6836-73

11-25-2994



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

NOV 2 5 2009

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

Subject:

Lonza Formulation S-38 EPA Reg. No. 6836-73 Notification Date: October 30, 2009 EPA Receipt Date: November 02, 2009

Dear Ms. Holcombe,

This letter acknowledges receipt of your notification submitted in connection with registration under the provisions of PR Notice 98-10 and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9.

Proposed Notification

Adding 2009 H1N1 Marketing Claims

General Comments

Based on a review of the submitted materials, your notification to add 2009 H1N1 Marketing Claims in accordance with the Agency guidance for testing labeling claims against Pandemic 2009 H1N1 Influenza A (Formerly called Swine Flu) is acceptable. A copy has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely./

Velma Noble Product Manager (3 CONCURRENCES Regulatory Management Branch I SYMBOL Antimicrobial. Division (75.10P) .. SURNAME

EPA		United States nental Protection A Washington, DC 20460	Agency	Registrat Amendm Other		OPP Ide	ntifier Numbe	
		Appli	ication for Pe	esticide - Section 1		•		
Company/Product Number		2. EPA Product Manager		3. Proposed Classification				
6836-073 4. Company/Product (Name)		<u></u>	Velma Noble		None			
LONZA FORMULATION S-38			31			· · · · ·		
5. Name and Address of Applicant (Include ZIP Code) Lonza Inc.				ited Review. In accordan I in composition and labe		ction 3(c)(3)(b)(I), m	y product is simila	
90 Boroline Road		EPA Reg. No. Product Name						
Allendale, NJ 07401								
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			Section					
Amendment - H	Explain below. In response to Agency	v letter dated		Final printed labe		Agency letter dated		
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Notification - Explain below. Explanation: Use additional page(s) if necessary. (nd Section II.)			· · · · · · · · · · · · · · · · · · ·	
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Via FedEx

Ms. Velma Noble, PM-31 Document Processing Desk (NOTIFY) Office of Pesticide Programs (7504P) US Environmental Protection Agency Room S-4900, One Potomac Yard 2777 S. Crystal Drive Arlington, VA 22202 Lonza Inc Allendale 90 Boroline Road Allendale, NJ 07401, USA

Joanna Holcombe Lonza Life Science Ingredients Commercial Regulatory Services

Tel 201-316-9297 Fax 201 696-3470 joanna.holcombe@lonza.com

October 30, 2009

SUBJECT: Lonza Formulation S-38, EPA Registration No. 6836-073 Application for Label Notification

Dear Ms. Noble:

The purpose of this notification is to add the following:

Add optional marketing language per EPA Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1.

Please find enclosed the following documents in support of this label notification.

- Application for Pesticide Notification
- One copy of the label with changes highlighted

Please provide your decision electronically to me at joanna.holcombe@lonza.com.and subsequently.... send me a letter confirming the Agency's decision. If you have any questions or need any additional information, please feel free to contact me at 201-316-9297.

Sincerely, Lonza Inc.

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Joanna Holcombe Sr. Commercial Regulatory Services Associate

LONZA FORMULATION S-38

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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:

KEEP OUT OF REACH OF CHILDREN

DANGER (PELIGRO)

See (left) (side) (right) (back) panel for Precautionary Statements and First Aid

Manufactured by:		
Lonza Inc. 90 Boroline Rd. Allendale, NJ 07401 LONZA FORMULATION S-38 (Note to reviewer: Language in () is optional or interchangeable) EPA Reg. No. 6836-73 EPA Stamped Label 7-9-07 w/ 4-3-09 Notif., Draft 10-30-09 Page 1 of 20	(, , , , , , , , , , , , , , , , , , ,	ز د ر ر ز

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. 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.



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LONZA FORMULATION S-38 (Note to reviewer: Language in () is optional or interchangeable) EPA Reg. No. 6836-73 EPA Stamped Label 7-9-07 w/ 4-3-09 Notif., Draft 10-30-09 Page 2 of 20

Lonza Formulation S-38

- 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) (is an alkaline pH 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).
- will not leave grit or soap scum.
- is a (versatile) disinfectant and sanitizer for hard, nonporous nonfood contact surfaces in Veterinarian, Animal care and Farm Premise applications.
- is a (versatile) cleaner and broad spectrum disinfectant formulated for use only on noncritical instruments in Ultrasonic Baths (Ultrasonic cleaning units).
- Cleans, shines, deodorizes and disinfects nonporous household surfaces.
- Inhibits the growth of mold and mildew leaving bathrooms and kitchens clean and smelling fresh.
- Kills (Eliminates) (99.9% of) (99.99% of) (household) germs**
- ** (Effective against) Pseudomonas aeruginosa (pseudomonas), Staphylococcus aureus (staph), Streptococcus faecalis (strep), Influenza A/Brazil and Trichophyton mentagrophytes (Athlete's foot fungus).
- (Eliminates) (Kills) 99.9% of (Household) Bacteria***
 ***Staphylococcus aureus and Klebsiella pneumoniae
- (Eliminates) (Kills) 99.9% of Staphylococcus aureus and Klebsiella pneumoniae in 60 seconds
- is a multi-surface cleaner, deodorizer, and disinfectant. Use on windows, mirrors and other glass surfaces.
- 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 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 sanitizer fungicide mildewstat virucide* in the presence of moderate amounts of organic soil (5% serum contamination).

LONZA FORMULATION S-38 (Note to reviewer: Language in () is optional or interchangeable) EPA Reg. No. 6836-73 EPA Stamped Label 7-9-07 w/ 4-3-09 Notif., Draft 10-30-09 Page 3 of 20 i cece

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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.

Concentrate (Concentrated) Disinfects (Disinfectant) Cleans (Cleaner) Deodorizes (Deodorant) This product contains no (phosphates or) phosphorous (compounds).

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

Concentrated product makes 64 gallons**** of use dilution. **** at 2 oz per gallon Concentrated product makes 128 gallons***** of use dilution. ***** at 1 oz per gallon

Concentrated product makes 256 gallons***** of use dilution.

****** at 1/2 oz per gallon

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LONZA FORMULATION S-38 (Note to reviewer: Language in () is optional or interchangeable) EPA Reg. No. 6836-73 EPA Stamped Label 7-9-07 w/ 4-3-09 Notif., Draft 10-30-09 Page 4 of 20

Use Lonza Formulation S-38

LONZA FORMULATION S-38

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- 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.
- on the multi-touch surfaces responsible for cross-contamination and infection.
- 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 sinks, showers and tubs, shower doors and curtains, glazed ceramic tiles, fiberglass, 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. Can 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.

(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)

(Note to reviewer: Language in () is optional or interchangeable)

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- 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 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.

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- 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.

- for Poultry Premise Sanitation (Hatcheries): Egg Receiving Area Tray Dumping Area Chick Processing Area Egg Holding Area Chick Holding Room Chick Loading Area Setter Room Hatchery Room **Poultry Buildings** Racks Travs **Buggies** Ceilings Egg Flats Sidewalls Floors Poultry House related equipment Drinkers other hard, nonporous surfaces in the Hatchery environment.
- for Swine Premise Sanitation: Farrowing Barns and areas Creep area Loading Equipment Hauling Equipment
 for Swine Premise Sanitation: Dressing Plants Waterers and Feeders Chutes Nursery blocks
- for Farm Premise Sanitation: floors walls feed racks mangers troughs forks, automatic feeders shovels, fountains and waterers scrapers

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

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 S-38 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-38 must be limited to areas where compost and mushrooms are not present.

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:

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Klebsiella pneumoniae Staphylococcus aureus

LONZA FORMULATION S-38 eliminates 99.9% of Staphylococcus aureus and Klebsiella pneumoniae in 60 seconds.

For *Virucidal Effectiveness:

LONZA FORMULATION S-38 is an effective virucide in the presence of 5% serum against the following organisms:

*Influenza A / Brazil *Herpes Simplex Type 1 and 2 *HIV-1 (AIDS virus) *Vaccinia

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) Staphylococcus aureus (Staph)

Salmonella choleraesuis (Salmonella)

Acinetobacter baumannii (Acinetobacter) Corvnebacterium 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:

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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:

Staphylococcus aureus (Staph) Salmonella choleraesuis (Salmonella) Brevibacterium ammoniagenes (Brevibacterium) Enterobacter aerogenes Escherichia coli (E. coli) Klebsiella pneumoniae (Klebsiella) Salmonella schottmuelleri (Salmonella) Serratia marcescens Shigella dysenteriae (Shigella) Streptococcus faecalis (Strep)

(AREAS OF USE:) Use Lonza Formulation S-38 in:

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 13

Camp grounds Play ground equipment

Animal laboratories Dairy 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

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Trains Transportation terminals Trucks (Box Trucks)

Trailers

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(TYPES OF SURFACES:) Use Lonza Formulation S-38 on washable hard, nonporous surfaces of:

Appliances, exteriors	Ultrasonic baths
Basins	Urinals
Bathroom fixtures	Walls
Bathtubs	Whirlpool [bathtubs] [tubs] [units]
Cabinets	Windows
Cages	•
Chairs	Non-critical medical device surfaces
Coils and drain pans of air conditioning and	[Medical] [Hospital] Beds
refrigeration equipment and heat pumps	Bed frames
Conductive flooring	Bed rails
Counters (countertops)	Crutches
Countertop laminates	Defibrillators
Desks	Gurneys
· · -	-
Doorknobs (and handles) Floors	Non-critical [hospital] [medical] equipment surfaces
• • • • • •	
Floors – high speed burnished	[Medical] Examining tables
Foot Spas	[Medical] [Hospital] Lamps
Garbage cans	Rescue tools
Highchairs	Resuscitators
Kennel runs	[Medical] [Hospital] Scales
Microwave ovens	Stands
Mirrors	Stretchers
Outdoor (patio) furniture except cushions	Stethoscopes
and wood frames	Walkers
Refrigerators, exteriors	Wheel chairs
Refrigerated storage and display equipment	-
Showers	Other hard nonporous surfaces made of:
(Fiberglass) Shower stalls	Fiberglass
(Fiberglass) Sinks (bathroom, kitchen)	Formica®
Stoves (stovetops)	Glass
Tables (picnic tables)	Glazed ceramic
Telephones	Glazed enameled surfaces
Toilets	Glazed porcelain
Toilet bowls	Metal
Toilet bowl surfaces	Plastic (such as polystyrene or
Tubs (Fiberglass)	polypropylene)
Tiles, glazed	Sealed stone
	Upholstery, vinyl and plastic
	Woodwork, finished
LONZA FORMULATION S-38 (Note to reviewer: Language in	() is optional or interchangeable)
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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 / 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:)

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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.

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 $\frac{1}{2}$ - 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.

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.

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.

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SALON / BARBER INSTRUMENTS AND TOOLS DISINFECTION (BACTERICIDE) / VIRUCIDE / FUNGICIDE DIRECTIONS:

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Use (Mix) 1 - 2 oz. of LONZA FORMULATION S-38 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-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 the 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 heavily soiled units.

[WHIRLPOOL] FOOT SPA DISINFECTION DIRECTIONS:

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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.

(Note to reviewer: Language in () is optional or interchangeable)

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*KILLS HIV 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). 18 23

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 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 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.

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

Eor 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:

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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.

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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 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 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

(Note to reviewer: Language in () is optional or interchangeable)

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Shoe Bath Sanitizer 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 $\frac{1}{2}$ 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.

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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. **SANIITIZING 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.

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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-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 receptacle. Prolonged soaking may cause damage to metal instruments.

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, Container is one gallon or less, Label has Household and Residential Uses only:)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls.

Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for recycling if available:

(or)

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, Container is one gallon or less, Label has **any uses other than** Household and Residential)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls.

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. Repeat two more times. Wrap [container] and put in trash or offer for recycling if available.

(or)

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. Repeat two more times. Wrap [container] and put in trash or offer for reconditioning if appropriate

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