UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D C 20460



United States Environmental Protection Office of Pesticide Programs

Ms Joanna Holcombe Lonza Inc. 90 Boroline Road

OCT 6 2012

Allendale, NJ 07401

SUBJECT Lonza Formulation S-38 and Lonza Formulation S-38F

EPA Registration Number 6836-73 and 6836-138

Application Dated May 15, 2012 Receipt Date May 19, 2012

Dear Ms Holcombe

The following amendments, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), section 3(C)(7)(A) are acceptable with comments

General Comments

Efficacy data must be provided for 2 of the three cold-associated viruses (1 e. Rhinovirus, Coronavirus and Respiratory Syncytial Virus (RSV)) to support claims for cold viruses To support claims for flu virus, acceptable efficacy data must be provided for any of the influenza viruses

A stamped copy of the accepted labeling with conditions is enclosed. Submit 1 copy of your final printed label before distributing or selling the product bearing the revised labeling

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c) (5) and section 4 (a) when the Agency requires all registrants of similar products to submit such data

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e) Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions Should you have any questions concerning this letter, please contact Velma Noble at (703) 308-6233 or Jamil Mixon at (703) 308-8032

Sincerely,

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510P)

Dunlla Copelal

LONZA FORMULATION S-38F

One-Step Disinfectant

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

Acid Free Cleaner Acid-Free Disinfectant

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

- Formulated for Effective Farm Premise Sanitation
- Formulated for Effective Poultry Premise Sanitation
- Formulated for Effective Swine Premise Sanitation
- Formulated for Effective Mushroom Farm Sanitation
- Formulated for Veterinary Practice / Animal Care / Animal Laboratory Disinfection

For use in federally inspected meat and poultry plants

An effective sanitizer for use on food contact surfaces

Staphylocidal	Pseudomonacidal	Bactericidal	Salmonellacidal	Fungicidal	Virucidal*
Active Ingredients					
Octyl decyl dimethyl ammonium chloride				1 140%	
Dioctyl dimethyl ammonium chloride				0 456%	
Didecyl dimethyl ammonium chloride				0 684%	
Alkyl (C ₁₄ 50% C ₁₂ 40% C ₁₆ 10%) dimethyl benzyl ammonium chloride				1 520%	
Inert [Other] Ingredients				96 200%	
Total				100 000%	

KEEP OUT OF REACH OF CHILDREN

[PELIGRO] DANGER

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

EPA Reg No 6836-138 EPA Est No (insert EPA Establishment No here) Net Contents (insert container size here)

[DOT Symbols] [Country of origin (insert country)] [Manufactured in (insert country)] [Barcode]

Manufactured by Lonza Inc 90 Boroline Road Allendale NJ 07401

ACCEPTED VITH COMMENTS in IPA Letter Dated OCT

Urder the Federal Insecticica Fingiciae and PoJenticide Act as michaed to the pesticiae erea under EPA Heg No 683 6-138

Lonza Formulation S-38F EPA Reg No 6836 138 Draft Label 2012 05-15

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} Page 1 of 17

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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

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.

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

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes streams ponds estuaries oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA

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{Note to reviewer The following is considered optional marketing language. All designators (i.e. asterisks and numbers) used throughout the label may be interchanged as needed on final printed label.}

Lonza Formulation S-38F

- Cleans and Disinfects in One Step
- Cleans Disinfects and Deodorizes
- · Cleans shines deodorizes and disinfects nonporous household surfaces
- delivers non acid disinfectant and cleaning performance in an economical concentrate
- deodorizes by killing microorganisms that cause offensive odors
- [Eliminates] [Kills] 99 9% of [Household] Bacteria¹
 Staphylococcus aureus and Klebsiella pneumoniae
- [Eliminates] [Kills] 99 9% of [Household] Bacteria²
 - ²Escherichia coli [E coli] Staphylococcus aureus [staph] Streptococcus faecalis [strep]
- [Eliminates] [Kills] 99 9% of Staphylococcus aureus and Klebsiella pneumoniae in 60 seconds
- has been cleared in 40 CFR §180 940 (a) for use on food processing equipment utensils and other foodcontact articles
- [improves labor results by] effectively controls [controlling] malodors
- Inhibits the growth of mold and mildew leaving bathrooms and kitchens clean and smelling fresh
- is a complete chemically balanced disinfectant [and sanitizer] [that provides clear use solutions]
- is a [concentrated] [one-step] [Hospital Use] disinfectant cleaner that is effective against a broad spectrum of bacteria is virucidal* [including HIV-1 the AIDS Virus] fungicidal and inhibits the growth of mold and mildew and their odors when used as directed
- [is a heavy duty disinfectant cleaner that] [is an alkaline pH disinfectant cleaner that] cleans disinfects and deodorizes in one labor saving step
- is a multi-surface cleaner deodorizer and disinfectant. Use on windows, mirrors and other glass surfaces
- is a proven one-step disinfectant cleaner sanitizer fungicide mildewstat virucide* in the presence of moderate amounts of organic soil [5% serum contamination]
- is a [versatile] cleaner and broad spectrum disinfectant formulated for use only on non-critical instruments in Ultrasonic Baths [Ultrasonic cleaning units]
- is a [versatile] disinfectant and sanitizer for hard inonporous 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 yet economical
- 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] [99 9% of] [99 99% of] [household] germs³
 ³[Effective against] Pseudomonas aeruginosa [pseudomonas] Staphylococcus aureus [staph]
 Streptococcus faecalis [strep] Influenza A/Brazil and Trichophyton mentagrophytes [Athlete's foot fungus]
- Kılls Flu Vırus⁴
 ¹Influenzã A/Brazıl
- Kılis İnfluenza A
- meets AOAC efficacy standards for hospital disinfectants
- meets AOAC Germicidal & Detergent standards for previously cleaned food-contact surfaces
- meets Sanitizer Test standards for non food contact sanitizers
- One Step [Cleaner and] Disinfectant
- 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

Lonza Formulation S-38F EPA Reg No 6836 138 Draft Label 2012 05-15 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]

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

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

Concentrated product makes 64 gallons⁵ of use dilution ⁵at 2 oz per gallon

Concentrated product makes 128 gallons⁶ of use dilution ⁶at 1 oz per gallon

Concentrated product makes 256 gallons⁷ of use dilution ⁷at 1/2 oz 'per gallon

Use Lonza Formulation S 38F

- · as a commercial sanitizer on dishes glassware and utensils
- as a disinfectant on hard nonporous surfaces
- as a Food-Grade Shell Egg sanitizer with best results achieved in water temperatures ranging from 78°110°F Lonza Formulation S-38F may be applied through automatic washing systems immersion tanks
 foaming apparatus and low-pressure sprayers
- as a sanitizer in beer fermentation and holding tanks
- as a sanitizer in bottling and beverage dispensing equipment
- as a sanitizer in sanitary filling of bottles and cans
- as a sanitizer on all surfaces not requiring a rinse in official establishments operating under the Federal meat poultry shell egg grading and egg products inspection
- fiberglass fixtures and toilet bowls
- for non-scratch cleaning of sinks showers and tubs shower doors and curtains glazed ceramic tiles in federally inspected Meat & Poultry Plants as a food contact sanitizer and / or disinfectant. This product was authorized by USDA as category D2 under the prior authorization program and its formula has not been changed – a sanitizer for all surfaces not always requiring a rinse.
- for sanitizing and disinfecting of ultrasound transducers probes mammography compressor plates and other hard nonporous surfaces
- In kitchens bathrooms and other household areas
- In sanitizing bottles or cans in the final rinse application, and for external spraying of filler and closing machines
- on coils and drain pans of air conditioning and refrigeration equipment and heat pumps. Follow the directions for sanitization of non-food contact surfaces.
- on the multi-touch surfaces responsible for cross-contamination
- to clean and disinfect finished floors. Can be applied with damp mop or autoscrubber. Cleans ariu disinfects without dulling gloss.
- to clean and disinfect finished floors sinks and tubs
- to clean and disinfect nonporous salon / barber tools and instruments combs brushes scissors blades and manicure instruments
- · with a mop and bucket trigger sprayer sponge or by soaking

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

Lonza Formulation S-38F is a phosphate free germicidal detergent effective in the presence of a moderate amount of organic soil on hard nonporous surfaces found at mushroom farms. Lonza Formulation S-38F has been designed for use between mushroom crops. Areas of intended use include breezeways and track alleys before spawning inside and outside walls of mushroom houses, lofts floors storage sheds and casing rings. Use of Lonza Formulation S-38F must be limited to areas where compost and mushrooms are not present.

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

Regular effective cleaning and sanitizing of equipment utensils and work or dining surfaces which could harbor 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 food poisoning organisms which may be present on equipment and utensils after cleaning, and reduces the potential for the transfer either directly through tableware such as glasses, cups and flatware or indirectly through food.

To 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-38F is a sanitizer for hard porous and nonporous non-food contact surfaces at 1 256 dilution [150 ppm active] [½ oz per gallon of water] according to the method for Sanitizers – Non-food Contact surfaces modified in the presence of 300 ppm hard water plus 5% organic serum in 60 seconds against

Klebsiella pneumoniae Staphylococcus aureus

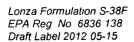
Lonza Formulation S-38F eliminates 99 9% of Staphylococcus aureus and Klebsiella pneumoniae in 60 seconds

Lonza Formulation S-38F fulfills the criteria of Appendix F of the Grade A Pasteurized Milk Ordinances 2007 Recommendations of the U S Public Health Services in waters up to 300 ppm of hardness calculated as CaCO₃ when evaluated by the AOAC Germicidal and Detergent Sanitizer Method

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

Escherichia coli

Staphylococcus aureus



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IAREAS OF USE 1

Use Lonza Formulation S-38F in

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

Bathrooms

Homes [households]

Kitchens

Clinics

Dental offices

Hospitals

Medical Offices

Medical related facilities

Nursing homes

Sick Rooms

Day care centers

Nurseries

Bars

Cafeterias

Convenience stores

Egg Processing Plants

Federally inspected meat and poultry plants

Food processing plants Food preparation areas Food storage areas

Institutional kitchens

Restaurants

USDA inspected food processing facilities

Athletic facilities

Barber shops

Business and office buildings

Colleges

Correctional facilities Dressing rooms

Exercise facilities

Factories

Hotels

Institutional facilities

Institutions Laundries

Locker rooms

Motels

Prisons

Public facilities Public rest rooms

Salons [Beauty] [Tanning]

Schools

Shower and bath areas

Universities

Camp grounds

Play ground equipment

Animal laboratories

Dairy farms

Farms

Hog farms

Kennels

Poultry farms Pet animal quarters

Pet shops

Turkey farms

Zoos

Airplanes

Airports

Ambulances

Boats

Buses

Campers

Cars

Emergency [Police] [EMS] [Fire] [Rescue] vehicles

Mobile homes

Railcars

Ships

Taxis

Trailers

Trains

Transportation terminals

Trucks [Box Trucks]

[TYPES OF SURFACES]

Use Lonza Formulation S-38F on washable hard nonporous surfaces of

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

Appliances exteriors

Basins

Bathroom fixtures

Bathtubs Cabinets Cages Chairs

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

Conductive flooring Counters [countertops] Countertop laminates

Desks

Doorknobs [and handles]

Fiberglass sinks tubs and showers

Floors

Floors - high speed burnished

Foot Spass Garbage cans Highchairs Kennel runs

Microwave ovens exterior surfaces of

Mirrors

Outdoor [patio] furniture except cushions and wood frames

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Refrigerators exteriors

Refrigerated storage and display equipment

Showers

[Fiberglass] Shower stalls

[Fiberglass] Sinks [bathroom kitchen]

Stoves [stovetops]
Tables [picnic tables]
Telephones

Toilets
Toilet bowls
Toilet bowl surfaces
Tubs [Fiberglass]

Tiles glazed Ultrasonic baths Urinals Walls

Whirlpool [bathtubs] [tubs] [units]

Windows

Beer fermentation and holding tanks

Blenders

Bottling or premix dispensing equipment Chopping blocks plastic and other nonporous

Cooking utensils

Coolers Cutlery

Cutting Boards plastic and other nonporous

Dishes

Eating Utensils Food processors Glassware Ice Chests

Kitchen equipment

Refrigerator bins used for meat fruit vegetables and

eggs Silverware Slurpy Machines

Tupperware®

Other hard nonporous surfaces made of

Fibergläss Formica® Glass

Glazed ceramic

Glazed enameled surfaces

Glazed porcelain

Metal

Plastic [such as polystyrene or polypropylene]

Sealed stone Stainless steel

Upholstery vinyl and plastic

Woodwork finished

Lonza Formulation S-38F EPA Reg No 6836 138 Draft Label 2012 05-15 Note to Reviewer

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For Poultry Premise Sanitation [Hatcheries]

Buggies Hatchery Room Ceilings Poultry Buildings

Chick Holding Room Poultry House related equipment

Chick Loading Area Racks Chick Processing Area Setter Room Drinkers Sidewalls

Egg Flats Tray Dumping Area

Egg Holding Area Trays

Egg Receiving Area

Floors

and other hard nonporous surfaces in the Hatchery environment

For Swine Premise Sanitation

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

For Farm Premise Sanitation

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

and other nonporous surfaces in barns pens stalls chutes and other facilities and fixtures occupied or

traversed by animals

For *Virucidal Effectiveness

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

*Influenza Vırus A/Brazıl

*Hepatitis B Virus [HBV]

*Hepatits C Virus [HCV]

*Herpes Simplex Virus Type 1 and 2

*HIV 1 [AIDS virus]

*Vaccinia Virus

- Respiratory illnesses attributable to Pandemic 2009 H1N1are 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 Virus A/Brazil 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 a influenza A viruses including Pandemic 2009 H1N1 influenza A virus
- This product has demonstrated effectiveness against Influenza Virus A/Brazil 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

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

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

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

Acinetobacter baumannii [Acinetobacter]

Corynebacterium ammoniagenes [Brevibacterium ammoniagenes]

Enterobacter aerogenes

Enterococcus faecalis - Vancomycin resistant [VRE]

Escherichia coli [E coli]

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

Klebsiella pneumoniae [Klebsiella]

Pseudomonas cepacia [Pseudomonas]

Salmonella schottmuelleri [Salmonella]

Serratia marcescens

Shigella dysenteriae [Shigella]

Staphylococcus aureus Methicillin-Resistant [MRSA]

Staphylococcus aureus - Vancomycin Intermediate Resistant - [VISA]

Streptococcus faecalis [Strep]

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

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

Staphylococcus aureus [Staph] Salmonella enterica [Salmonella]

Corynebacterium ammoniagenes [Brevibacterium ammoniagenes]

Enterobacter aerogenes

Escherichia coli [E coli]

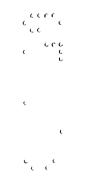
Klebsiella pneumoniae [Klebsiella]

Salmonella schottmuelleri [Salmonella]

Serratia marcescens

Shigella dysenteriae [Shigella]

Streptococcus faecalis [Strep]



Dilution

Disinfection – Medical [1 64] Disinfection – Non Medical [1 128] Sanitizer [1 256]

Sanitizer [1 96]

2 oz per gallon of water 1 oz per gallon of water ½ oz per gallon of water [150 ppm active] [1½ oz per gallon of water] [400 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 Use-Solution

Disinfection – Medical [1 64]

Disinfection – Non Medical [1 128]

Virucide [1 128]

1 oz per gallon of water

1 oz per gallon of water

2 oz per gallon of water

2 oz per gallon of water

2 oz per gallon of water

5 per gallon of water

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

Apply use-solution to hard nonporous surfaces thoroughly wetting surfaces with a cloth mop sponge sprayer or by immersion. Treated surfaces must remain wet for 10 minutes. Wipe dry with a cloth sponge or mop or allow to air dry. For heavily soiled areas, a preliminary cleaning is required.

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

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

For sprayer applications use a coarse spray device Spray 6 - 8 inches from the surface rub with a brush sponge or cloth Do not breathe spray

For fungicidal activity

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

For mold and mildew control

At 1 oz per gallon of water **Lonza Formulation S-38F** will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard non-porous surfaces. Allow to dry on surface. Repeat every seven days or more often if new growth appears

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

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that [4] 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

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

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

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

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

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

Contact Time Leave surface wet for 10 minutes

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

NON-ACID TOILET BOWL AND URINAL DISINFECTANT / CLEANER DIRECTIONS

If surfaces are visibly dirty preclean first

From Concentrate

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

From Use Solution

Empty toilet bowl or urinal and apply a 1-2 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

Use [Mix] 1 - 2 oz of **Lonza Formulation S-38F** per gallon of water [$\frac{1}{4}$ - $\frac{1}{2}$ oz per quart of water] [or equivalent dilution] to disinfect hard nonporous instruments and tools Completely immerse combs brushes rollers manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools a preliminary cleaning is required. Rinse thoroughly and dry before use. Prepare fresh solution daily or more often if solution becomes diluted or soiled.

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

ULTRASONIC BATH DISINFECTANT DIRECTIONS

Use **Lonza Formulation S-38F** to disinfect hard nonporous non-critical objects compatible with Ultrasonic cleaning units. Pour fresh use-solution of 1 - 2 oz of **Lonza Formulation S-38F** per gallon of water directly into bath chamber. Pre clean heavily soiled objects. Place objects into unit and operate for a minimum of 10 minutes according to the manufacturer's directions. Remove objects and wash with sterile water [sterile water.fo^c injection] or allow to air dry. Prepare fresh solution for each use

DISINFECTION OF WHIRLPOOL UNITS After using the whirlpool unit drain and refill with fresh war is reto just cover the intake valve Add 1 – 2 oz of Lonza Formulation S-38F for each gallon of fresh water added Start the pump to circulate the solution. Wash down the unit sides seat of the chair lift and any related equipment with a clean swab brush or sponge. Treated surfaces must remain wet for 10 minutes. After the unit has been thoroughly cleaned drain the solution from the unit and rinse cleaned surfaces with fresh water. Repeat for heavily soiled units.

FOR USE ON FINISHED FLOORS To limit gloss reduction use Lonza Formulation S-38F at 1 – 2 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

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

For cleaning and disinfecting hard nonporous surfaces equipment used for animal food or water utensils instruments cages kennels stables catteries. Remove all animals and feeds from premises animal transportation vehicles crates etc. Remove all litter droppings and manure from floors walls and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 1-2 oz. of **Lonza Formulation S-38F** per gallon of water [or equivalent dilution] for a period of 10 minutes. Wipe or allow to air dry Immerse all halters ropes and other types of equipment used in handling and restraining animals as well as forks shovels and scrapers used for removing litter and manure. Rinse all surfaces that come in contact with food including equipment used for feeding or watering with potable water before reuse. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

FARM PREMISE USE

Remove all animals and feed from premises vehicles and enclosures. Remove all litter and manure from floors walls and surfaces of barns pens stalls chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with a use-solution of 1-2 oz of **Lonza Formulation S-38F** per gallon of water [or equivalent dilution] for a period of 10 minutes. Immerse all halters ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. Ventilate buildings cars trucks boats and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

POULTRY AND SWINE PREMISE DISINFECTION DIRECTIONS

Remove all animals and feeds from premises vehicles and enclosures such as coops and crates. Remove all litter droppings and manure from floors walls and surfaces of barns pens stalls chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Use 1 – 2 oz. of **Lonza Formulation S-38F** per gallon of water. Saturate surfaces with the recommended disinfecting solution for 10 minutes. Immerse all halters ropes and other types of equipment used in handling and restraining animals as well as forks shovels and scrapers used for removing letter and manure. Ventilate buildings cars trucks coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

Hatcheries Use 1-2 oz of **Lonza Formulation S-38F** per gallon of water to treat hatchers setters trays racks carts sexing tables delivery trucks and other hard surfaces. Leave all treated surfaces wet for 10 minutes or more. Wipe or allow to air dry

Vehicles Clean all vehicles including mats crates cabs and wheels with water and Lonza Formulation S-38F Use 1 - 2 oz of Lonza Formulation S-38F per gallon of water to treat all vehicles Leave alltitieated surfaces wet for 10 minutes or more. Wipe or allow to air dry

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 ½ oz per gallon of water solution for 60 seconds prior to entering area. Change the solution in the bath daily or more often if solution appears diluted or soiled

Dressing Plant Disinfectant Directions Disinfect equipment utensils walls and floors in politity 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 1 – 2 oz per gallon of water use solution of **Lonza Formulation S-38F**. Scrub to loosen all soils. Surfaces must remain wet for 10 minutes, then thoroughly rinsed with potable water before operations are resumed.

Lonza Formulation S-38F EPA Reg No 6836 138 Draft Label 2012 05 15 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]

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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 1 – 2 oz of **Lonza Formulation S-38F** per gallon of water [or equivalent dilution] Apply use solution with a cloth mop sponge sprayer or by immersion to thoroughly wet the surfaces. Treated surfaces must be allowed to remain 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.

For Heavy Duty Cleaning When greater cleaning is desired use 2 oz of **Lonza Formulation S-38F** 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

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

LAUNDRY SANITIZER DIRECTIONS This product sanitizes by controlling or reducing the growth of odor-causing bacteria when used on washable laundry items such as bed spreads—sheets—pillow cases—diapers towels and other wet linens. Use 1 oz per 25 lbs—of dry weight fabric—Dilute the appropriate amount of **Lonza Formulation S-38F** in one to two gallons of water—then add to the wash wheel in the final rinse—Laundered fabric may also be treated by soaking

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

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

TO SANITIZE FOOD CONTACT SURFACES {or}

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

Use **Lonza Formulation S-38F** to sanitize 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 ½ oz [to 1½ oz] of Lonza Formulation S-38F per gallon of water [or equivalent dilution] [150 ppm [to 400 ppm] active] to precleaned hard surfaces thoroughly wetting surfaces with a cloth more 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 brush or coarse spray

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

Lonza Formulation S-38F can be used in accordance with the U.S. Public Health Service food service sanitization recommendations

U.S. PUBLIC HEALTH SERVICE FOOD SERVICE SANITIZATION RECOMMENDATIONS

CLEANING AND SANITIZING Equipment and utensils shall be thoroughly pre-flushed or pre-scraped and when necessary pre-soaked to remove 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 ½ oz [to 1½ oz] of **Lonza Formulation S-38F** per gallon of water [150 ppm [to 400 ppm] active quat] [or equivalent dilution] for at least 60 seconds at a temperature of 75°F
- 4 For equipment and utensils too large to sanitize by immersion apply a use-solution of ½ oz [to 1⅓ oz] of **Lonza Formulation S 38F** per gallon of water [150 ppm [to 400 ppm] active quat] [or equivalent dilution] by rinsing spraying or swabbing until thoroughly wet
- 5 Allow sanitized surface to drain and air dry Do not rinse

TO SANITIZE BEVERAGE DISPENSING EQUIPMENT

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

TO SANITIZE SANITARY FILLING EQUIPMENT

Wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing. Prepare a use-solution of ½ oz [to 1 ½ oz] of **Lonza Formulation S-38F** per gallon of water [or equivalent dilution] [150 ppm [to 400 ppm] active] for final washer and rinser applications. Allow surfaces to remain wet for at least 60 seconds. Drain thoroughly before reuse and allow to air dry

TO SANITIZE BEER FERMENTATION AND STORAGE TANKS

Wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing Prepare a use-solution of ½ oz [to 1½ oz] of **Lonza Formulation S-38F** per gallon of water [or equivalent dilution] [150 ppm [to 400 ppm] active] for mechanical or automated systems Allow surfaces to remain wet for at least 60 seconds Drain thoroughly and allow to air dry before reuse

TO SANITIZE EGG SHELLS INTENDED FOR FOOD

To sanitize previously cleaned food-grade eggs in shell egg and egg product processing plants spray with a use-solution of ½ oz [to 1½ oz] of **Lonza Formulation S-38F** per gallon of warm water [or equivalent dilution] [150 ppm [to 400 ppm] active] The solution must be equal to or warmer than the eggs but not to exceed 430°F Wet eggs thoroughly and allow to drain Eggs sanitized with this product shall be subjected to a thorough potable water rinse only if they are to be broken immediately for use in the manufacture of egg products Eggs must be reasonably dry before casing or breaking. The solution must not be re-used for sanitizing eggs.

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

TO CLEAN AND DEODORIZE

Mix 1 –2 oz of Lonza Formulation S-38F per gallon of water to clean and deodorize surfaces. Apply using a cloth mop sponge or sprayer. Wipe or allow to air dry

GLASS CLEANING / DEODORIZING DIRECTIONS

Add ½ - 2 oz of **Lonza Formulation S-38F** per gallon of water to clean and deodorize windows nuriors and glass surfaces. Use a coarse spray device. Spray 6 - 8 inches from surface. Rub with a sponge or cloth. Do not breathe spray.

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Note to Reviewer

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For Bag - In - Box Containers

How to use this package

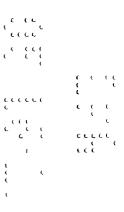
This package is designed to be used with dilution control systems only. Open package and connect to dispense according to directions on box top

Trigger Sprayers

Fill bottle from dispenser Apply to surfaces as specified in directions above

Mop Buckets

Fill bucket from dispenser Set up Wet Floor' signs Mop floor surface as specified in directions above



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

STORAGE AND DISPOSAL

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

{or

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

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

STORAGE AND DISPOSAL

Do not contaminate water food or feed by storage or disposal

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

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance

Container Disposal

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

(Metal containers only) DO NOT cut or weld metal containers

{Bag in Box Containers} Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill or by incineration or by other procedures allowed by state and local authorities.

{Note to reviewer For Nonrefillable Sealed Containers Packaging options can be in sealed containers or bottles designed for use dilution systems to reduce worker exposure to the concentrate. None of these can be triple rinsed because they are closed sealed containers. The following text will be used on these sealed container types }

STORAGE AND DISPOSAL

Do not contaminate water food or feed by storage or disposal

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

Pesticide Disposal. Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

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

(SECONDARY CONTAINER LABEL)

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

LONZA FORMULATION S-38F

Active Ingredients

Octyl decyl dimethyl ammonium chloride

Dioctyl dimethyl ammonium chloride

Didecyl dimethyl ammonium chloride

O 456%

Didecyl dimethyl ammonium chloride

O 684%

Alkyl (C₁₄ 50%, C₁₂ 40% C₁₆ 10%) dimethyl benzyl ammonium chloride

Ingredients

O 684%

Total

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

KEEP OUT OF REACH OF CHILDREN

CAUTION [PRECAUCIÓN]

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIG ANIMALS

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

EPA Reg No 6836-138

