



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 4, 2017

Kathryn Rosario
Regulatory Assurance Specialist
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

Subject: Label Amendment – Addition of emerging pathogens language
Product Name: Lonza Formulation S-21
EPA Registration Number: 6836-75
Application Date: June 5, 2017
Decision Number: 530308

Dear Ms. Rosario:

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. 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"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, 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 of 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:
 1. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 2. 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),
 3. 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/Deaseinformation/WI](http://www.oie.int/wahis_2/public/wahid.php/Deaseinformation/WI))
 - b. 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 or large, non-enveloped.
 - c. 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.

5. Terms 1 through 4 above shall become immediately void and ineffective if registration for use against Feline calicivirus (surrogate for *Norwalk virus*) is suspended or canceled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms 1 through 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 the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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 Tara Flint via email at flint.tara@epa.gov or Eric Miederhoff at Miederhoff.eric@epa.gov.

Sincerely,



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

Enclosure

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-21

One-Step Disinfectant

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

Effective in hard water up to 200 ppm hardness [calculated as CaCO₃] in the presence of 5% serum contamination

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

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

[Citrus] [Floral] [Fresh] [Lavender] [Lemon] [Lime] [Mint], [Peppermint] [Pine] [Woody] [Scent] [Scented] [Fragrance] [Odor]

Active Ingredients:

| | |
|---|---------|
| Octyl decyl dimethyl ammonium chloride..... | 1.65% |
| Dioctyl dimethyl ammonium chloride..... | 0.66% |
| Didecyl dimethyl ammonium chloride..... | 0.99% |
| Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride | 2.20% |
| Other Ingredients: | 94.50% |
| Total:..... | 100.00% |

KEEP OUT OF REACH OF CHILDREN

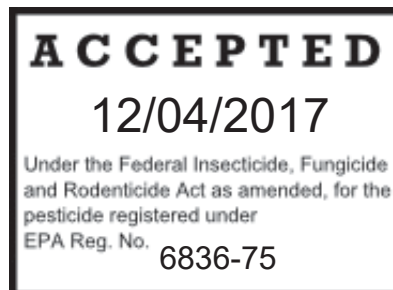
DANGER [PELIGRO]

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

EPA Reg. No. 6836-75
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:
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401



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 (rubber or chemical resistant) gloves and protective clothing. Harmful if swallowed or absorbed through the skin. 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.

FIRST AID

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

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

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

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

Call a poison control center or doctor for treatment advice.

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

{If container size is 5 gallons or 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 3-10 are considered optional marketing language.}

Cleans [Cleaner]

Concentrate [Concentrated]

Deodorizes [Deodorant]

Disinfects [Disinfectant]

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

Lonza Formulation S-21:

- deodorizes by killing microorganisms that cause offensive odors.
- delivers non-acid disinfectant and cleaning performance in an economical concentrate.
- eliminates 99.9% of Staphylococcus aureus and Klebsiella pneumoniae on hard, non-porous surfaces in 60 seconds.
- [improves labor results by] effectively controls [controlling] malodors.
- is effective yet economical.
- is a complete, chemically balanced disinfectant [and sanitizer] [that provides clear use solutions even in the presence of hard water].
- is a [concentrated] [one-step] [Hospital Use] disinfectant cleaner that is effective against a broad spectrum of bacteria, is virucidal* [including HIV-1, the AIDS Virus] [and Hepatitis B Virus] [and Hepatitis C Virus], fungicidal, and inhibits the growth of mold and mildew, and their odors, when used as directed.
- [is a heavy duty disinfectant cleaner that] cleans, disinfects and deodorizes in one labor saving step.
- is a mildewstat and will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard nonporous surfaces.
- is a proven one-step disinfectant - cleaner - sanitizer - fungicide - mildewstat - virucide* which is effective in water up to 200 ppm hardness in the presence of 5% serum contamination.
- is a proven "one-step" cleaner - sanitizer which is effective in water up to 500 ppm hardness in the presence of 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-cleaner for use on non-food contact surfaces.
- is effective against Citrus Canker Disease [Xanthomonas axonopodis pv. citri] at 2000-ppm active quat.
- is effective at controlling mold and mildew odor on mattresses, pillows and shower curtains. **{Not for use in California}**
- is formulated for use in daily maintenance programs with a balance of detergents, biocides and malodor counteractants that deliver effective cleaning, disinfecting and malodor control.
- [Kills] [Eliminates] [Removes] [Destroys] avian influenza A (H3N2) [and] (H5N1) on pre-cleaned environmental surfaces
- [Kills] [Eliminates] [Removes] [Destroys] *(Insert pathogen or pathogens from lists on pages 8-10)* on [pre-cleaned] environmental surfaces
- [Kills] [Eliminates] [Removes] [Destroys] [Germs] [Bacteria] [Viruses*] [on [pre-cleaned] environmental surfaces]
- leaves a clean fresh scent.
- meets AOAC testing standards for hospital disinfectants.
- meets Sanitizer Test standards for non-food contact sanitizers.
- provides long lasting freshness against tough [pet] odors such as odors from litter boxes and pet accidents.
- 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.

- Quaternary blend disinfectant effective in 200ppm hard water and 5% organic load.
- Formulated for effective farm, poultry, and swine premise and veterinary practice.
- Broad spectrum kill of molds, bacteria, viruses and fungi.
- Effective against *Aspergillus fumigatus* at a 2 oz. per gallon dilution
- Effective against [Carbapenem-resistant Enterobacteriaceae] [CRE], including:
 - *Escherichia coli* – NDM-1 positive
 - *Klebsiella pneumoniae* – NDM-1 positive

{Note to reviewer: below claims require TO SANITIZE SOFT SURFACES Directions on page 16}

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

Use Lonza Formulation S-21

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

[AREAS OF USE:]

Use **Lonza Formulation S-21** 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 | Prisons |
| Homes [Households] | Public facilities |
| Kitchens | Public rest rooms, Schools |
| Clinics | Shower and bath areas |
| Dental offices | Salons [Beauty] [Tanning] |
| Health Care Facilities | Universities |
| Hospitals | |
| Medical Offices | Camp grounds |
| Medical Related facilities | Play ground equipment |
| Nursing homes | |
| Sick Rooms | Animal laboratories |
| Day care centers | Dairy farms |
| Nurseries | Farms Hog farms |
| Bars | Kennels |
| Cafeterias | Mushroom Farms |
| Convenience stores | Poultry farms |
| Food Preparation Areas | Pet animal quarters |
| Food processing plants | Pet shops |
| Food storage areas | Turkey farms |
| Institutional kitchens | Zoos |
| Restaurants [Front of House] | |
| USDA inspected food processing facilities | Airplanes Airports Ambulances |
| Athletic facilities | Boats |
| Barber shops | Buses |
| Business and office buildings | Campers |
| Colleges | Cars |
| Correctional facilities | Emergency [Police] [EMS] [Fire] [Rescue] vehicles |
| Dressing rooms | Mobile homes |
| Exercise facilities | |
| Factories | Ships |
| Hotels | Taxis |
| Institutional facilities | Trailers |
| Institutions | Trains |
| Locker rooms | Transportation terminals |
| Motels | |

Cross-contamination is of major housekeeping concern. **Lonza Formulation S-21** has been formulated to aid in the reduction of cross-contamination on treated hard nonporous surfaces not only in hospitals, but in schools, institutions and industry.

Lonza Formulation S-21 is a phosphate free, germicidal detergent effective in the presence of a moderate amount of organic soil on hard nonporous surfaces found at mushroom farms. **Lonza Formulation S-21** 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-21** must be limited to areas where compost and mushrooms are not present.

Other suggested Uses: Homes, Veterinary Clinics, Fish Markets, Kennels, Trash Compactors, Offices, Beauty Salons, Locker Rooms, Health Spas, Conference rooms, Elevators, Smoking Areas, Lounges, Day Care Centers, Dry Cleaners, Theaters, Farms, Auditoriums and Churches.

Lonza Formulation S-21

EPA Reg. No. 6836-75

EPA Notification 2017-05-10 EPA Submission 2017-06-05

[TYPES OF SURFACES:]

Use **Lonza Formulation S-21** 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
Bathroom fixtures
Bathtubs [fiberglass]
Cabinets

Cages
Chairs
Coils and drain pans of air conditioning and refrigeration
equipment and heat pumps

Conductive flooring
Counters [Countertops]
Countertop laminates

Desks
Doorknobs
Floors
Garbage cans
Highchairs

Kennel runs
Microwave ovens, exteriors of
Outdoor [patio] furniture except cushions and wood
frames

Refrigerators, exteriors of
Refrigerated storage and display equipment
Showers

Shower stalls [Fiberglass]
Sinks [bathroom] [kitchen] [Fiberglass]
Stoves [stovetops]

Tables [Non-wooden picnic tables]
Tanning beds
Telephones

Toilets
Toilet bowls
Toilet bowl surfaces

Tubs [Fiberglass]
Tiles, glazed
Ultrasonic baths

Urinals
Walls
Whirlpool bathtubs

Non-critical medical device surfaces:

Beds [Medical] [Hospital]

Bed frames

Bed rails

Crutches

Defibrillators

Gurneys

Non-critical [hospital] [medical] equipment surfaces:

[Medical] Examining tables

[Medical] [Hospital] Lamps

Rescue tools

Resuscitators

[Medical] [Hospital] Scales

Stands

Stretchers

Stethoscopes

Walkers

Wheel chairs

Other hard nonporous surfaces made of:

Glazed ceramic

Glazed enameled surfaces

Glazed porcelain

Laminated surfaces

Metal

Plastic [such as polystyrene or polypropylene]

Sealed stone

Stainless steel

Upholstery, vinyl and plastic

Woodwork, finished

Use **Lonza Formulation S-21** on soft surfaces of:

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)

Lonza Formulation S-21 is effective at eliminating odors on porous surfaces such as upholstery, drapes, carpets, bedding, shower curtains, mattresses and non-porous surfaces such as walls and floors. Excellent for fire restoration.

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

Lonza Formulation S-21 is a sanitizer for hard nonporous non-food contact surfaces according to the method for Sanitizers - Non-Food Contact Surfaces, modified in the presence of 500 ppm hard water plus 5% organic serum in 60 seconds against:

Klebsiella pneumoniae Staphylococcus aureus

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

Lonza Formulation S-21 is a [one-step] [Hospital use] disinfectant, Bactericidal according to the current AOAC Use-Dilution Test Method, Fungicidal according to the AOAC Fungicidal Test and Virucidal* according to the virucidal qualification modified in the presence of 200 ppm hard water plus 5% organic serum against:
{or}

As a disinfectant, Lonza Formulation S-21 [kills] [is effective against]:

[Bacteria:]

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

Acinetobacter baumannii [Acinetobacter]
Burkholderia cepacia
Campylobacter jejuni [Campylobacter]
Corynebacterium ammoniagenes
Enterobacter aerogenes
Enterobacter cloacae NDM-1 positive
Enterococcus faecalis [Enterococcus]
Enterococcus faecalis - Vancomycin resistant [VRE]
Escherichia coli [E. coli]
Escherichia coli, New Delhi Metallo-Beta Lactamase (NDM-1)
ESBL Escherichia coli [Extended spectrum beta-lactamase producing E. coli]
Klebsiella pneumoniae [Klebsiella]
Klebsiella pneumoniae – NDM-1 positive
Legionella pneumophila
Listeria monocytogenes [Listeria]
Salmonella schottmuelleri [Salmonella]
Salmonella typhi [Salmonella]
Serratia marcescens
Shigella dysenteriae [Shigella]
Staphylococcus aureus - Community Associated Methicillin-Resistant [CA-MRSA] [NRS384] [USA300]
Staphylococcus aureus - Community Associated Methicillin-Resistant [CA-MRSA] [NRS123] [USA400]
Staphylococcus aureus - Methicillin-Resistant [MRSA]
Staphylococcus aureus - Multi-Drug Resistant [resistant to tetracycline [Tc], penicillin [Pc], streptomycin [Sm] and erythromycin [Em] and susceptible to chloramphenicol [Cm] *in vitro*]
Staphylococcus aureus - Vancomycin Intermediate Resistant [VISA]
Streptococcus pyogenes [Strep] [a cause of scarlet fever]
Vibrio cholerae

[Viruses:]

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

*Hepatitis B Virus [HBV]
*Hepatitis C Virus [HCV]
*Herpes Simplex Virus Type 1 [Herpes]
*Herpes Simplex Virus Type 2 [Herpes]
*HIV-1 [the AIDS Virus]
*Human Coronavirus
*Influenza Type A Virus / Brazil [Influenza]
*Influenza Virus Type A / Hong Kong [Influenza]
*2013 Influenza A Virus (H7N9)
*Respiratory Syncytial Virus [RSV]
*SARS Associated Coronavirus [SARS] [cause of Severe Acute Respiratory Syndrome]
*Vaccinia [Pox Virus]

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

*Adenovirus Type 5 [Adenovirus] [at 1:16 dilution [8 oz. per gallon] [of water]]

*Adenovirus Type 7 [Adenovirus] [at 1:16 dilution [8 oz. per gallon] [of water]]

*Norwalk Virus [Feline Calicivirus] [Norovirus]

*Rotavirus

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

Lonza Formulation S-21 [kills] [is effective against] [the following animal viruses:]

Avian Infectious Bronchitis Virus

Avian Influenza Virus (H3N2)

Avian Influenza Virus (H5N1)

Canine Distemper Virus

Feline Calicivirus

Feline Panleukopenia Virus [32 oz. per gallon] [of water]

Murine Norovirus¹

Newcastle's Disease Virus

Pseudorabies Virus

[Fungi:]

Aspergillus fumigatus

Aspergillus niger

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

¹Tested in deionized water

EMERGING VIRAL PATHOGEN CLAIMS

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

Lonza Formulation S-21 meets the criteria for use against the following categories of emerging viral pathogens when used according to the Norovirus use directions on hard, non-porous surfaces:

- Enveloped viruses
- Large, non-enveloped viruses

Lonza Formulation S-21 has demonstrated effectiveness against viruses similar to [*name of emerging virus*] on hard, non-porous surfaces. Therefore, **Lonza Formulation S-21** can be used against [*name of large, non-enveloped, emerging virus*] when used in accordance with the directions for use against (Feline Calicivirus (surrogate for Norwalk virus)) on hard, non-porous surfaces. Refer to the [*CDC or OIE*] website at [*pathogen-specific website address*] for additional information.

[*Name of illness/outbreak*] is caused by [*name of large, non-enveloped, emerging virus*]. **Lonza Formulation S-21** kills similar viruses and therefore can be used against [*name of large, non-enveloped, emerging virus*] when used in accordance with the directions for use against (Feline calicivirus (surrogate for Norwalk virus)) on hard, non-porous surfaces. Refer to the [*CDC or OIE*] website at [*website address*] for additional information.

Dilution:

- Disinfection [1] [Soft Surface Sanitization] [1:64] 2 oz. per gallon of water
- Disinfection [1:32] 4 oz. per gallon of water
- Disinfection [1:16] 8 oz. per gallon of water
- Sanitizer [1:256] 2 oz. per 4 gallons of water [200 ppm active]

{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 Disinfectant Use-Solution:

[Add] [Mix] 2 oz. per gallon of water [1:64] or [2 - 4 oz. per gallon of water] or [2 – 8 oz. per gallon of water]. For heavy duty use, [add] [mix] 8 oz. per gallon of water [1:16]. Use 8 oz. per gallon of water to kill Adenovirus Type 5 and Type 7. [Use 32 oz. per gallon of water to kill Feline Panleukopenia Virus.]

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

Apply use-solution to hard, nonporous surfaces, thoroughly wetting the surfaces, with a cloth, mop, sponge, sprayer or by immersion. Treated surfaces must remain wet for 10 minutes. {Note to reviewer: if using reduced contact time for Influenza Virus Type A and/or Human Coronavirus, the following sentence will be required:}

[For [Influenza Virus Type A] [and] [Human Coronavirus], treated surfaces must remain wet for 1 minute.]

Wipe dry with a cloth, sponge or mop or allow to air dry. For heavily soiled areas, a preliminary cleaning is required.

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

For fungicidal activity, Lonza Formulation S-21 is an effective fungicide against *Trichophyton mentagrophytes* [the athlete's foot fungus] in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities. Dilute 2 oz. per gallon of water or [2 - 4 oz. per gallon of water] or [2 – 8 oz. per gallon of water] and allow surface to remain wet for 10 minutes.

Lonza Formulation S-21 is a one-step fungicide at 2 oz. per gallon of water or [2 - 4 oz. per gallon of water] or [2 – 8 oz. per gallon of water] in 200 ppm hard water and 5% serum.

For mold and mildew At 2 oz. per gallon or [2 - 4 oz. per gallon] or [2 – 8 oz. per gallon], **Lonza Formulation S-21** will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, nonporous surfaces. Follow disinfection instructions. Repeat treatment every seven days, or more often if new growth appears.

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.

{Note to reviewer: one of the following two statements will be used:}

BACTERICIDAL STABILITY OF USE-DILUTION: [Tests confirm that] the use solution of this product, when stored in a sealed container such as a spray bottle, remains effective for [up to 7 days] [for up to one week] [for up to one month] [for up to 2 months] [for up to 3 months] [for up to 4 months] [for up to 5 months] [for up to 6 months] [for up to 12 months] [for up to 1 year]. 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. Bactericidal 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.

{Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must be used:}

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that [1] is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or [2] contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. [This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.]

{or}

This product is not for use on medical device surfaces.

***KILLS HIV AND HBV AND HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES / OBJECTS**

PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces / objects with blood or body fluids, and in which the surfaces / objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 [HIV-1] [associated with AIDS] or Hepatitis B Virus [HBV] or Hepatitis C Virus [HCV].

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

Personal Protection: Clean up should 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-21**.

Contact Time: Leave surface wet for 1 minute [60 seconds] for HIV-1 and 10 minutes for HBV and HCV with a 2 oz. or [2 - 4 oz.] or [2 – 8 oz.] per gallon use-solution. Use 8 oz. per gallon of water to kill Adenovirus Type 5 and Type 7. Use a 10-minute contact time for disinfection against all other viruses, bacteria and fungi claimed.

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

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

Remove gross filth prior to disinfection.

From Concentrate:

Add 2 oz. or [2 - 4 oz.] or [2 – 8 oz.] to the bowl. Use 8 oz. to kill Adenovirus Type 5 and Type 7.

Thoroughly brush or swab over exposed surfaces and 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 2 oz. per gallon or [2 - 4 oz. per gallon] or [2 – 8 oz. per gallon] use-solution to exposed surfaces and under the rim with a cloth, mop, sponge or sprayer. Use 8 oz. per gallon of water to kill Adenovirus Type 5 and Type 7. 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 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:

Mix 4 oz. [120 mL] or [4 - 8 oz. [120 -240 ml]] of **Lonza Formulation S-21** per gallon of water [1 oz. [30 mL] or [1 - 2 oz. [30 - 60 ml]]] of **Lonza Formulation S-21** per quart of water] to disinfect hard, nonporous instruments and tools. Use 8 oz. per gallon of water to kill Adenovirus Type 5 and Type 7. Completely immerse combs, brushes, rollers, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Fresh solution should be prepared 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 [VIRUCIAL*] DIRECTIONS:

Use **Lonza Formulation S-21** to disinfect hard nonporous non-critical objects compatible with Ultrasonic cleaning units. Pour fresh use-solution of 2 oz. or [2 - 4 oz.] or [2 - 8 oz.] of **Lonza Formulation S-21** per gallon of water directly into bath chamber. Use 8 oz. per gallon of water to kill Adenovirus Type 5 and Type 7. Pre-clean heavily soiled objects. Place objects into unit and operate for a minimum of 10 minutes, according to the manufacturer's directions. Remove objects and wash with sterile water [sterile water for injection] or allow to air dry. Prepare fresh solution for each use.

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

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 2 oz. or [2 - 4 oz.] or [2 - 8 oz.] of **Lonza Formulation S-21** for each gallon of fresh water added. Use 8 oz. per gallon of water to kill Adenovirus Type 5 and Type 7. 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 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 heavily soiled units.

WHIRLPOOL FOOT SPA DISINFECTION:

After using whirlpool foot spa, drain the water. Use 2 oz. of product per gallon of water [8 oz. per gallon of water to kill Adenovirus Type 5 and 7] to cover intake valve or 2 inches above highest jet. Start pump to circulate the solution. Swab exposed surfaces including unit sides, chair, and any related equipment thoroughly with cloth, sponge, or brush and allow treated surfaces and solution to stand for 10 minutes. After unit has been thoroughly disinfected, rinse all disinfected surfaces with fresh water.

FOR USE ON FINISHED FLOORS: To limit gloss reduction use **Lonza Formulation S-21** at 2 oz. per gallon or [2 - 4 oz. per gallon]. Apply with a damp mop or autoscrubber. Allow surface to remain wet for 10 minutes. Wipe or allow to air dry. Do not use on floor finish at 8 oz. per gallon.

["SPECIAL INSTRUCTIONS FOR INACTIVATING AVIAN INFLUENZA" AND OTHER ANIMAL VIRUSES LISTED ON THIS LABEL]

{or}

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

For cleaning and disinfecting hard nonporous surfaces: equipment used for feeding or watering animals, utensils, instruments, cages, kennels, stables, catteries, pens, stalls and etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, pens, stalls and etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 2 oz. or [2 - 4 oz.] or [2 – 8 oz.] of **Lonza Formulation S-21** per gallon of water [or equivalent dilution] for a period of 10 minutes. Use 8 oz. per gallon of water to kill Adenovirus Type 5 and Type 7. Use 32 oz. per gallon of water to kill Feline Panleukopenia Virus. For murine norovirus use dilution must be made with deionized water. Wipe or allow to air dry. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for removing litter and manure. Thoroughly scrub all treated surfaces, then rinse all surfaces that come in contact with food, including equipment used for feeding or watering, with potable water before reuse. Ventilate buildings, animal enclosures, [vehicles] and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

FARM PREMISE USE:

Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with a use-solution of 2 oz. or [2 - 4 oz.] or [2 – 8 oz.] of **Lonza Formulation S-21** per gallon of water [or equivalent dilution] for a period of 10 minutes. Use 8 oz. per gallon of water to kill Adenovirus Type 5 and Type 7. 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 [/ VIRUCIAL*] 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 2 oz. or [2 - 4 oz.] or [2 – 8 oz.] of **Lonza Formulation S-21** per gallon of water. Saturate surfaces with the recommended disinfecting solution for 10 minutes. Use 8 oz. per gallon of water to kill Adenovirus Type 5 and Type 7. 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 2 oz. of **Lonza Formulation S-21** per gallon of water to treat the following hard nonporous surfaces: hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces wet for 10 minutes or more. Wipe dry with a clean cloth or sponge or allow to air dry.

Vehicles: Treat all vehicles including mats, crates, cabs and wheels with water and **Lonza Formulation S-21**. Use 2 oz. of **Lonza Formulation S-21** per gallon of water to treat all vehicles. Leave all treated surfaces wet for 10 minutes or more. Wipe dry with a clean cloth or sponge or allow to air dry.

Dressing Plant Disinfectant Directions: Disinfect equipment, utensils, walls and floors in poultry and animal dressing plants. Disinfect offal rooms, exterior walls and loading platforms of dressing plants. Cover or remove all food and packaging materials. Remove all heavy soils prior to application. Saturate all surfaces with a 2 oz. of **Lonza Formulation S-21** per gallon of water solution. Use 8 oz. to kill Adenovirus Type 5 and Type 7. Scrub to loosen all soils. Surfaces must remain 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 gross contamination and debris. This may be accomplished by using a shovel, broom, or vacuum, depending on the area to be disinfected.

Cleaning and Disinfection: For general cleaning and disinfection, use 2 oz. or [2 - 4 oz.] or [2 – 8 oz.] of **Lonza Formulation S-21** 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 wet for 10 minutes. Wipe or allow to air dry. For heavily 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 8 oz. of **Lonza Formulation S-21** per gallon of water. Heavily 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.

CITRUS CANKER DISEASE CONTROL:

For prevention of Citrus Canker Disease through treatment of precleaned equipment. Effective against *Xanthomonas axonopodis* pv. *citri* [Citrus Canker Disease] at 2000 ppm active quat. Treatments can be applied to trucks, attached trailers, field harvesting equipment including cargo area, wheels, tires, undercarriage, hood, roof, fenders, and any other hard nonporous part of the equipment that can be taken into infested areas.

Thoroughly clean all surfaces with soap or detergent and rinse with water. Then saturate surfaces with a 1:27.5 use-dilution [4 ¾ oz. of **Lonza Formulation S-21** per gallon of water] [19 oz. of **Lonza Formulation S-21** per 4 gallons of water] [or equivalent dilution] [2000 ppm active quat] for a period of 10 minutes. Allow to air dry. All surfaces that come in contact with food or crop must be rinsed with potable water before reuse. To prevent the spread of Citrus Canker Disease by this artificial means of transportation, treatments are made by trigger spraying, dipping or brushing. Clothing must be either rinsed or laundered before reuse. Footwear must be rinsed before reuse.

TO SANITIZE NON-FOOD CONTACT SURFACES:

[Add] [Mix] 2 oz. of **Lonza Formulation S-21** per 4 gallons of water [$\frac{1}{2}$ oz. of **Lonza Formulation S-21** per gallon of water] to sanitize hard nonporous surfaces. Treated surfaces must remain wet for 60 seconds. Wipe dry with a sponge, mop or cloth or allow to air dry.

TO SANITIZE BARBER / SALON INSTRUMENTS AND TOOLS: {Not For Use in California}

Immerse precleaned barber / salon instruments and tools [such as combs, brushes, razors, scissors, blades and manicure instruments] in a use-solution of 2 oz. of **Lonza Formulation S-21** per 4 gallons 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.

SANITIZATION OF [WHIRLPOOL [BATH[S]] [UNIT[S]]:

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 2 ounces of **Lonza Formulation S-21** for each 2 – 4 gallons of fresh water added. Start the pump to circulate the solution. Wash down the [[deck] [seat of chair lift] [any related equipment] and] any uncovered surfaces on the [bath] [unit] with a clean swab, brush or sponge with the solution. Treated surfaces must remain wet for at least 60 seconds. Drain bath and wipe dry with a clean sponge or cloth or allow to air dry.

{For food processing or other facilities that have installed entryway sanitizing systems}

SHOE BATH SANITIZER DIRECTIONS: To prevent cross contamination into 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 2 oz. per 4 gallons 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.

SHOE FOAM SANITIZER DIRECTIONS:

To prevent cross contamination into animal areas, apply a foam layer approximately $\frac{1}{2}$ to 2 inches thick made from a solution of 2 oz. of **Lonza Formulation S-21** per 2 – 5 $\frac{1}{2}$ gallons of water [400 – 150 ppm active quat] [or equivalent dilution], at all entrances to buildings, hatcheries, production and packaging rooms by using a foam generating machine or aerator to apply the foam layer. Follow the foaming directions as specified by the manufacturer of the foam generator or aerator. Scrape waterproof [work boots] [shoes]. Stand or walk through foamed area for 60 seconds prior to entering area. Wash and replace Foam Area at least daily or more often if the Foam Area appears diluted or soiled.

TO SANITIZE SOFT SURFACES:

For treatment of soft surfaces: Use [2 oz.] or [2 - 4 oz.] or [2 – 8 oz.] of **Lonza Formulation S-21** per gallon of water. Apply use-solution to soft, porous surfaces, with sprayer. Hold bottle 6" – 8" from surface and spray until fabric is wet. Fabric must remain wet for 5 minutes. Allow fabric to air dry. (Reapply as necessary.) (Highly)(Heavily) soiled areas must be cleaned prior to sanitizing.

TO CLEAN AND DEODORIZE: [Mix] [Use] 2 oz. per gallon of water or [2 - 4 oz. per gallon of water] or [2 – 8 oz. per gallon of water] to clean and deodorize surfaces. Apply using a cloth, mop, sponge or sprayer. Wipe or allow to air dry.

Cleaning Solution: Dilute 2 - 4 oz. per gallon of water for cleaning of kitchen counters, tables, walls, bathrooms, toilet seats, mopping floors and large routine applications. Apply to surfaces using cloth, mop or sponge. Remove excess liquid or allow surfaces to air dry.

Deodorizing directions:

Nursing Homes, Hospitals, Hotels, Schools, Restaurants: 2 - 4 oz. in chemical toilets, waste receptacles, bed pans, drainage bottles, diaper pails, hampers, disposals, commodes and air conditioner pans will eliminate odors.

Mopping Solutions, Automatic Scrubbers: 2 - 4 oz. per gallon of water eliminates undesirable odors. Allow surfaces to air dry.

Laundry: 2 oz. per load added during the final rinse cycle deodorizes all offensive odors.

Air Freshener/Automotive Uses: 8 ounces per gallon of water or desired concentration will effectively neutralize damp musty odors caused by mildew in storage areas, basements, closets and bathrooms. Effective on smoking and cooking odors [garlic, fish, onions, etc.]. Automobile odors from tobacco, musty carpet smell and beverage smells will be eliminated.

Carpets: 2 - 4 oz. per gallon of water eliminates odors associated with urine, vomit, smoke, and mildew. Reapply after cleaning for freshening effects. Allow to dry.

RV Holding Tanks: Toilet waste: cover bottom of holding tank with water and add 2 - 4 oz. If odors return before time to empty, simply add 2 - 4 oz. to the tank. Kitchen waste: 2 - 4 oz. of Lonza **Formulation S-21** to gray water tank as needed to control malodors created by dirty dish water.

Pet Odors: Use 8 - 12 oz. per gallon of water or desired concentration, for urine, feces, and vomit, in carpet and upholstery. Clean prior to application then spray onto affected areas. Test hidden area for colorfastness. Allow 10 minutes contact time. Then blot with clean cloth. Allow to dry. Also effective on pet bedding and litter boxes.

Sewage Backup, Water Damage: 4 – 8 oz. per gallon of water or desired concentration. Spray over affected areas before and after cleaning and extraction. Allow ten minutes contact time. Use proper ventilation; open windows.

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

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

Sewer Backup and River Flooding: During mitigation procedures, dilute 2 – 4 oz. of the concentrate per gallon of water, allowing for the diluting effect of absorbed water within saturated materials. Remove gross filth or heavy soil along with non-salvageable materials. Saturate all affected areas with a coarse spray device before and after cleaning and extraction.

Carpets, Carpet Cushions and Other Porous Materials such as Subfloors, Drywall, Trim and Frame Lumber, Tackless Strip and Paneling: For water damage from a clean source, extract excess water. Test hidden area for colorfastness. Dilute 2 – 4 oz. of the concentrate per gallon of water, allowing for the diluting effect of absorbed water within saturated materials. Remove gross filth or heavy soil. Saturate all affected areas with a coarse spray device. Roll, brush or agitate into the materials and allow materials to remain wet for 10 minutes. Follow with a thorough extraction. Dry rapidly and thoroughly.

Special instructions For Cleaning / Sanitizing Carpet Against Odor Causing Bacteria: Use this product in [industrial and institutional] areas such as [homes], motels, hotels, nursing homes, schools, and hospitals. Use on wet-cleanable synthetic fibers. Do not use on wool. Vacuum carpet thoroughly prior to cleaning / sanitizing. Test fabric for colorfastness.

For portable extraction units: Mix 2 oz. of concentrate per gallon of water.

For truck mounted extraction machines: Mix 2 – 4 oz. of concentrate per gallon of water and meter at 4 gallons per hour.

For rotary floor machines: Mix 2 oz. of concentrate per gallon of water and apply at the rate of 300 – 500 sq. ft. per gallon. Do not mix this product with other cleaning products. Follow the cleaning procedures specified by the manufacturer of the cleaning equipment. After using the product, set the carpet pile and protect the carpet from furniture legs and bases while drying. Do not over-wet. If applied to stain resistant nylon carpet, apply a fabric protector according to the manufacturer's directions.

{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:

{Plastic and Metal Containers:} Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. 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:} Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. 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.

{Note to reviewer: For Refillable Containers – 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. Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose.

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:

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before refilling is the responsibility of the refiller. Cleaning the container before final disposal is the responsibility of the person disposing of the container.

[Plastic or Metal Containers:] To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat this rinsing procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in sanitary landfill. 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.

PACKET LABEL TO BE USED WITH MASTER CONTAINER LABEL

FOR DISINFECTION

*Note to reviewer: the following will be used for 1/2 oz. of concentrate:
MIX EACH PACKET WITH 1 QUART OF WATER*

*Note to reviewer: the following will be used for 4 oz. of concentrate:
MIX EACH PACKET WITH 2 GALLONS OF WATER*

*Note to reviewer: the following will be used for 8 oz. of concentrate:
MIX EACH PACKET WITH 4 GALLONS OF WATER*

*Note to reviewer: the following will be used for 16 oz. of concentrate
MIX EACH PACKET WITH 8 GALLONS OF WATER*

{If other packet sizes are desired, new packet label will be identical and the only things that will vary are the net contents, amount of water to dilute with and ppm active quat. Those 3 items will have to match or be equivalent to the dilution chart that is shown on page 11.}

LONZA FORMULATION S-21

Active Ingredients:

| | |
|---|---------|
| Octyl decyl dimethyl ammonium chloride..... | 1.65% |
| Dioctyl dimethyl ammonium chloride..... | 0.66% |
| Didecyl dimethyl ammonium chloride..... | 0.99% |
| Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride | 2.20% |
| Other Ingredients: | 94.50% |
| Total:..... | 100.00% |

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

See outer container for Precautionary Statements and Use directions

Disposal: Nonrefillable container. Do not reuse packet. Wrap and put in trash.

[Not for retail sale]

EPA Reg. No. 6836-75
EPA Est. No. (*insert EPA Establishment No. here*)
Net Contents (*insert container size here*)

Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

SECONDARY CONTAINER LABEL

{Note to reviewer: When this product is diluted in accordance with the directions on this label, the dilution container must bear the following statements:}

LONZA FORMULATION S-21

Active Ingredients:

| | |
|---|---------------|
| Octyl decyl dimethyl ammonium chloride | 1.65% |
| Dioctyl dimethyl ammonium chloride | 0.66% |
| Didecyl dimethyl ammonium chloride | 0.99% |
| Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride | 2.20% |
| Other Ingredients: | <u>94.50%</u> |
| Total: | 100.00% |

The product in this container must be diluted at the use rate of 8 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

Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

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

EPA Reg. No. 6836-75

Diluted product not for sale or distribution.

{Note to Reviewer: The following are optional graphics}

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



[Any Kosher Symbol such as:]

[Kosher]

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



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

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

{Note to reviewer: Optional proprietary graphics}
 {Section 1}

ACTION PAC®

For use in Smart System or
 Action Control System® II
 automatic dilution systems.

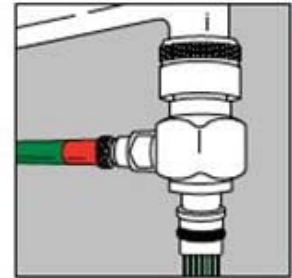
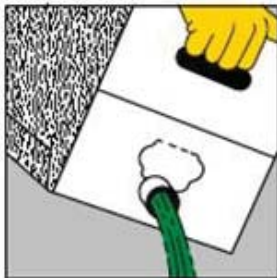
COLOR CODED
 ACTION LOCK CONNECTOR II



NORMAL CLEANING



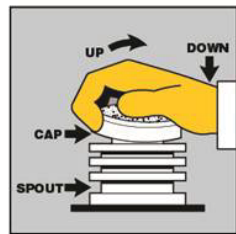
HEAVY CLEANING



THIS END UP TO ATTACH Quick-Draw® SPIGOT
 Note: Do not remove liner from Action Pac® until empty.

CAP REMOVAL

With carton in upright position, hold spout firmly with one hand while removing cap with other hand. Position fingertips under edge of top flange of cap and pull up and back.



PARA QUITAR LA TAPA

Con la caja en posición vertical, sostenga firmemente el pico con una mano mientras quita la tapa con la otra. Coloque las puntas de los dedos debajo del borde de la pestaña superior de la tapa y tire para arriba y atrás.



ACTION PAC®

1. Punch out circle.
2. Lift flap and slide spout into circle.
3. Lower flap and lock spout in place.
4. Attach spigot before tipping box or placing on shelf.

1. Perforar el círculo.
2. Levantar la solapa y pasar poco a poco el pico en el círculo.
3. Bajar la solapa y trabar el pico en su sitio.
4. Conectar el grifo antes de inclinar la caja o colocarla en el estante.

{Note to reviewer: Optional proprietary graphics}
{Section 2}

