UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D C 20460



United States Environmental Protection Office of Pesticide Programs Agency

Ms Joanna Holcombe Lonza Inc 90 Boroline Road Allendale, NJ 07401

OCT 6 2012

SUBJECT

Lonza Formulation S-38 and Lonza Formulation S-38F EPA Registration Number <u>6836-73</u> 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,

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510P)

LONZA FORMULATION S-38

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

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

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

For use in federally inspected meat and poultry plants

Staphylocidal	Pseudomonacidal	Bactericidal	Salmonellacidal	Fungicidal •	Virucidal*	
Active Ingredients						
Octyl decyl dimethyl ammonium chloride				1 1	1 140%	
Dioctyl dimethyl ammonium chloride				0.4	0 456%	
Didecyl dimethyl ammonium chloride				0.6	0 684%	
Alkyl (C ₁₄ 50% C ₁₂ 40% C ₁₆ 10%) dimethyl benzyl ammonium chloride				e 15	1 520%	
Inert [Other] Ingredients					96 200%	
Total				100 0	100 000%	

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

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

EPA Reg No 6836-73 EPA Est No (*insert EPA Establishment No here*) Net Contents (*insert container size here*)

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

Manufactured by Lonza Inc 90 Boroline Rd Allendale NJ 07401 ACCEPTED at the COMMENTS on Englishment of the Comments of the Comment of the Com

OCT 6 2012

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Lonza Formulation S-38 EPA Reg No 6836-73 Draft Label 2012 05-15 Note to Reviewer
[Items in brackets [AAA] are optional and may/may not be included on final label]
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Page 1 of 16

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 a 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.

{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 38

- 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
- [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 vet 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]
- Kills Flu Virus⁴
 Influenza A/Brazil
- Kills Influenza A
- meets AOAC efficacy standards for hospital disinfectants
- 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 carricalise malodors
- will not leave grit or soap scum

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

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-38

- as a disinfectant on hard nonporous surfaces
- for non-scratch cleaning of sinks showers and tubs shower doors and curtains glazed ceramic tiles fiberglass fixtures and toilet bowls
- for sanitizing and disinfecting of ultrasound transducers probes mammography compressor plates and other hard nonporous surfaces
- in inedible processing areas non processing areas and or exterior areas in official establishments operating under the Federal meat poultry egg shell grading and egg products inspection programs
- In federally inspected Meat & Poultry Plants as a non-food contact sanitizer and / or disinfectant. This
 product was authorized by USDA as category D1 under the prior authorization program and its formula has
 not been changed.
- In kitchens bathrooms and other household areas
- on coils and drain pans of air conditioning and refrigeration equipment and heat pumps. Follow the directions for sanitization of non-food contact surfaces
- on the multi-touch surfaces responsible for cross-contamination and infection
- to clean and disinfect finished floors. Can be applied with damp mop or autoscrubber. Cleans and disinfects without dulling gloss.
- to clean and disinfect finished floors sinks and tubs
- to clean and disinfect nonporous salon / barber tools and instruments combs brushes scissors blades and manicure instruments
- with a mop and bucket trigger sprayer sponge or by soaking

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

Lonza Formulation S 38 is a phosphate free germicidal detergent effective in the presence of a moderate amount of organic soil on hard nonporous surfaces found at mushroom farms. **Lonza Formulation 3-38** has been designed for use between mushroom crops. Areas of intended use include breezeways and tract alleys before spawning inside and outside walls of mushroom houses lofts floors storage sheds and casing rings. Use of **Lonza Formulation S-38** must be limited to areas where compost and mushrooms are not present

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

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

[AREAS OF USE]

Use Lonza Formulation S-38 in

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

Bathrooms

Homes [households]

Kitchens

Clinics

Dental offices

Hospitals

Medical Offices

Medical related facilities

Nursing homes Sick Rooms

Day care centers

Nurseries

Bars

Cafeterias

Convenience stores Egg Processing plants

Federally inspected meat and poultry plants

Food processing plants Food preparation areas Food storage areas Institutional kitchens

Restaurants

USDA inspected food processing facilities

Athletic facilities Barber shops

Business and office buildings

Colleges

Correctional facilities Dressing rooms Exercise facilities

Factories Hotels

Institutional facilities

Institutions Locker rooms Motels

Prisons

Public facilities
Public rest rooms

Salons [Beauty] [Tanning]

Schools

Shower and bath areas

Universities

Camp grounds

Play ground equipment

Animal laboratories

Dairy farms
Farms
Hog farms
Kennels
Poultry farms
Pet animal quarters

Pet shops Turkey farms

Zoos

Airplanes Airports Ambulances

Boats Buses Campers Cars

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

Mobile homes Railcars Ships Taxis Trailers

Trains

Transportation terminals Trucks [Box Trucks]

Lonza Formulation S-38 EPA Reg No 6836 73 Draft Label 2012 05-15 Note to Reviewer
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Page 5 of 16

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

[TYPES OF SURFACES]

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

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

Appliances exteriors

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 Spas
Garbage cans
Highchairs
Kennel runs

Microwave ovens exterior surfaces of

Mirrors

Outdoor [patio] furniture except cushions and wood

frames

Refrigerators exteriors

Refrigerated storage and display equipment

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

Non-critical medical device surfaces

[Medical] [Hospital] Beds

Bed frames Bed rails Crutches Defibrillators Gurneys

Non-critical [hospital] [medical] equipment surfaces

[Medical] Examining tables [Medical] [Hospital] Lamps

Rescue tools Resuscitators

[Medical] [Hospital] Scales

Stands Stretchers Stethoscopes Walkers Wheel chairs

Other hard nonporous surfaces made of

Fiberglass 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

For Poultry Premise Sanitation [Hatcheries]

Buggies Hatchery Room
Ceilings Poultry Buildings

Chick Holding Room Poultry House related equipment

Chick Loading Area Racks
Chick Processing Area Setter Room
Drinkers Sidewalls

Egg Flats Tray Dumping Area

Egg Holding Area Trays
Egg Receiving Area

Floors

and other hard nonporous surfaces in the Hatchery environment

For Swine Premise Sanitation

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

For Farm Premise Sanitation

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

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

traversed by animals

For *Virucidal Effectiveness

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

- *Influenza Virus A / Brazil
- *Hepatitis B Virus [HBV]
- *Hepatits C Virus [HCV]
- *Herpes Simplex Type 1 and 2
- *HIV-1 [AIDS virus]
- *Vaccinia
 - 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 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 iliactivate all 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

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Page 7 of 16

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

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

Pseudomonas aeruginosa [Pseudomonas] Salmonella enterica [Salmonella]

Staphylococcus aureus [Staph]

Acinetobacter baumannii [Acinetobacter]

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

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

Brevibacterium ammoniagenes [Brevibacterium]

Enterobacter aerogenes

Escherichia coli [E coli]

Klebsiella pneumoniae [Klebsiella]

Salmonella enterica [Salmonella]

Salmonella schottmuelleri [Salmonella]

Serratia marcescens

Shigella dysenteriae [Shigella]

Staphylococcus aureus [Staph]

Streptococcus faecalis [Strep]

Lonza Formulation S-38 is a sanitizer for hard porous and nonporous non-food contact surfaces at 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

Preparation of Use-Solution

Disinfection [- Medical][1 64] 2 oz per gallon of water Disinfection [- Non Medical][1 128] 1 oz per gallon of water Virucide [1 128] 1 oz per gallon of water

Sanitizer [1 256] 1/2 oz per gallon of water [150 ppm active]

Mold and Mildew Control 1 oz per gallon of water Heavy Duty Use 8 oz per gallon of water

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

{If the following Spanish statement is used it must appear directly above DIRECTIONS FOR USE}
Si usted no entiende la etiqueta busque a alguien para que se la explique a usted en detalle [If you do not understand the label find someone to explain it to you in detail]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

Before use in federally inspected meat and poultry food processing plants and dairies food products and packaging materials must be removed from the room or carefully protected

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 recommended.

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-38** is an effective fungicide against Trichophyton mentagrophytes [the athlete's foot fungus] when used on surfaces in areas such as locker rooms dressing rooms shower and bath areas and exercise facilities

For mold and mildew control

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

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

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

This product is not for use on medical device surfaces

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

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

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

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

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

Contact Time Leave surface wet for 10 minutes

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

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

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-38** per gallon of water [¼ - ½ 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-38** to disinfect hard nonporous non-critical objects compatible with Ultrasonic cleaning units. Pour fresh use-solution of 1 - 2 oz of **Lonza Formulation S-38** 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 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 he highest jet] [2 inches above the highest jet]. Add 1 – 2 oz of **Lonza Formulation S-38** for each gallon of fresh water added. Start the pump to circulate the solution. Wash down [the [deck] [seat of chair lift] [any related equipment]] any uncovered surfaces on the [bath] [unit] with a clean swab brush or sponge with the solution. Treated surfaces must remain wet for 10 minutes. After the [bath] [unit] has been thoroughly disinfected drain and rinse surfaces with fresh water. Wipe dry with a clean sponge or cloth or allow to air dry. Repeat for neavily soiled units.

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Page 10 of 16

[WHIRLPOOL] FOOT SPA DISINFECTION DIRECTIONS

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

FOR USE ON FINISHED FLOORS To limit gloss reduction use Lonza Formulation S-38 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

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-38** per gallon of water [or equivalent dilution] for a period of 10 minutes. Wipe or allow to air dry immerse all halters ropes and other types of equipment used in handling and restraining animals as well as forks shovels and scrapers used for removing litter and manure. Rinse all surfaces that come in contact with food including equipment used for feeding or watering with potable water before reuse. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

FARM PREMISE USE

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

POULTRY AND SWINE PREMISE DISINFECTION DIRECTIONS

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

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

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

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Page 11 of 16

Shoe Bath Sanitzer Directions To prevent the cross contamination of organisms into animal areas shoe baths containing one inch of freshly made solution should 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 poultry and animal dressing plants. Disinfect offal rooms exterior walls and loading platforms of dressing plants. Cover or remove all food and packaging materials. Remove all heavy soils prior to application. Saturate all surfaces with a 1-2 oz per gallon of water use solution of **Lonza Formulation S-38**. 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 should 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-38 per gallon of water [or equivalent dilution] Apply use solution with a cloth mop sponge sprayer or by immersion to thoroughly wet the surfaces. Treated surfaces should be allowed to remain wet for 10 minutes. Wipe or allow to air dry. For heavily soiled areas, preclean first. Prepare fresh solution for each use or more often if solution becomes visibly diluted, clouded or soiled.

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

SANITIZING NON FOOD CONTACT SURFACES [such as floors walls and tables] Add ½ oz of **Lonza Formulation S-38** per gallon of water **Lonza Formulation S-38** is an effective sanitizer against Staphylococcus aureus and Klebsiella pneumoniae in the presence of 5% serum on 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 {Not for Use in California}

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

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

TO CLEAN AND DEODORIZE Mix 1-2 oz of Lonza Formulation S-38 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-38** per gallon of water to clean and deodorize windows mirrors and glass surfaces. Use a coarse spray device. Spray 6 - 8 inches from surface. Rub with a sponge or cloth. Do not breathe spray

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Page 12 of 16

For Bag - In - Box Containers

How to use this package

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

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

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

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

(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

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Page 14 of 16

{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-38

Active Ingredients

Octyl decyl dimethyl ammonium chloride

Dioctyl dimethyl ammonium chloride

Didecyl dimethyl ammonium chloride

Didecyl dimethyl ammonium chloride

O 684%

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

Inert [Other] Ingredients

Total

100 000%

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 DOMESTIC ANIMALS

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

EPA Reg No 6836-73

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

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



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