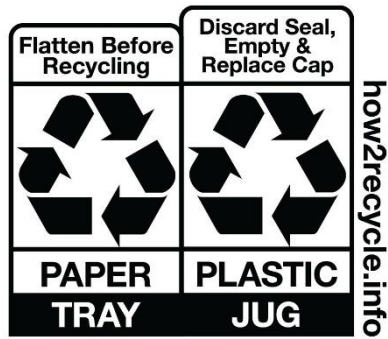
{Note to reviewer. The following may be used only if the supplemental registrant has obtained an NSF listing. Allowed on back or side panel only.}



{or}

[NSF Listed]

(Insert NSF 6-Digit Listing Number here)



**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 optional, proprietary claims}
{Section 1}

{Note to reviewer: below claims require **TO SANITIZE SOFT SURFACES** Directions shown below}

- [proven] [effective] soft surface spot sanitizer treatment
- [proven] [effective] for use on soft surfaces as a spot treatment
- [proven] [effective] on fabric surface[s] as a spot treatment
- For use as a spot treatment on [soft surfaces] such as {insert from soft surface use sites}
- Cost effective [Concentrate] for use on soft surfaces as a spot treatment
- One step spot sanitizer treatment for soft surfaces
- One step spot sanitizer treatment for fabric surface[s]
- Sanitizes soft surfaces as a spot treatment [in 5 minutes]
- Sanitizes fabric surfaces as a spot treatment [in 5 minutes]
- Is a proven soft surface spot sanitizer treatment against:
 - Staphylococcus aureus
 - Klebsiella aerogenes

[TYPES OF SURFACES:]

Soft [household] surfaces

Upholstery

Fabric

[upholstered] Couches[es], Sofa[es] Chair[s], seat cushion[s]

[upholstered] cushions[s], pillow[s]

[upholstered] furniture

[fabric] Window treatment[s], Curtain[s], Draperies, Shower curtain[s]

[fabric] [Gym] [Laundry] [diaper] Bags, back pack[s]

[Fabric] Hamper[s]

[Fabric] [Dog] [Pet] Bedding, Blankets

[fabric] [upholstered] [car] seat[s]

[fabric] stuffed animal[s], toy[s]

Preparation of Use-Solution:

Soft Surface Sanitization [1:48].....2 fl. oz. per 3 quarts of water [8 oz. per 3 gallons]

TO SANITIZE SOFT SURFACES:

For spot treatment only. Apply soft surface sanitization use solution with a sprayer. Hold bottle 6" – 8" from surface and spray until fabric is wet. Fabric must remain visibly wet for 5 minutes. Allow fabric to air dry [reapply as necessary]. Visibly soiled areas must be cleaned prior to sanitizing.

*{Optional proprietary graphics}
{Section 2}*

