

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 3, 2022

Deanna Mansueto Senior Regulatory Affairs Associate ARXADA, LLC deanna.mansueto@arxada.com

Subject: PRIA Label Amendment – To add claims for soft surface sanitization and

Emerging Viral Pathogens, to update label language Product Name: LONZA FORMULATION S-38-F

EPA Registration Number: 6836-138

Received Date: 3/3/2022

Action Case Number: 00343813

Dear Ms. Mansueto:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 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.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), <a href="https://www.epa.gov/sites/production/files/2016-09/documents/emerging viral pathogen program guidance final 8 19 16 001 0.pdf">https://www.epa.gov/sites/production/files/2016-09/documents/emerging viral pathogen program guidance final 8 19 16 001 0.pdf</a>, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

- 2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
- 3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
  - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
    - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
      - A. CDC Current Outbreak List for "U.S. Based Outbreaks" (www.cdc.gov/outbreaks),
      - B. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process)
      - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
    - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis 2/public/wahid.php/Diseaseinformation/WI).
      - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is enveloped.
      - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
- 4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE's publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

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Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Human Rotavirus (ATCC VR-2018), Strain WA is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

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 section2(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 with FIFRA section 6. If you have any questions, please contact <a href="FlintSilva.Tara@epa.gov">FlintSilva.Tara@epa.gov</a> or <a href="Oiguenblik.Emilia@epa.gov">Oiguenblik.Emilia@epa.gov</a>.

Sincerely,

Tara Flint Silva, Acting Product Manager 31 Regulatory Management Branch I

Regulatory Management Branch Antimicrobials Division

Office of Pesticide Programs

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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-38F**

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

# ACCEPTED

10/03/2022

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 6836-138

### 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 [left] [side] [right] [back] panel for Precautionary Statements

#### **FIRST AID**

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5 minutes, then continue rinsing eye.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

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

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

EPA Reg. No. 6836-138 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: The following is 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<sup>2,3</sup>

Cleaner - Sanitizer - Fungicide - Mildewstat - Virucide\* - Deodorizer

Acid-Free Cleaner Acid-Free Disinfectant

For Farm, School, Dairy, Restaurant, Food Handling and Processing Areas, Bar and Institutional Kitchen Use

- 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

An effective sanitizer for use on food contact surfaces

• Staphylocidal<sup>5</sup> • Pseudomonacidal<sup>6</sup> • Bactericidal • Fungicidal • Virucidal\*

#### **Lonza Formulation S-38F**

- Cleans and Disinfects in One Step<sup>2,3</sup>
- Cleans, Disinfects, and Deodorizes
- Cleans, shines, deodorizes and disinfects nonporous household surfaces.
- delivers non-acid disinfectant and 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<sup>2,3</sup>]
- Effective against SARS-Related Coronavirus 2<sup>2</sup> [SARS-CoV-2] [USA-WA1/2020] [in 1 minute]
- [Effective against] [Disinfects] [Kills] [99.9%] SARS-CoV-2<sup>2</sup> [virus]
- [Effective against] [Disinfects] [Kills] [99.9%] SARS-CoV-2<sup>2</sup> [virus]
- [Effective against] [Disinfects] [Kills] [99.9%] SARS-CoV-2 virus<sup>2</sup>, the cause of COVID-19
- [Eliminates] [Kills] 99.9% of [Household] Bacteria<sup>8</sup>
- [Eliminates] [Kills] 99.9% of [Household] Bacteria9
- [Eliminates] [Kills] 99.9% of Staphylococcus aureus and Klebsiella pneumoniae in 60 seconds<sup>2</sup>
- has been cleared in 40 CFR §180.940 (a) for use on food processing equipment, utensils and other foodcontact articles.
- Inhibits the growth of mold and mildew leaving bathrooms and kitchens clean and smelling fresh.
- is a complete, chemically balanced disinfectant [and sanitizer] [that provides clear use solutions].
- is a [concentrated] [one-step<sup>2,3</sup>] [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 mold and mildew, and their odors, when used as directed.
- is a multi-surface<sup>2</sup> cleaner, deodorizer, and disinfectant. Use on windows, mirrors and other glass surfaces.
- is a proven "one-step" disinfectant<sup>2,3</sup> sanitizer<sup>4</sup> 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<sup>4</sup> 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 [Eliminates 99.9% of] [household] germs
- [Effective against] Pseudomonas aeruginosa [pseudomonas], Staphylococcus aureus [staph], Streptococcus faecalis [strep], Influenza A and Trichophyton interdigitale (formerly mentagrophytes) [Athlete's foot fungus]<sup>2</sup>.
- Kills Flu Virus [Influenza A]
- Kills Influenza A
- [Kills] [Effective against] the virus<sup>1,2</sup> that causes COVID-19
- [Kills] [Eliminates 99.9%] SARS-Related Coronavirus<sup>2</sup> [SARS-CoV-2] [USA-WA1/2020] [causative agent of COVID-19] [the virus that causes COVID-19]
- Kills coronavirus<sup>1,2</sup> that causes COVID-19
- Kills the virus<sup>1,2</sup> that causes COVID-19
- Kills the coronavirus<sup>1,2</sup> that causes COVID-19
- Kills [99.9% of] SARS-CoV-22, which causes COVID-19
- One Step [Cleaner and] Disinfectant<sup>2,3</sup>
- [Proven to] kills[s] coronavirus<sup>1,2</sup>
- [Proven to] kills[s] the virus<sup>1,2</sup> that causes COVID-19
- Sanitizes<sup>2</sup> 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<sup>†</sup> of use dilution.

†at 2 fl. oz. per gallon

Concentrated product makes 128 gallons\* of use dilution.

<sup>‡</sup>at 1 fl. oz. per gallon

Concentrated product makes 256 gallons<sup>∆</sup> of use dilution.

<sup>∆</sup>at 1/2 fl. oz. per gallon

#### Use Lonza Formulation S-38F

- as a commercial sanitizer on dishes, glassware, and utensils.
- as a disinfectant on hard, nonporous non-food surfaces.
- as a Food-Grade Shell Egg sanitizer, with best results achieved in water temperatures ranging from 78°110°F. Lonza Formulation S-38F may be applied through automatic washing systems, immersion tanks,
  foaming apparatus and low-pressure sprayers.
- as a sanitizer in beer fermentation and holding tanks.
- as a sanitizer in bottling and beverage dispensing equipment.
- as a sanitizer in sanitary filling of bottles and cans.
- as a sanitizer on all surfaces not requiring a rinse in official establishments operating under the Federal meat, poultry, shell egg grading and egg products inspection
- fiberglass, fixtures and toilet bowl exteriors.
- for non-scratch cleaning of sinks, showers and tubs, shower doors and curtains, glazed ceramic tiles, in federally inspected Meat & Poultry Plants as a food contact sanitizer and / or disinfectant. This product was authorized by USDA as category D2 under the prior authorization program and its formula has not been changed a sanitizer for all surfaces not always requiring a rinse.
- for sanitizing and disinfecting of ultrasound transducers, probes, mammography compressor plates and other hard nonporous surfaces.
- in kitchens, bathrooms and other household areas.
- in sanitizing bottles or cans in the final rinse application, and for external spraying of filler and closing machines.
- on coils and drain pans of air conditioning and refrigeration equipment and heat pumps. Follow the directions for sanitization of non-food contact surfaces.<sup>7</sup>
- on the multi-touch surfaces responsible for cross-contamination.
- 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-38F** is a phosphate free, germicidal detergent effective on visibly clean hard nonporous surfaces found at mushroom farms. **Lonza Formulation S-38F** 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-38F** must be limited to areas where compost and mushrooms are not present.

Cross-contamination is of major housekeeping concern. Lonza Formulation S-38F 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.

Regular, effective cleaning and sanitizing of equipment, utensils, and work or dining surfaces which could harbor pathogenic bacteria minimizes the probability of contaminating food during preparation, storage or service. Effective cleaning will remove soil and prevent the accumulation of food residues, which may decompose or support the rapid development of bacteria or toxins. Application of effective sanitizing procedures reduces the number of pathogenic bacteria which may be present on equipment and utensils after cleaning, and reduces the potential for the transfer, either directly through tableware such as glasses, cups and flatware or indirectly through food.

To reduce cross-contamination between treated surfaces, kitchenware and food-contact surfaces of equipment must be washed, rinsed with potable water and sanitized after each use and following any interruption of operation during which time contamination may have occurred.

Where equipment and utensils are used for the preparation of foods on a continuous or production-line basis, utensils and the food-contact surfaces of equipment must be washed, rinsed with potable water and sanitized at intervals throughout the day on a schedule based on food temperature, type of food, and amount of food particle accumulation.

Articles that can be immersed in solution must remain in solution for 60 seconds. Articles or surfaces too large for immersing must be thoroughly wetted or flooded by rinsing, spraying or swabbing. Allow all sanitized surfaces to drain thoroughly [and air dry].

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 Walls Fountains and waterers

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

#### [AREAS OF USE:]

#### Use Lonza Formulation S-38F 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

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

Laundries

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-38F 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

Basins

Bathroom fixtures

Bathtubs Cabinets Cages

Chairs
Coils and drain pans of air conditioning and refrigeration equipment and heat pumps<sup>7</sup>

Conductive flooring Counters [countertops] Countertop laminates

Desks

Doorknobs [and handles]

Fiberglass sinks, tubs, and showers

Floors

Floors - high speed burnished

Foot Spas Garbage cans Highchairs Kennel runs

Microwave ovens, exterior surfaces of

Mirrors

Outdoor [patio] furniture except cushions and wood

frames

Refrigerators, exteriors

Refrigerated storage and display equipment<sup>7</sup>

Showers

[Fiberglass] Shower stalls

[Fiberglass] Sinks [bathroom, kitchen]

Stoves<sup>7</sup> [stovetops]<sup>7</sup> Tables [picnic tables]

Telephones
Toilet exteriors
Toilet bowl exteriors
Toilet bowl surfaces
Tubs [Fiberglass]
Tiles, glazed
Ultrasonic baths

Urinals Walls

Whirlpool [bathtubs] [tubs] [units]

Windows

Beer fermentation and holding tanks

Blenders

Bottling or premix dispensing equipment Chopping blocks, plastic and other nonporous

Cooking utensils

Coolers Cutlery

Cutting Boards, plastic and other nonporous

Dishes

Eating Utensils Food processors Glassware Ice Chests

Kitchen equipment

Refrigerator bins used for meat, fruit, vegetables and

eggs Silverware Slurpy Machines Tupperware®

Other hard nonporous surfaces made of:

Fiberglass Formica<sup>®</sup> Glass

Glazed ceramic

Glazed enameled surfaces

Glazed porcelain

Metal

Plastic [such as polystyrene or polypropylene]

Sealed stone Stainless steel

Upholstery, vinyl and plastic

Woodwork, finished

{Note to reviewer: The following is considered optional marketing language. ATCC numbers are listed on the data matrix.}

**Lonza Formulation S-38F** is a sanitizer for hard nonporous non-food contact surfaces at 1:256 dilution [150 ppm active] [½ fl. oz. per gallon of water] 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

**Lonza Formulation S-38F** eliminates 99.9% of Staphylococcus aureus and Klebsiella pneumoniae in 60 seconds.

**Lonza Formulation S-38F** fulfills the criteria of Appendix F of the Grade "A" Pasteurized Milk Ordinances Recommendations of the U.S. Public Health Services in waters up to 300 ppm of hardness calculated as CaCO<sub>3</sub> when evaluated by the AOAC Germicidal and Detergent Sanitizer Method.

**Lonza Formulation S-38F** is an effective sanitizer for use on food contact surfaces in 60 seconds at 150 ppm active against:

Escherichia coli Staphylococcus aureus

**Lonza Formulation S-38F** is an effective sanitizer for use on food contact surfaces at 150 ppm active in waters up to 250 ppm hardness in 60 seconds against:

Listeria monocytogenes Salmonella enterica

**Lonza Formulation S-38F** is an effective sanitizer for use on food contact surfaces at 400 ppm active in waters up to 500 ppm hardness in 60 seconds against:

Listeria monocytogenes

#### For \*Virucidal Effectiveness:

At 1 fl. oz. per gallon of water, **Lonza Formulation S-38F** was evaluated in the presence of 5% serum and found to be effective against the following viruses:

- \*Influenza Virus A
- \*Hepatitis B Virus [HBV]
- \*Hepatits C Virus [HCV]
- \*Herpes Simplex Virus Type 1 and 2
- \*HIV-1 [AIDS virus]
- \*Rotavirus, at 2 fl. oz. per gallon
- \*SARS-Related Coronavirus 2 [SARS-CoV-2] [cause of COVID-19]
- \*Vaccinia Virus

{Note to reviewer: The following is considered optional marketing language. ATCC numbers are listed on the data matrix.}

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

At 2 fl. oz. per gallon of water, the activity of **Lonza Formulation S-38F** has been evaluated in the presence of 5% organic serum by the AOAC use-dilution test and found to be effective against the following gram negative and gram positive organisms [Bacteria:]:

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

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:

At 1 fl. oz. per gallon of water, the activity of **Lonza Formulation S-38F** has been evaluated in the presence of 5% organic serum by the AOAC use-dilution test and found to be effective against:

Staphylococcus aureus [Staph] Salmonella enterica [Salmonella]

Corynebacterium ammoniagenes Klebsiella aerogenes Escherichia coli [E. coli] Klebsiella pneumoniae [Klebsiella] Salmonella schottmuelleri [Salmonella] Serratia marcescens Shigella dysenteriae [Shigella] Streptococcus faecalis [Strep] {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	follow the directions for use for the following
that is a/an	organisms on the label:
Enveloped virus	Human Rotavirus (ATCC VR-2018), Strain WA

[LONZA FORMULATION S-38F] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, [LONZA FORMULATION S-38F] 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-38F] 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."

#### **Dilution:**

Disinfection – Medical [1:64]	2 fl. oz. per gallon of water
Disinfection – Non Medical [1:128]	1 fl. oz. per gallon of water
Virucide [Rotavirus] [1:64]	2 fl. oz. per gallon of water
Sanitizer [1:256]	
	[150 ppm active]
Sanitizer [1:96]	[11/3 fl. oz. per 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.

#### 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]	
Virucide [Rotavirus] [1:64]	2 fl. oz. per gallon of water

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

### 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.

Prepare fresh solution daily or more often if the solution becomes visibly dirty or diluted.

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.

#### For funcicidal activity:

At 1 fl. oz. per gallon of water, **Lonza Formulation S-38F** is an effective fungicide against Trichophyton interdigitale [the athlete's foot fungus] when used on hard nonporous 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-38F** 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.

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-38F.** 

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-38F** per gallon of water [¼ - ½ 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-38F** 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-38F** 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 UNITS:** After using the whirlpool unit, drain, and refill with fresh water to just cover the intake valve. Add 1-2 fl. oz. of **Lonza Formulation S-38F** for each gallon of fresh water added. Start the pump to circulate the solution. Wash down the unit sides, seat of the chair lift and any related equipment with a clean swab, brush or sponge. Treated surfaces must remain visibly 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 visibly soiled units.

**FOR USE ON SEALED FINISHED FLOORS:** To limit gloss reduction use **Lonza Formulation S-38F** 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-38F** 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-38F** 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-38F** per gallon of water. Saturate surfaces with the recommended 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 letter 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-38F** 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 water and **Lonza Formulation S-38F**. Use 1 - 2 fl. oz. of **Lonza Formulation S-38F** 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-38F**. 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-38F 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 a 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-38F** 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-38F** per gallon of water. **Lonza Formulation S-38F** 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:** 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-38F** 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 SANITIZE FOOD CONTACT SURFACES:

{or}

# TO SANITIZE FOOD PROCESSING EQUIPMENT AND OTHER HARD SURFACES IN FOOD PROCESSING LOCATIONS, DAIRIES, RESTAURANTS AND BARS:

Use **Lonza Formulation S-38F** to sanitize precleaned hard nonporous surfaces of food processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage and display equipment<sup>7</sup> and other hard surfaces.

Prior to application, pre-flush, or pre-scrape and, when necessary, pre-soak all surfaces. Then thoroughly wash or flush objects with a good detergent or compatible cleaner followed by a potable water rinse before application of the sanitizing solution.

Apply a use-solution of  $\frac{1}{2}$  fl. oz. [to  $\frac{1}{3}$  fl. oz.] of **Lonza Formulation S-38F** per gallon of water [or equivalent dilution] [150 ppm [to 400 ppm] active] to precleaned hard surfaces thoroughly wetting surfaces with a cloth, mop, sponge, coarse sprayer or by immersion. Surfaces must remain wet for at least 60 seconds [one minute] followed by adequate draining and air drying. Do not rinse. Prepare a fresh solution for each use. For mechanical application, use- solution may not be reused for sanitizing applications but may be reused for other purposes such as cleaning.

Apply to sink tops, countertops, refrigerated storage and display equipment<sup>7</sup> and other stationary hard nonporous surfaces by cloth, sponge, brush or coarse spray.

Sanitize dishes, silverware, glasses, cooking utensils and other similar size food processing equipment by immersion.

Lonza Formulation S-38F EPA Reg. No. 6836-138 EPA Amendment March 3, 2022 **Lonza Formulation S-38F** can be used in accordance with the U.S. Public Health Service food service sanitization recommendations.

#### U.S. PUBLIC HEALTH SERVICE FOOD SERVICE SANITIZATION RECOMMENDATIONS

**CLEANING AND SANITIZING:** Equipment and utensils shall be thoroughly pre-flushed or pre-scraped and when necessary, pre-soaked to remove visible food particles and soil.

- 1. Thoroughly wash equipment and utensils in hot detergent solution.
- 2. Rinse utensils and equipment thoroughly with clean water.
- 3. Sanitize equipment and utensils by immersion in a use solution of ½ fl. oz. [to 1⅓ fl. oz.] of **Lonza Formulation S-38F** per gallon of water [150 ppm [to 400 ppm] active quat] [or equivalent dilution] for at least 60 seconds at a [minimum] temperature of 75°F.
- 4. For equipment and utensils too large to sanitize by immersion, apply a use-solution of ½ fl. oz. [to 1⅓ fl. oz.] of **Lonza Formulation S-38F** per gallon of water [150 ppm [to 400 ppm] active quat] [or equivalent dilution] by rinsing, spraying or swabbing until thoroughly wet.
- 5. Allow sanitized surface to drain and air dry. Do not rinse.

#### TO SANITIZE BEVERAGE DISPENSING EQUIPMENT7:

- 1. Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing.
- 2. Fill equipment with a solution of ½ fl. oz. [to 1½ fl. oz.] **Lonza Formulation S-38F** per gallon of water [or equivalent dilution] [150 ppm [to 400 ppm] active].
- 3. Allow solution to remain in equipment for at least 60 seconds.
- 4. Drain thoroughly before reuse and allow to air dry.

#### TO SANITIZE SANITARY FILLING EQUIPMENT:

Wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing. Prepare a use-solution of  $\frac{1}{2}$  fl. oz. [to 1  $\frac{1}{3}$  fl. oz.] of **Lonza Formulation S-38F** per gallon of water [or equivalent dilution] [150 ppm [to 400 ppm] active] for final washer and rinser applications. Allow surfaces to remain wet for at least 60 seconds. Drain thoroughly before reuse and allow to air dry.

#### TO SANITIZE BEER FERMENTATION AND STORAGE TANKS7:

Wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing. Prepare a use-solution of  $\frac{1}{2}$  fl. oz. [to  $\frac{1}{3}$  fl. oz.] of **Lonza Formulation S-38F** per gallon of water [or equivalent dilution] [150 ppm [to 400 ppm] active] for mechanical or automated systems. Allow surfaces to remain wet for at least 60 seconds. Drain thoroughly and allow to air dry before reuse.

#### TO SANITIZE EGG SHELLS INTENDED FOR FOOD:

To sanitize previously cleaned food-grade eggs in shell egg and egg product processing plants, spray with a use-solution of ½ fl. oz. [to 1½ fl. oz.] of **Lonza Formulation S-38F** per gallon of warm water [or equivalent dilution] [150 ppm [to 400 ppm] active]. The solution must be equal to or warmer than the eggs, but not to exceed 130°F. Wet eggs thoroughly and allow to drain. Eggs sanitized with this product shall be subjected to a thorough potable water rinse only if they are to be broken immediately for use in the manufacture of egg products. Eggs must be reasonably dry before casing or breaking. The solution must not be re-used for sanitizing eggs.

Note: Only clean, whole eggs can be used for sanitizing. Dirty, cracked or punctured eggs cannot be sanitized.

#### TO SANITIZE STATIONARY KITCHEN AND FOOD PROCESSING EQUIPMENT:

**Lonza Formulation S-38F** can be used to clean and sanitize equipment such as deli slicers, beverage equipment<sup>7</sup>, ice machines<sup>7</sup> and dispensers<sup>7</sup>. Refer to the equipment manufacturer's instructions to determine how to clean and sanitize the equipment in place or to disassemble the equipment for cleaning & sanitizing by immersion.

Clean with **Lonza Formulation S-38F** according to the label directions. To sanitize, preclean/clean surfaces and apply a use-solution of  $\frac{1}{2}$  - 1 1/3 fl. oz. of **Lonza Formulation S-38F** per gallon of water [150 [to 400ppm] active quat] [or equivalent dilution] by spraying or swabbing until thoroughly wet. Allow surfaces to remain wet for at least 60 seconds. Drain thoroughly before reuse and allow to air dry.

### TO CLEAN [AND DEODORIZE] {or} CLEANING DIRECTIONS:

Mix [1 - 2 fl. oz.] [1 - 1 1/3 fl. oz.] of **Lonza Formulation S-38F** per gallon of water to clean [and deodorize] surfaces. Apply using a cloth, mop, sponge or sprayer [or by immersion]. Wipe or allow to air dry.

#### **GLASS CLEANING / DEODORIZING DIRECTIONS:**

Add ½ - 2 fl. oz. of **Lonza Formulation S-38F** 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.

#### 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

(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.

- <sup>1</sup>SARS-Related Coronavirus 2
- <sup>2</sup>On hard, non-porous, non-food surfaces
- <sup>3</sup>When used according to the disinfection directions.
- <sup>4</sup>When used according to the sanitization directions.
- <sup>5</sup>Staphylococcus aureus
- <sup>6</sup>Pseudomonas aeruginosa
- <sup>7</sup>Allow the surface to adjust to room temperature before disinfection. <sup>8</sup>Staphylococcus aureus and Klebsiella pneumoniae
- <sup>9</sup>Escherichia 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-38F**

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**

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

EPA Reg. No. 6836-138

Diluted product not for sale or distribution.

{Note to reviewer, the following is optional marketing language to be used with Insta-Use Refill Cartridge and bottle}

Individual cartridges are not for resale.

{Note to reviewer, the following are instructions for Insta-Use Refill Cartridge and bottle}

### Cartridge Instructions (choose one of the following):

Fill bottle with water to fill line on spray bottle. Insert cartridge as shown into spray bottle. Note: Do not overfill bottle. Overfilling will prevent cartridge from emptying.

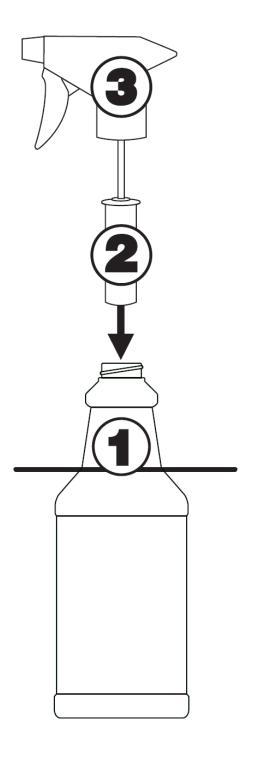
OR

Fill bottle with water as directed on the product label. Insert cartridge as shown into spray bottle. Note: Do not overfill bottle. Over filling will prevent cartridge from emptying.

### **Storage and Disposal:**

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

# Refill Directions



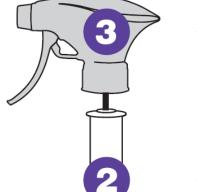
3) Attach sprayer to bottle & shake gently.

2) Insert cartridge into bottle neck.

1) Fill with water to fill line.

**NOTE:** Overfilling will prevent the cartridge from emptying completely.

# Refill Directions





3) Attach sprayer to bottle & shake gently.



2) Insert cartridge into Bottle neck.



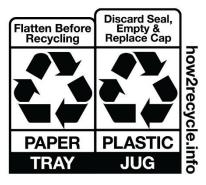
1) Water fill level

**NOTE:** Overfilling will prevent the cartridge from emptying completely.

{Note to reviewer: the following are optional graphics}







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{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:**

#### 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}

