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Systems Integration Group, Inc.

6836-

Page 1 7 12 CTION AGENCY

AUG - 4 2003

Mr. Robert Sloan Lonza Inc. 17-17 Route 208 Fair Lawn, NJ 07410

Subject: Lonza Formulation S-38F EPA Registration No. 6836-138 Amendment Date: May 14, 2003 EPA Receipt Date: May 15, 2003

Dear Mr. Sloan,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

TED STATES ENVIRONMENTAL PRO

• Addition of 400 ppm active use dilution for Food Contact Sanitization

Conditions:

Revise the label as follows:

- 1. Page 3: Revise the 3rd bullet in the left panel by deleting the term, "infection," so the phrase reads "on the multi-touch surfaces responsible for cross contamination.
- 2. Page 4: Under "Types of Surfaces," revise the following sites to read: "exterior surfaces of microwave ovens" and "exterior surfaces of refrigerators."

The Agency continues to classify these two surfaces as food contact surfaces. We are particularly concerned about the use of this product in residential setting where we

believe that the user will not conduct a potable water rinse on interior surfaces of microwave ovens and refrigerators. If you desire that all surfaces of microwave ovens and refrigerators be treated in a commercial setting and are willing to limit the use on these surfaces by homeowners, you should propose modified labeling to the Agency.

It is suggested that this label have separate surfaces and directions for use in commercial settings and residential settings. These directions would continue to indicate the necessity for a potable water rinse on food contact surfaces for commercial use and could include treatment of microwave ovens and refrigerators. The residential directions would limit the product to use on exterior surfaces of microwave ovens and refrigerators.

	1	 	CONCURRENC	ES		
SYMBOL	** * * * * * * * * * * * * * * * * *					
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DATE					 	

EPA Form 1320-1A (1/90)

- 3. Page 4: The surface "fiberglass" is a porous material. However, there are fiberglass surfaces which are treated to render them water tight or non-porous. Thus, revise your label to identify these types of non-porous surfaces: "Fiberglass, *sinks*, *tubs*, *and showers*".
- 4. Page 6: Under Fungicidal activity, qualify "surfaces" as *hard nonporous* by stating so in the phrase, "when used on surfaces."

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

If you have any questions or comments regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely

Vélma Noble Product Manager (31) Regulatory Management Branch I Antimicrobials Division (7510C)

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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 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.

ACCEPTED with COMMENTS in EPA Letter Dated:

AUG 4 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 6836-138

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 (C14, 50%; C12, 40%; C16, 10%)	
dimethyl benzyl ammonium chloride	. 1.520%
Inert (Other) Ingredients:	96.200%
Total:	

KEEP OUT OF REACH OF CHILDREN

DANGER (

(PELIGRO)

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

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

Manufactured by: A Nonza INC., 17-17 Route 208, Fair Lawn, NJ 07410

LONZA FORMULATION S-38F EPA Reg. No. 6836-138 EPA DRAFT LABEL DATED 5-2-03 (Note to reviewer: Language in () is optional or interchangeable)

Page 1 of 10

(Note to reviewer: The following is considered optional marketing language.)

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

Lonza Formulation S-38F

- 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 non-critical 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 household germs; effective against Pseudomonas aeruginosa (pseudomonas), Staphylococcus aureus (staph), Streptococcus faecalis (strep), Influenza A/Brazil and Trichophyton mentagrophytes (Athlete's foot fungus).
- 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.

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- is an effective one-step sanitizer-cleaner for use on non-food contact surfaces.
- meets AOAC efficacy standards for hospital disinfectants.
- meets EPA 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).
- meets AOAC Germicidal & Detergent standards for previously cleaned food-contact surfaces.
- has been cleared by the FDA in 21 CFR §178.1010 for use on food processing equipment, utensils and other food-contact articles.

LONZA FORMULATION S-38F EPA Reg. No. 6836-138 EPA DRAFT LABEL DATED 5-2-03 (Note to reviewer: Language in () is optional or interchangeable)

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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.

Use Lonza Formulation S-38F

- 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
- 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.
- on the multi-touch surfaces responsible for crosscontamination 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.
- for Poultry Premise Sanitation (Hatcheries):

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E	Egg Receiving Area	Tray Dumping Area
(Chick Processing Area	Egg Holding Area
(Chick Holding Room	Chick Loading Area
5	Setter Room	Hatchery Room
F	Poultry Buildings	Racks
	Buggies	Trays
E	Egg Flats	Ceilings
5	Sidewalls	Floors
[Drinkers	Poultry House related
		equipment
	other hard, nonporous environment.	surfaces in the Hatchery

- for Swine Premise Sanitation: Farrowing Barns and areas Creep area Loading Equipment Hauling Equipment
- for Farm Premise Sanitation: floors feed racks troughs automatic feeders fountains and waterers

Dressing Plants Waterers and Feeders Chutes Nursery blocks

walls mangers forks, shovels, scrapers

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

- as a commercial sanitizer on dishes, glassware, and utensils.
- as a sanitizer in bottling and beverage dispensing equipment.
- as a sanitizer in sanitary filling of bottles and cans.
- in sanitizing bottles or cans in the final rinse application, and for external spraying of filler and closing machines.
- as a sanitizer in beer fermentation and holding tanks.
- as a Food-Grade Shell Egg sanitizer, with best results achieved in water temperatures ranging from 78°-110°F. LONZA FORMULATION S-38F may be applied through automatic washing systems, immersion tanks, foaming apparatus and low-pressure sprayers.

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 should be limited to areas where compost and mushrooms are not present.

LONZA FORMULATION S-38F EPA Reg. No. 6836-138 EPA DRAFT LABEL DATED 5-2-03 (Note to reviewer: Language in () is optional or interchangeable)

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(Note to reviewer: The following is considered optional marketing language.)

(AREAS OF USE:) Use Lonza Formulation S-38F 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 proparation 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) Schools Shower and bath areas

Camp grounds Play ground equipment

Animal laboratories Dairy farms Farms Hog farms Kennels Poultry farms Pet animal quarters Pet shops Turkey farms Zoos Airports Airplanes **Boats Buses** Campers Cars Emergency vehicles Mobile homes Ships Taxis Trailers Trains Transportation terminals Vehicles (Emergency) (TYPES OF SURFACES:)

Use Lonza Formulation S-38F on washable hard, nonporous surfaces of: Appliances 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) Floors Floors - high speed burnished Garbage cans Highchairs Kennel runs Microwave ovens Mirrors Outdoor furniture Refrigerators Refrigerated storage and display equipment Showers

Shower stalls Sinks (bathroom, kitchen) Stoves (stovetops) Tables (picnic tables) Telephones Toilets **Toilet bowls Toilet bowl surfaces** Tubs Tiles, glazed Ultrasonic baths Urinals Walls Whirlpool bathtubs Windows Beer fermentation and holding tanks Blenders Bottling or premix dispensing equipment Chopping blocks, plastic and other nonporous **Cooking utensils** Coolers Cutlerv 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 Tupperware⁶ Other hard nonporous surfaces made of: Fiberglass Formica Glass Glazed ceramic Giazed enameled surfaces Glazed porcelain Metal Plastic (such as polystyrene or

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Sealed stone Stainless steel Upholstery, vinyl and plastic Woodwork, finished

LONZA FORMULATION S-38F EPA Reg. No. 6836-138 EPA DRAFT LABEL DATED 5-2-03 (Note to reviewer: Language in () is optional or interchangeable)

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(Note to reviewer: The following is considered optional marketing language.)

LONZA FORMULATION S-38F is a sanitizer for hard For Hospitals, Medical and Dental Offices, Nursing porous and nonporous non-food contact surfaces at 1:256 Homes and other Medical Facilities: dilution (150 ppm active) (1/2 oz. per gallon of water) At 2 oz. per gallon of water, the activity of LONZA according to the method for Sanitizers - Non-food Contact FORMULATION S-38F has been evaluated in the presence surfaces, modified in the presence of 300 ppm hard water of 5% organic serum by the AOAC use-dilution test and plus 5% organic serum in 60 seconds against: found to be effective against the following gram negative and gram positive organisms (Bacteria:): Klebsiella pneumoniae Staphylococcus aureus Pseudomonas aeruginosa (Pseudomonas) LONZA FORMULATION S-38F eliminates 99.9% of Staphylococcus aureus (Staph) Staphylococcus aureus and Klebsiella pneumoniae in 60 Salmonella choleraesuis (Salmonella) seconds. Acinetobacter baumannii (Acinetobacter) LONZA FORMULATION S-38F is an effective sanitizer for Corynebacterium ammoniagenes (Brevibacterium ammoniagenes) Enterobacter aerogenes use on food contact surfaces in 60 seconds at 150 ppm Enterococcus faecalis - Vancomycin resistant (VRE) active against: Escherichia coli (E. coli) ESBL Escherichia coli - (Extended spectrum beta-Escherichia coli Staphylococcus aureus lactamase producing E. coli) Klebsiella pneumoniae (Klebsiella) Regular, effective cleaning and sanitizing of equipment, Pseudomonas cepacia (Pseudomonas) utensils, and work or dining surfaces which could harbor Salmonella schottmuelleri (Salmonella) hazardous microorganisms minimizes the probability of Serratia marcescens contaminating food during preparation, storage or service. Shigella dysenteriae (Shigella) Effective cleaning will remove soil and prevent the Staphylococcus aureus Methicillin-Resistant (MRSA) accumulation of food residues, which may decompose or Staphylococcus aureus - Vancomycin Intermediate Resistant - (VISA) support the rapid development of food poisoning organisms Streptococcus faecalis (Strep) or toxins. Application of effective sanitizing procedures reduces the number of those disease organisms which may For Schools, Public Rest Rooms, Athletic Facilities, be present on equipment and utensils after cleaning, and reduces the potential for the transfer, either directly through Food Processing Plants, Food Storage Areas, Kitchens, Restaurants, Bars, Transportation Terminals, Hotels, tableware such as glasses, cups and flatware or indirectly Motels and Other Non-Medical Institutional and through food. To prevent cross-contamination, kitchenware and food-Industrial Uses: contact surfaces of equipment must be washed, rinsed with At 1 oz. per gallon of water, the activity of LONZA potable water and sanitized after each use and following FORMULATION S-38F has been evaluated in the presence any interruption of operation during which time of 5% organic serum by the AOAC use-dilution test and contamination may have occurred. found to be effective against: Where equipment and utensils are used for the preparation Staphylococcus aureus (Staph) of foods on a continuous or production-line basis, utensils Salmonella choleraesuis (Salmonella) and the food-contact surfaces of equipment must be washed, rinsed with potable water and sanitized at intervals Corynebacterium ammoniagenes (Brevibacterium ammoniagenes) throughout the day on a schedule based on food Enterobacter aerogenes temperature, type of food, and amount of food particle Escherichia coli (E. coli) accumulation. Klebsiella pneumoniae (Klebsiella) Salmonella schottmuelleri (Salmonella) LONZA FORMULATION S-38F fulfills the criteria of Serratia marcescens Appendix F of the Grade "A" Pasteurized Milk Ordinances Shigella dysenteriae (Shigella) 1999 Recommendations of the U.S. Public Health Services Streptococcus faecalis (Strep) 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 EPA Reg. No. 6836-138 EPA DRAFT LABEL DATED 5-2-03 (Note to reviewer: Language in () is optional or interchangeable)

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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 A/Brazil

*Herpes Simplex Type 1 and 2

*HIV-1 (AIDS virus) *Vaccinia

Dilution:

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Disinfection – Medical (1:64)	2 oz. per gallon of water
Disinfection - Non Medical (1	:128)1 oz. per gallon of water
Sanitizer (1:256)	1/2 oz. per gallon of water
	(150 ppm active)
Sanitizer (1:96)	(11/3 oz. per gallon of water)
	(400 ppm active)

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-38F 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 galion 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.

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(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 semicritical 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-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 $\frac{1}{2}$ - 2 oz. of LONZA FORMULATION S-38F 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-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.

LONZA FORMULATION S-38F EPA Reg. No. 6836-138 EPA DRAFT LABEL DATED 5-2-03 (Note to reviewer: Language in () is optional or interchangeable)

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

Use (Mix) 1 - 2 oz. of LONZA FORMULATION S-38F per gallon of water ($\frac{1}{2}$ 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, noncontaminated 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 for 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 water to 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 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 *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).

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SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS.

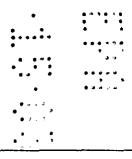
PERSONAL PROTECTION: Clean up should always be done wearing protective gloves, gowns, masks and eye protection.

CLEANING PROCEDURE: Blood and other body fluids containing HIV-1 must be thoroughly cleaned from surfaces and objects before application of LONZA FORMULATION S-38F.

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:

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.



LONZA FORMULATION S-38F EPA Reg. No. 6836-138 EPA DRAFT LABEL DATED 5-2-03 (Note to reviewer: Language in () is optional or interchangeable)

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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-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 Do not house livestock or employ closed spaces. 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 all treated surfaces wet for 10 minutes or more. Wipe or allow to air dry Shoe Bath Sanitizer Directions: To prevent tracking harmful 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-38F. 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-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 should be allowed to remain wet for 10 minutes. Wipe or allow to air dry. For heavily solled areas, preclean first. Prepare a fresh solution for each use or more often if solution becomes visibly diluted, clouded or soiled.

For Heavy Duty Cleaning: When greater cleaning is desired, use 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.

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

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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.

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LAUNDRY SANITIZER DIRECTIONS: This product sanitizes by controlling or reducing the growth of odorcausing 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:

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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, mop, sponge, coarse sprayer or by immersion. Surfaces must remain wet for at least 60 seconds (one minute) followed by adequate draining and air drying. Do not rinse. Prepare a fresh solution for each use. For mechanical application, use- solution may not be reused for sanitizing applications but may be reused for other purposes such as cleaning.

Apply to sink tops, countertops, refrigerated storage and display equipment and other stationary hard nonporous surfaces by cloth, sponge, brush or coarse spray.

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

TO SANITIZE BEVERAGE DISPENSING EQUIPMENT:

- 1. Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing.
- 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.

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TO SANITIZE BEER FERMENTATION AND STORAGE TO SANITIZE BEVERAGE DISPENSING EQUIPMENT: TANKS:

Wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing. Prepare a usesolution of 1/2 oz. [to 11/3 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 usesolution of 1/2 oz. [to 11/3 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 130°F. Wet eggs thoroughly and allow to drain. Eggs sanitized with this product shall be subjected to a thorough potable water rinse only if they are to be broken immediately for use in the manufacture of egg products. Eggs must be reasonably dry before casing or breaking. The solution must not be re-used for sanitizing eggs.

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

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 1/2 oz. [to 11/3 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 1/2 oz. [to 11/3 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.

1. Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing.

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- Fill equipment with a solution of 1/2 oz. [to 11/3 oz.] 2. Lonza Formulation S-38F per gallon of water (or equivalent dilution) (150 ppm [to 400 ppm] active quat).
- 3. Allow solution to remain in equipment for at least 60 seconds.
- 4. Drain thoroughly and allow to air dry before reuse.

(Note to reviewer: If container is one gallon or less, the following Storage and Disposal statements will be used:)

STORAGE AND DISPOSAL

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

(Note to reviewer: If container is greater than one gallon, the following Storage and Disposal statements will be used:)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage

Do not store on side. Avoid creasing or impacting of side walls.

Pesticide Disposal

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

Container Disposal

(Plastic containers): Triple rinse (or equivalent), then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(Metal Containers): Triple rinse (or equivalent), then offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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