

6836-140

08/02/2012

1/29

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D C 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Ms Joanna Holcombe
Lonza Inc
90 Boroline Road
Allendale NJ 07401

AUG -2 2012

SUBJECT Lonza Formulation S 21F
 EPA Registration Number 6836 140
 Application Dated June 29 2012
 Receipt Date July 02 2012
 Decision # 919543

Dear Ms Holcombe

This letter acknowledges receipt of your notification submitted under the provision of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) section 3(c)9 and PR Notice 98 10

Proposed Notification

- Delete the term Sanitizer (two instances) from the FOGGING DEVICE HACHARY ROOMS SANITIZER DIRECTIONS and FOGGING DEVICE INCUBATOR and HACHARY SANITIZER DIRECTIONS section page 20


General Comments

Based on a review of the submitted materials your notification is acceptable
A copy has been placed in our records for future reference

Should you have any questions concerning this letter please contact Velma Noble at (703) 308 6233 or Jamil Mixon at (703) 308 8032

Sincerely

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

	United States Environmental Protection Agency Washington DC 20460	<input type="checkbox"/> Registrator <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide Section I

1 Company/Product Number 6836 140	2 EPA Product Manager Velma Noble	3 Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4 Company/Product (Name) Lonza Formulation S 21F	PM# 31	
5 Name and Address of Applicant (Include ZIP Code) Lonza Inc 90 Boroline Road Allendale NJ 07401 <input type="checkbox"/> Check if this is a new address	6 Expedited Review In accordance with FIFRA Section 3(c)(3)(b)(I) my product is similar or identical in composition and labeling to EPA Reg No Product Name	

Section - II

<input type="checkbox"/> Amendment Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> Me Too Application
<input checked="" type="checkbox"/> Notification Explain below	<input type="checkbox"/> Other Explain below

Explanation Use additional page(s) if necessary (For Section I and Section II)

Not Subject to PRIA

Label Notification to make a correction per EPA stamped label dated 2 16 2012 Please see cover letter for details

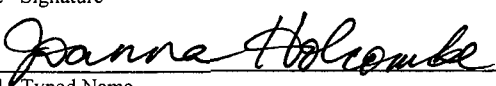
This notification is consistent with the provisions of PR Notice 98 10 and EPA regulations at 40 CFR 152 46 and no other changes have been made to the labeling or the confidential statement of formula of this product I understand that it is a violation of 18 U S C Sec 1001 to willfully make any false statement to EPA I further understand that if this notification is not consistent with the terms of PR Notice 98 10 and 40 CFR 152 46 this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA

Signature Joanna Holcombe Date 6-29-12

Section - III

1 Material This Product Will Be Packaged In				2 Type of Container	
Child Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <i>*Certification must be submitted</i>	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If Yes Unit Packaging wgt No per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If Yes Package wgt No per container	<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) bag in box		
3 Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4 Size(s) Retail Container Various		5 Location of Lab Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On labeling accompanying product	
6 Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled					

Section - IV

1 Contact Point (Complete items directly below for identification of individual to be contacted if necessary to process this application)		
Name Joanna Holcombe	Title Sr Commercial Regulatory Services Associate	Telephone No (Include Area Code) 678 627 2336
Certification I certify that the statements I have made on this form and all attachments thereto are true accurate and complete I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law		6 Date Application Received (Stamped)
2 Signature 		
4 Typed Name Joanna Holcombe	3 Title Sr Commercial Regulatory Services Associate	
5 Date June 29 2012		



Via FedEx

Lonza Inc
90 Boroline Road
Allendale NJ 07401 USA

Ms Velma Noble PM 31
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S 4900 One Potomac Yard
2227 S Crystal Drive
Arlington VA 22202

Joanna Holcombe
Lonza Microbial Control
Commercial Regulatory Services

Tel 678 627 2336
Fax 678 627 2081
joanna.holcombe@lonza.com

June 29 2012

**SUBJECT Lonza Formulation S 21F EPA Reg No 6836 140
Application for Label Notification**

Dear Ms Noble

Lonza is submitting an application to correct the header for the fogging directions on the Lonza Formulation S 21F label Condition 3 of the 2 16 2012 EPA stamped label read

Delete the term 'Sanitizer' (two instances) from the FOGGING DEVICE HATCHERY ROOM SANITIZER DIRECTIONS and FOGGING DEVICE INCUBATOR AND HATCHER SANITIZER DIRECTIONS section on page 20 The Agency has not approved a method to support a sanitizing claim associated with fogging

Lonza stated its intention to comply with this request in the cover letter of the 3 13 2012 submission but inadvertently did not remove the language on the label which later became the 4 11 2012 EPA stamped label The purpose of this notification is to correct that oversight

Please find the enclosed documents in support of this notification

- Application for Notification
- Certification with Respect to Label Integrity
- CD with label and
- One copy of the proposed label

If you have any questions or need any additional information please feel free to contact me at 678 627 2336

Sincerely
Lonza Inc

Joanna Holcombe
Sr Commercial Regulatory Services Associate

LONZA FORMULATION S-21F

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

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

Staphylocidal Pseudomonacidal Bactericidal Salmonellacidal Fungicidal Virucidal

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%

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

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

EPA Reg No 6836 140
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 The following is considered optional marketing language }

- Concentrate [Concentrated]
- Disinfects [Disinfectant]
- Cleans [Cleaner]
- Deodorizes [Deodorant]
- This product contains no [phosphates or] phosphorous [compounds]

Lonza Formulation S 21F

- delivers non acid disinfectant and cleaning performance in an economical concentrate
- is effective yet economical
- is an economical concentrate [that can be diluted for use] [with a mop and bucket trigger sprayers sponge or by soaking]
- [is a heavy duty disinfectant cleaner that] cleans disinfects and deodorizes in one labor saving step
- deodorizes by killing microorganisms that cause offensive odors
- [improves labor results by] effectively controls [controlling] malodors
- 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
- 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
- is a complete chemically balanced disinfectant [and sanitizer] [that provides clear use solutions even in the presence of hard water]
- will not leave grit or soap scum
- is a [versatile] disinfectant and sanitizer for hard nonporous surfaces in Veterinarian Animal care and Farm Premise applications
- is a [versatile] cleaner and broad spectrum disinfectant formulated for use only on non critical instruments in Ultrasonic Baths [Ultrasonic cleaning units]
- is a [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 an effective one step sanitizer cleaner for use on non food contact surfaces
- meets AOAC efficacy standards for hospital disinfectants
- meets Sanitizer Test standards for non food contact sanitizers
- is a proven one step disinfectant cleaner 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
- [Kills] [Eliminates] [Removes] [Destroys] avian influenza A Virus (H3N2) [and] (H5N1) on pre cleaned environmental surfaces
- [Kills] [Eliminates] [Removes] [Destroys] *[Insert pathogen or pathogens from lists on pages 12 or 3, 8 10]* [pre cleaned] environmental surfaces
- [Kills] [Eliminates] [Removes] [Destroys] [Germs] [Bacteria] [Viruses] [on pre cleaned environmental surfaces]
- is effective at controlling mold and mildew odor on mattresses pillows and shower curtains **{Not for use in California}**
- leaves a clean fresh scent
- provides long lasting freshness against tough [pet] odors such as odors from litter boxes and pet accidents
- eliminates 99.9% of Staphylococcus aureus and Klebsiella pneumoniae in 60 seconds
- is effective against Citrus Canker Disease [Xanthomonas axonopodis pv citri] at 2000 ppm active quat
- 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
- meets AOAC Germicidal & Detergent standards for previously cleaned food contact surfaces
- has been cleared by 40 CFR §180.940 (a) for use on Food contact surfaces in public eating places dairy processing equipment food processing equipment utensils and other food contact articles

{Note to reviewer The following is considered optional marketing language }

Use **Lonza Formulation S 21F**

- 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
- as a disinfectant on hard nonporous surfaces
- in kitchens bathrooms and other household areas
- to clean and disinfect finished floors sinks and tubs
- with a mop and bucket trigger sprayer sponge or by soaking
- for non scratch cleaning of showers and tubs shower doors and curtains fixtures and toilet bowls
- to clean and disinfect nonporous salon / barber tools and instruments combs brushes scissors blades and manicure instruments
- for sanitizing and disinfecting of ultrasound transducers probes mammography compressor plates and other hard nonporous surfaces
- to clean and disinfect finished floors Must be applied with damp mop or autoscrubber Cleans and disinfects without dulling gloss
- on coils and drain pans of air conditioning and refrigeration equipment and heat pumps Follow the directions for sanitization of non food contact surfaces
- To clean and disinfect nonporous fire fighting bunker / turnout gear trousers overcoats gloves boots hoods helmets air masks
- [on] [to clean and disinfect] [to clean and sanitize] nonporous personal protective safety equipment wrestling headgear boxing headgear protective headgear athletic helmets hard hats half mask respirators full face breathing apparatus gas masks goggles spectacles face shields hearing protectors and ear muffs Rinse all equipment that comes in prolonged contact with skin with clean warm water [about 120 F] and allow to air dry before reuse [Precaution Cleaning at 120°F temperature will avoid overheating and distortion of the personal safety equipment that would necessitate replacement]
- [on] [to clean and disinfect] nonporous athletic mats wrestling mats gymnastic mats exercise equipment and training tables
- 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 Swine Premise Sanitation Waterers and Feeders Hauling Equipment Dressing Plants Loading Equipment Farrowing Barns and areas Nursery blocks Creep area Chutes
- for Farm Premise Sanitation of hard nonporous surfaces floors walls feed racks mangers troughs automatic feeders fountains and waterers forks shovels scrapers and other nonporous surfaces in barns pens stalls chutes and other facilities and fixtures occupied or traversed by animals
- in the laundry to control odors on musty bedding and linens Test on a small inconspicuous area before using **{Not for use in California}**
- in mildew stains in damp areas such as bathrooms showers kitchens basements and laundry rooms
- in work areas such as tool rooms and garages for odor control and light duty cleaning
- to remove odors caused by flooding and smoke from fires
- to clean and sanitize tables chairs and countertops
- as a [commercial] sanitizer on dishes glassware and utensils
- as a sanitizer in bottling and beverage dispensing equipment
- as a sanitizer in sanitary filling of bottles and cans
- in sanitizing bottles or cans in the final rinse application and for external spraying of filler and closing machines
- as a sanitizer in beer fermentation and holding tanks
- as a Food Grade Shell Egg sanitizer with best results achieved in water temperatures ranging from 78 110 F **Lonza Formulation S 21F** may be applied through immersion tanks foaming apparatus and low pressure sprayers

Cross contamination is of major housekeeping concern **Lonza Formulation S 21F** has been formulated to aid in the reduction of cross contamination not only in hospitals but in schools institutions and industry

{Note to reviewer The following is considered optional marketing language }

Lonza Formulation S 21F 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 21F** 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 21F** must be limited to areas where compost and mushrooms are not present

Lonza Formulation S 21F 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

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 21F 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*

Regular effective cleaning and sanitizing of equipment utensils and work or dining surfaces which could harbor food poisoning microorganisms 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 food poisoning organisms or toxins Application of effective sanitizing procedures reduces the number of those organisms 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 prevent cross contamination 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]

Lonza Formulation S 21F fulfills the criteria of Appendix F of the Grade A Pasteurized Milk Ordinance 2007 Recommendations of the U S Public Health Services in waters up to 500 ppm of hardness calculated as CaCO_3 when evaluated by the AOAC Germicidal and Detergent Sanitizer Method

{Note to reviewer The following is considered optional marketing language }

[AREAS OF USE]

Use **Lonza Formulation S 21F** in

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

Bathrooms
Homes [Households]
Kitchens

Clinics
Dental offices
Health Care Facilities
Hospitals
Medical Offices
Medical Related facilities
Nursing homes
Sick Rooms
Day care centers
Nurseries

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

Athletic facilities
Barber shops
Business and office buildings
Colleges
Correctional facilities
Dressing rooms
Exercise facilities
Factories
Hotels
Institutional facilities
Institutions
Locker rooms
Motels

Prisons
Public facilities
Public rest rooms
Schools
Shower and bath areas
Salons [Beauty] [Tanning]
Universities

Camp grounds
Play ground equipment

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

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

Mobile homes
Ships
Taxis
Trailers
Trains
Transportation terminals

{Note to reviewer The following is considered optional marketing language }

[TYPES OF SURFACES]

Use **Lonza Formulation S 21F** 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
- Foot Spas
- Garbage cans
- Highchairs
- Kennel runs
- Microwave ovens exteriors
- Outdoor [patio] furniture except cushions and wood frames
- Refrigerators exteriors
- Refrigerated storage and display equipment
- Showers
- Shower stalls
- [Fiberglass] Shower stalls
- [Fiberglass] Sinks [bathroom] [kitchen]
- Sinks [bathroom] [kitchen]
- Stoves [stovetops]
- Tables [Non wooden picnic tables]
- Telephones
- Toilets
- Toilet bowls
- Toilet bowl surfaces
- Tubs [Fiberglass]
- Tiles glazed
- Ultrasonic baths
- Urinals
- Walls
- Whirlpool [bathtubs] [tubs] [units]
- Beer fermentation and holding tanks
- Beverage dispensing equipment
- Blenders
- Bottling or premix dispensing equipment
- Cooking utensils
- Chopping blocks plastic and other nonporous
- Coolers
- Cutlery
- Cutting Boards plastic and other nonporous
- Dishes
- Eating Utensils
- Food processors
- Food dispensing equipment
- Frozen Drink Machines
- Glassware
- Ice Chests
- Ice Machines
- Ice cream dispensing equipment [Soft Serve]
- Plastic Food Storage Containers
- Kitchen equipment
- Refrigerator bins used for meat fruit vegetables and eggs
- Silverware
- Non critical [hospital] [medical] equipment surfaces
- Beds [Medical] [Hospital]
- Bed frames
- Bed rails
- Crutches
- Defibrillators
- Gurneys
- [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

{Note to reviewer one or more of the following must be used when making sanitizing claims depending on the use dilution selected ATCC numbers are listed on the data matrix }

LONZA FORMULATION S 21F is an effective sanitizer for use on pre cleaned food contact surfaces at 150 – 200 ppm in waters up to 500 ppm hardness in 60 seconds against
Campylobacter jejuni
Escherichia coli
Staphylococcus aureus

LONZA FORMULATION S 21F is an effective sanitizer for use on pre cleaned food contact surfaces at 200 300 ppm in waters up to 500 ppm hardness in 60 seconds against
Campylobacter jejuni
Escherichia coli
ESBL Escherichia coli – [Extended spectrum beta lactamase producing E coli]
Shigella sonnei
Staphylococcus aureus
Vibrio cholerae
Yersinia enterocolitica

LONZA FORMULATION S 21F is an effective sanitizer for use on pre cleaned food contact surfaces at 300 400 ppm in waters up to 500 ppm hardness in 60 seconds against
Campylobacter jejuni
Escherichia coli
ESBL Escherichia coli – [Extended spectrum beta lactamase producing E coli]
Salmonella enterica
Shigella sonnei
Staphylococcus aureus
Vibrio cholerae
Yersinia enterocolitica

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

Lonza Formulation S 21F 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 21F** [kills] [is effective against]

[Bacteria]

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

- Acinetobacter baumannii [Acinetobacter]
- Brevibacterium ammoniagenes [Brevibacterium]
- Campylobacter jejuni [Campylobacter]
- Enterobacter aerogenes
- Enterococcus faecalis [Enterococcus]
- Enterococcus faecalis Vancomycin resistant [VRE]
- Escherichia coli [E coli]
- ESBL Escherichia coli – [Extended spectrum beta lactamase producing E coli]
- Klebsiella pneumoniae [Klebsiella]
- Legionella pneumophila
- Listeria monocytogenes [Listeria]
- Pseudomonas cepacia [Pseudomonas]
- 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]

- Adenovirus Type 5 [Adenovirus]
- Adenovirus Type 7 [Adenovirus]
- 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 Virus Type A / Brazil [Influenza]
- Influenza Virus Type A / Hong Kong [Influenza]
- Norwalk Virus [Norovirus]
- Respiratory Syncytial Virus [RSV]
- Rotavirus
- SARS Associated Coronavirus [SARS] [cause of Severe Acute Respiratory Syndrome]
- Vaccinia [Pox Virus]

- 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 21F [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

Newcastle s Disease virus

Pseudorabies virus

[Fungi]

Aspergillus niger

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

Dilution

Disinfection [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 [1 128]	4 oz per 4 gallons of water
	[2 oz per 2 gallons of water]
	[1 oz per gallon of water] [400 ppm active]
Sanitizer [1 171]	3 oz per 4 gallons of water
	[1 oz per 1 1/3 gallons of water]
	[3/4 oz per gallon of water] [300 ppm active]
Sanitizer [1 256]	2 oz per 4 gallons of water
	[1 oz per 2 gallons of water]
	[1/2 oz per gallon of water] [200 ppm active]
Sanitizer [1 352]	2 oz per 5 1/2 gallons of water
	[1 oz per 2 3/4 gallons of water]
	[3/8 oz per gallon of water] [150 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 or [2 4 oz] or [2 – 8 oz] per gallon of water [1 64]
 For heavy duty use add [mix] 8 oz per gallon of water [1 16]

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 fo 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 21F 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

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

For mold and mildew At 2 oz or [2 4 oz] or [2 – 8 oz] per gallon **Lonza Formulation S 21F** 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 as a disinfectant

{Note to reviewer ONE OF the following two statements will be used }

BACTERICIDAL STABILITY OF USE DILUTION Tests confirm that **Lonza Formulation S 21F** when diluted in [water up to 200 ppm of hardness] [soft water] [via use of automatic dispensing devices] remains effective against *Pseudomonas aeruginosa* *Staphylococcus aureus* and *Salmonella enterica* for [up to 7 days] [[up to one week] [for up to one month] [up to 2 months] [up to 3 months] [to 4 months] [to 5 months] [up to 6 months] [up to 7 months] [up to 8 months] [up to 9 months] [up to 10 months] [up to 11 months] [up to 12 months] [up to one year] [up to two years] when stored in a sealed container such as a spray bottle. 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 solution becomes visibly dirty or diluted.

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

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

{or}

This product is not for use on medical device surfaces.

KILLS HIV AND HBV AND HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS

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

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

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

Cleaning Procedure Blood and other body fluids containing HIV-1 or HBV or HCV must be thoroughly cleaned from surfaces and objects before application of **Lonza Formulation S 21F**.

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 must be autoclaved and disposed of according to local regulations for infectious waste disposal.

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

Remove gross filth prior to disinfection.

From Concentrate

Add 2 oz. or [2 - 4 oz.] or [2 - 8 oz.] to the bowl. 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. or [2 - 4 oz.] or [2 - 8 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 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 21F** per gallon of water [1 oz [30 mL] or [1 - 2 oz [30 - 60 ml]] of Lonza Formulation S 21F per quart of water] to disinfect hard nonporous instruments and tools Completely immerse combs brushes razors scissors blades plastic rollers manicure and other salon instruments and tools for 10 minutes Use 8 oz per gallon of water to kill Adenovirus Type 5 and type 7 For heavily soiled instruments and tools a preliminary cleaning is required Rinse thoroughly and dry before use Fresh solution must 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 [/ VIRUCIDAL] DIRECTIONS

Use **Lonza Formulation S 21F** 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 21F** 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] [UNITS]]]

After using the [whirlpool [bath] [unit]] drain and refill with fresh water to [just cover the intake valve] [cover the highest jet] [2 inches above the highest jet] Add 2 oz or [2 - 4 oz] or [2 - 8 oz] of **Lonza Formulation S 21** for each gallon of fresh water added Start the pump to circulate the solution Wash down [the [deck] [seat of chair lift] [any related equipment]] any uncovered surfaces on the [bath] [unit] with a clean swab brush or sponge with the solution Treated surfaces must remain wet for 10 minutes Use 8 oz per gallon of water to kill Adenovirus Type 5 and type 7 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

DISINFECTION OF PEDICURE FOOT SPAS

For heavily soiled units drain the water and thoroughly clean all hard nonporous surfaces with soap of detergent After using pedicure foot spa drain and refill with fresh water to cover the intake valve or highest jet up 2 inches Add 2 oz or [2 - 4 oz] or [2 - 8 oz] of product per gallon of fresh water Start pump to circulate the solution Turn the pump off to allow the solution to sit for 10 minutes Wash down the unit sides and seat with a clean swab brush or sponge such that these surfaces remain wet for 10 minute contact time drain the solution from the pedicure foot spa and rinse with fresh water

FOR USE ON FINISHED FLOORS To limit gloss reduction use **Lonza Formulation S 21F** at 2 oz 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

[Animal Viruses]
 Avian Infectious Bronchitis Virus
 Avian Influenza virus (H3N2)
 Avian Influenza virus (H5N1)
 Canine Distemper Virus
 Feline Calicivirus
 Newcastle s Disease Virus
 Pseudorabies Virus

[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 21F** 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 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 to remove 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 21F** 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 acls mangers troughs automatic feeders fountains and waterers with soap or detergent and rinse with potable water before reuse

POULTRY AND SWINE PREMISE DISINFECTION [/ VIRUCIDAL] DIRECTIONS

Remove all animals and feeds from premises vehicles and enclosures such as coops and crates Remove all litter droppings and manure from floors walls and surfaces of barns pens stalls chutes and other facilities and fixtures occupied or traversed by animals Empty all troughs racks and other feeding and watering appliances Thoroughly clean all surfaces with soap or detergent and rinse with water Use 2 oz or [2 - 4 oz] or [2 - 8 oz] of **Lonza Formulation S 21F** per gallon of water Saturate surfaces with the 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 or [2 - 4 oz] or [2 - 8 oz] of **Lonza Formulation S 21F** 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 21F** Use 2 oz of **Lonza Formulation S 21F** per gallon of water to treat all vehicles Use 8 oz per gallon of water to kill Adenovirus Type 5 and type 7 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 ofal 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 or [2 - 4 oz] or [2 - 8 oz] of **Lonza Formulation S 21F** per gallon of water solution 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 is 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 21F** 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 21F** 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 must 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 3/4 oz of **Lonza Formulation S 21F** per gallon of water or 19 oz of **Lonza Formulation S 21F** 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 21F per 4 gallons of water [1/2 oz of Lonza Formulation S 21F 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

{Note to reviewer If this product is to be used as a sanitizer solely on non food contact surfaces the following statement must be included }

Do not use in food preparation food handling and food storage areas This product is not to be used on glassware dishware cookware or utensils

TO SANITIZE BARBER / SALON INSTRUMENTS AND TOOLS Immerse precleaned barber / salon instruments and tools [such as combs brushes razors scissors blades plastic rollers and manicure instruments] in a use solution of 2 oz of Lonza Formulation S 21F 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] [UNITS]

After using the whirlpool [bath] [unit] drain and refill with fresh water to [just cover the intake valve] [cover the highest jet] [2 inches above the highest jet] Add 2 ounce of **Lonza Formulation S 21F** 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

{Note to reviewer On a final printed label only one of the following dilution rates will be used in the sanitization sections below }

For Food Contact Surfaces Food Processing Equipment and Utensils in Dairies Public Eating Establishments and Food Processing Plants [40 CFR 180 940 (a)]

1 oz Lonza Formulation S 21F per 2 3/4 gallons of water [150 active quat] [or equivalent dilution]

{or}

1 oz Lonza Formulation S 21F per 2 gallons of water [200 active quat] [or equivalent dilution]

{or}

1 oz Lonza Formulation S 21F per 2 – 2 3/4 gallons of water [150 – 200 ppm active quat] [or equivalent dilution]

{or}

1 oz Lonza Formulation S 21F per 1 – 2 3/4 gallons of water [150 – 400 ppm active quat] [or equivalent dilution]

{or}

1 oz Lonza Formulation S 21F per 1 – 2 gallons of water [200 – 400 ppm active quat] [or equivalent dilution]

{or}

1 oz Lonza Formulation S 21F per 1 1/3 gallons of water [300 active quat] [or equivalent dilution]

{or}

1 oz Lonza Formulation S 21F per 1 gallon of water [400 active quat] [or equivalent dilution]

{or}

1 oz Lonza Formulation S 21F per 1 – 1 1/3 gallons of water [300 – 400 ppm active quat] [or equivalent dilution]

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 21F** to sanitize hard nonporous surfaces of food processing equipment dairy equipment food utensils dishes silverware glasses sink tops countertops refrigerated storage and display equipment and other hard surfaces

Prior to application remove gross food particles and soil by a pre flush or pre scrape and when necessary pre-soak 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 *(insert appropriate dilution here)* [or equivalent dilution] to pre cleaned 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 and other stationary hard nonporous surfaces by cloth sponge or brush or coarse spray

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

Lonza Formulation S 21F 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 gross 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 *(insert appropriate dilution here)* [or equivalent dilution] for at least 60 seconds at a temperature of 75 F
- 4 For equipment and utensils too large to sanitize by immersion apply a use solution of *(insert appropriate dilution here)* by rinsing spraying or swabbing until thoroughly wet
- 5 Allow sanitized surface to drain and air dry Do not rinse

WISCONSIN STATE BOARD OF HEALTH DIRECTIONS FOR EATING ESTABLISHMENTS

- 1 Scrape and pre wash utensils and glasses whenever possible
- 2 Wash with a good detergent or compatible cleaner
- 3 Rinse with potable water
- 4 Sanitize in a use solution of 0.4 ounces per gallon of water [150-200 ppm active quat] Immerse all utensils for at least two minutes or for contact time specified by governing sanitary code
- 5 Place sanitized utensils on a rack or drain board to air dry
- 6 Prepare a fresh sanitizing solution at least daily or when visibly soiled or diluted

NOTE A clean potable water rinse following sanitization is not permitted under Section HFS 196 Appendix 7 204.11 of the Wisconsin Administrative Code [reference CFR 180.940 (a)]

TO SANITIZE [BEVERAGE] [SOFT SERVE ICE CREAM] [OTHER FOOD] DISPENSING EQUIPMENT

- 1 Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing
- 2 Fill equipment with a solution of *(insert appropriate dilution here)*
- 3 Allow solution to remain in equipment for at least 60 seconds
- 4 Drain thoroughly before reuse and allow to air dry

TO SANITIZE ICE MACHINES

- 1 Turn off refrigeration
- 2 Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing
- 3 Apply a solution of *(insert appropriate dilution here)* by mechanical spray directly pouring or by recirculating through the system
- 4 Allow surfaces to remain wet or solution to remain in equipment for at least 60 seconds
- 5 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 *[insert appropriate dilution here]* 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 TANKS

Wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing Prepare a use solution of *(insert appropriate dilution here)* [or equivalent dilution] 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 *(insert appropriate dilution here)* [or equivalent dilution] 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

{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 and the packaging and storage areas of food plants Apply a foam layer approximately 1/2 to 2 inches thick made from a solution of 2 oz of **Lonza Formulation S 21F** per 2 – 5 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 aera cr 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

FOGGING DEVICE HATCHERY ROOM / FOGGING DEVICE INCUBATOR AND HATCHER DIRECTIONS

All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging

Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices

Remove all animals and feed from premises vehicles and enclosures Remove all litter and manure from floors walls and surfaces of the room to be treated Empty all troughs racks and other feeding and watering appliances Thoroughly clean all surfaces with soap or detergent and rinse with water Close room off so fog is confined to room to be treated Wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus

[For Hatchery Room Mix two parts of product to one part water [2 gallons to 1 gallon of water] Insert nozzle of fogger through suitable opening to room With the setting in maximum output for one minute for each 4000 cubic feet of space in the room]

[For Incubator and Hatcher Mix 24 oz per 104 oz of water Fog 3 8 oz into setters and hatchers immediately after transfer Repeat daily in setters and every 12 hours in hatchers Discontinue hatchers treatment at least 24 hours prior to pulling the hatch It is acceptable to fog setters and hatchers with 2 oz per gallon on an hourly or every other hourly basis If this solution is used fog for 30 90 seconds once per hour or once every 2 hours Only for treatment of setters and hatchers after poultry/chicks/eggs have been removed Not for treatment of hatchers which contain chicks/eggs]

When fogging is completed ventilate buildings and other closed spaces Under no circumstances must a room or building be entered by anyone within two hours of the actual fogging and a minimum of 4 air exchanges [ACH] per hour in the facility Do not allow people to contact or breathe this fog Do not house livestock or employ equipment until treatment has been absorbed or dried Thoroughly scrub all treated feed racks mangers troughs and rinse with potable water before reuse

TO CLEAN AND DEODORIZE Mix 2 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

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 cleaning solution eliminates undesirable odors

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

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 21F** 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

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 concrete brick 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 Concrete Brick 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 Carpet against Odor Causing Bacteria Use this product in industrial and institutional areas such as homes motels hotels nursing homes schools and hospitals Use on wet cleanable synthetic fibers Do not use on wool Vacuum carpet thoroughly prior to cleaning Test fabric for colorfastness

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

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-21F

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%

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

EPA Reg No 6836 140

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 This secondary container label will be used only when the product is diluted at the 2 oz or less per gallon of water}

LONZA FORMULATION S-21F

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 is diluted as directed on the pesticide product label

KEEP OUT OF REACH OF CHILDREN

CAUTION [PRECAUCIÓN]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Caution Causes moderate eye irritation Avoid contact with eyes or clothing Wash thoroughly with soap and water after handling

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

EPA Reg No 6836 140

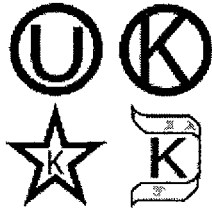
{Note to reviewer The following is an optional graphic }

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



[NSF Listed]
(Insert 6 Digit NSF Listing Number here)

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



{Any Kosher Symbol such as }

[Kosher]

