

6836-138

1/6/2010

1 of 15

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JAN - 6 2010

Joanna Holcombe  
Sr. Commercial Regulatory Services Associate  
Lonza Inc.  
90 Boroline Road  
Allendale, NJ 07401

Subject: Lonza Formulation S-38F  
EPA Reg. No. 6836-138  
Application Dated: December 03, 2009  
Receipt Date: December 07, 2009

Dear Joanna Holcombe

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9. is acceptable.

**Proposed Amendment**

Adding Marketing language for the Pandemic 2009 H1N1

**Comments**

Based on a review of the material submitted, the following comments apply:  
This application for notification to add marketing language for the Pandemic 2009 H1N1 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 (31)  
Regulatory Management Branch1 Antimicrobi  
Division (7510P)

**CONCURRENCES**

SYMBOL							
SURNAME							
DATE							

**EPA**

United States  
Environmental Protection Agency  
Washington, DC 20460

- Registration
- Amendment
- Other

OPP Identifier Number

**Application for Pesticide - Section 1**

1. Company/Product Number <b>6836-138</b>	2. EPA Product Manager <b>Velma Noble</b>	3. Proposed Classification  <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>IONZA FORMULATION S-38F</b>	PM# <b>31</b>	
5. Name and Address of Applicant (Include ZIP Code) <b>Lonza Inc. 90 Boroline Road Allendale, NJ 07401</b>	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:  EPA Reg. No. Product Name	

**Section - II**

- Amendment - Explain below.
- Resubmission in response to Agency letter dated \_\_\_\_\_
- Notification - Explain below.
- Final printed labels in response to Agency letter dated \_\_\_\_\_
- "Me Too" Application
- Other - Explain below

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

**Notification of label change to add optional marketing language per EPA Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1**

**\*Not Subject to PRIA\***

*This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.*

Signature: Joanna Holcombe    Date: 12/3/09

**Section - III**

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

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name <b>Joanna Holcombe</b>	Title <b>Sr. Commercial Regulatory Services Associate</b>	Telephone No. (Include Area Code) <b>203-316-9297</b>
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received  <b>(Stamped)</b>
2. Signature 	3. Title <b>Sr. Commercial Regulatory Services Associate</b>	
4. Typed Name <b>Joanna Holcombe</b>	5. Date <b>December 3, 2009</b>	

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

December 3, 2009

**SUBJECT: Lonza Formulation S-38F, EPA Registration No. 6836-138  
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.

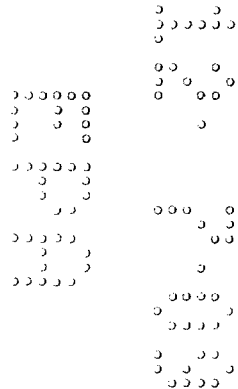
- Application for Pesticide Notification
- One copy of the label with changes highlighted

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.



Joanna Holcombe  
Sr. Commercial Regulatory Services Associate



**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**

This pesticide is toxic to fish and aquatic invertebrates. 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.

**LONZA FORMULATION S-38F**

One-Step Disinfectant

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

Acid-Free Cleaner  
Acid-Free Disinfectant

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

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

For use in federally inspected meat and poultry plants

An effective sanitizer for use on food contact surfaces

- Staphylocidal • Pseudomonacidal • Bactericidal
- Salmonellacidal • Fungicidal • Virucidal\*

**Active Ingredients:**

Octyl decyl dimethyl ammonium chloride .....	1.140%
Dioctyl dimethyl ammonium chloride .....	0.456%
Didecyl dimethyl ammonium chloride .....	0.684%
Alkyl (C <sub>14</sub> , 50%; C <sub>12</sub> , 40%; C <sub>16</sub> , 10%) dimethyl benzyl ammonium chloride .....	1.520%
Inert (Other) Ingredients: .....	96.200%
Total:.....	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. 6836-138

EPA Est. No. *(insert EPA Establishment No. here)*

Net Contents *(insert container size here)*

[Country of origin (insert country)]

[Manufactured in (insert country)]

[Barcode]

Manufactured by:  
LONZA INC., 90 Boroline Road, Alendale, NJ 07400

(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 Virus 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.
- 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).
- meets AOAC Germicidal & Detergent standards for previously cleaned food-contact surfaces.
- has been cleared in 40 CFR §180.940 (a) for use on food processing equipment, utensils and other food-contact articles.

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 cross-contamination.
- 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):
 

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
Buggies	Trays
Egg Flats	Ceilings
Sidewalls	Floors
Drinkers	Poultry House related equipment

other hard, nonporous surfaces in the Hatchery environment.

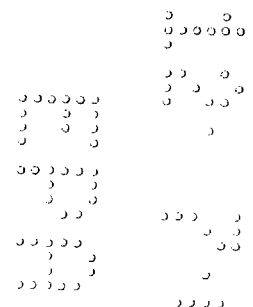
- for Swine Premise Sanitation:
 

Farrowing Barns and areas	Dressing Plants
Creep area	Waterers and Feeders
Loading Equipment	Chutes
Hauling Equipment	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.
- 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** must be limited to areas where compost and mushrooms are not present.



(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 preparation areas
- Food storage areas
- Institutional kitchens
- Restaurants
- USDA inspected food processing facilities
  
- Athletic facilities
- Barber shops
- Business and office buildings
- Colleges
- Correctional facilities
- Dressing rooms
- Exercise facilities
- Factories
- Hotels
- Institutional facilities
- Institutions
- Laundries
- Locker rooms
- Motels
- Prisons
- Public facilities
- Public rest rooms
- Salons (Beauty)
- 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)
  - Fiberglass sinks, tubs, and showers
  - Floors
  - Floors – high speed burnished
  - Garbage cans
  - Highchairs
  - Kennel runs
  - Exterior surfaces of Microwave ovens
  - Mirrors
  - Outdoor furniture
  - Exterior surfaces of 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
- Cutlery
- Cutting Boards, plastic and other nonporous
- Dishes
- Eating Utensils
- Food processors
- Glassware
- Ice Chests
- Kitchen equipment
- Refrigerator bins used for meat, fruit, vegetables and eggs
- Silverware
- Slurpy Machines
- Tupperware®
  
- Other hard nonporous surfaces made of:
- 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

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

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

Klebsiella pneumoniae      Staphylococcus aureus

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

**LONZA FORMULATION S-38F** is an effective sanitizer for use on food contact surfaces in 60 seconds at 150 ppm active against:

Escherichia coli                      Staphylococcus aureus

Regular, effective cleaning and sanitizing of equipment, utensils, and work or dining surfaces which could harbor food poisoning microorganisms minimizes the probability of contaminating food during preparation, storage or service. Effective cleaning will remove soil and prevent the accumulation of food residues, which may decompose or support the rapid development of food poisoning organisms or toxins. Application of effective sanitizing procedures reduces the number of those food poisoning organisms which may be present on equipment and utensils after cleaning, and reduces the potential for the transfer, either directly through tableware such as glasses, cups and flatware or indirectly through food.

To prevent cross-contamination, kitchenware and food-contact surfaces of equipment must be washed, rinsed with potable water and sanitized after each use and following any interruption of operation during which time contamination may have occurred.

Where equipment and utensils are used for the preparation of foods on a continuous or production-line basis, utensils and the food-contact surfaces of equipment must be washed, rinsed with potable water and sanitized at intervals throughout the day on a schedule based on food temperature, type of food, and amount of food particle accumulation.

**LONZA FORMULATION S-38F** fulfills the criteria of Appendix F of the Grade "A" Pasteurized Milk Ordinances 1999 Recommendations of the U.S. Public Health Services in waters up to 300 ppm of hardness calculated as CaCO<sub>3</sub> when evaluated by the AOAC Germicidal and Detergent Sanitizer Method.

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

At 2 oz. per gallon of water, the activity of **LONZA FORMULATION S-38F** has been evaluated in the presence of 5% organic serum by the AOAC use-dilution test and found to be effective against the following gram negative and gram positive organisms (*Bacteria*):

Pseudomonas aeruginosa (Pseudomonas)  
Staphylococcus aureus (Staph)  
Salmonella enterica (Salmonella)

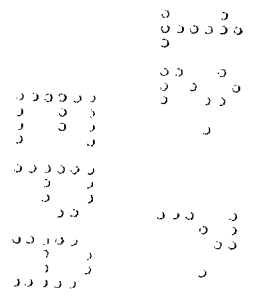
Acinetobacter baumannii (Acinetobacter)  
Corynebacterium ammoniagenes (Brevibacterium ammoniagenes)  
Enterobacter aerogenes  
Enterococcus faecalis - Vancomycin resistant (VRE)  
Escherichia coli (E. coli)  
ESBL Escherichia coli – (Extended spectrum beta-lactamase producing E. coli)  
Klebsiella pneumoniae (Klebsiella)  
Pseudomonas cepacia (Pseudomonas)  
Salmonella schottmuelleri (Salmonella)  
Serratia marcescens  
Shigella dysenteriae (Shigella)  
Staphylococcus aureus Methicillin-Resistant (MRSA)  
Staphylococcus aureus - Vancomycin Intermediate Resistant – (VISA)  
Streptococcus faecalis (Strep)

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

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

Staphylococcus aureus (Staph)  
Salmonella enterica (Salmonella)

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







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

**Dilution:**

Disinfection – Medical (1:64) ..... 2 oz. per gallon of water  
 Disinfection – Non Medical (1:128) 1 oz. per gallon of water  
 Sanitizer (1:256) ..... ½ oz. per gallon of water  
 .....(150 ppm active)  
 Sanitizer (1:96) .....(1½ 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 – 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  
 For heavy duty use, add (mix) 8 oz. of Lonza Formulation S-38F per gallon of water.

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

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

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

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

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

**For fungicidal activity:**

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

**For mold and mildew control:**

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

*(Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must be used:)*

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (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-38F per gallon of water to clean and deodorize surfaces. Apply using a cloth, mop, sponge or sprayer. Wipe or allow to air dry.

**GLASS CLEANING / DEODORIZING DIRECTIONS:**

Add ½ - 2 oz. of LONZA FORMULATION S-38F per gallon of water to clean and deodorize windows, 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.

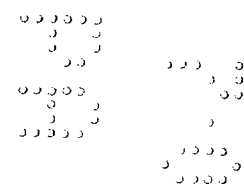
**From Use Solution:**

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 2 oz. per gallon.



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

Use (Mix) 1 - 2 oz. of **LONZA FORMULATION S-38F** 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-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).

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

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

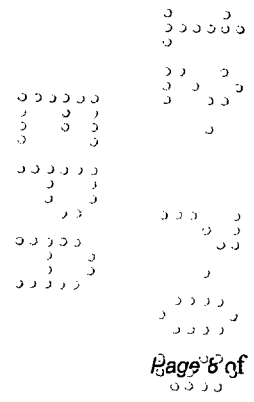
**CLEANING PROCEDURE:** Blood and other body fluids containing HIV-1 must be thoroughly cleaned from surfaces and objects before application of **LONZA FORMULATION S-38F**.

**CONTACT TIME:** Leave surface wet for 10 minutes

**DISPOSAL OF INFECTIOUS MATERIAL:** Blood, body fluids, cleaning materials and clothing must be autoclaved and disposed of according to local regulations for infectious waste disposal.

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

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



**FARM PREMISE USE:**

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

**POULTRY AND SWINE PREMISE DISINFECTION DIRECTIONS:**

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

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

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

**Shoe Bath Sanitizer Directions:** To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made solution must be placed at all entrances to buildings and hatcheries. Scrape waterproof work boots and place in a 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.

**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.

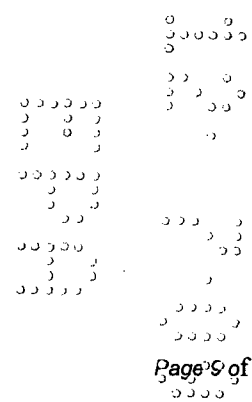
**MUSHROOM FARM PREMISE USE:**

**Site Preparation:** The first step in any on-going sanitation program must be the removal of gross contamination and debris. This may be accomplished by using a shovel, broom, or vacuum, depending on the area to be disinfected.

**Cleaning and Disinfection:** For general cleaning and disinfection, use 1 - 2 oz. of **Lonza Formulation S-38F** per gallon of water (or equivalent dilution). Apply use solution with a cloth, mop, sponge, sprayer or by immersion to thoroughly wet the surfaces. Treated surfaces must be allowed to remain wet for 10 minutes. Wipe or allow to air dry. For heavily soiled areas, preclean first. Prepare a fresh solution for each use or more often if solution becomes visibly diluted, 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.



**SANITIZING NON FOOD CONTACT SURFACES:** (such as floors, walls, and tables.) Add 1/2 oz. of LONZA FORMULATION S-38F per gallon of water. LONZA FORMULATION S-38F is an effective sanitizer against Staphylococcus aureus and Klebsiella pneumoniae in the presence of 5% serum on porous and non-porous environmental surfaces. Treated surfaces must remain wet for 60 seconds. Wipe dry with a sponge, mop, or cloth or allow to air dry.

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

**TO SANITIZE BARBER / SALON INSTRUMENTS AND TOOLS:** Immerse hard, nonporous barber / salon instruments and tools (such as combs, brushes, razors, scissors, blades and manicure instruments) in a use-solution of 1/2 oz. of **Lonza Formulation S-38F** per gallon of water (or equivalent dilution) for at least 60 seconds (one minute). Rinse thoroughly and dry before use. Prepare a fresh solution daily or more often if solution becomes visibly diluted, cloudy or soiled.

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

**TO SANITIZE FOOD CONTACT SURFACES:**

(or)  
**TO SANITIZE FOOD PROCESSING EQUIPMENT AND OTHER HARD SURFACES IN FOOD PROCESSING LOCATIONS, DAIRIES, RESTAURANTS AND BARS:**

Use **Lonza Formulation S-38F** to sanitize hard nonporous surfaces of food processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage and display equipment and other hard surfaces.

Prior to application, remove gross food particles and soil by a pre-flush, or pre-scrape and, when necessary, pre-soak. Then thoroughly wash or flush objects with a good detergent or compatible cleaner followed by a potable water rinse before application of the sanitizing solution.

Apply a use-solution of 1/2 oz. [to 1 1/2 oz.] of **Lonza Formulation S-38F** per gallon of water (or equivalent dilution) (150 ppm [to 400 ppm] active) to pre-cleaned hard surfaces thoroughly wetting surfaces with a cloth, mop, sponge, coarse sprayer or by immersion. Surfaces must remain wet for at least 60 seconds (one minute) followed by adequate draining and air drying. Do not rinse. Prepare a fresh solution for each use. For mechanical application, use- solution may not be reused for sanitizing applications but may be reused for other purposes such as cleaning.

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

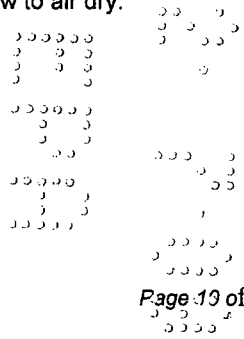
Sanitize dishes, silverware, glasses, cooking utensils and other similar size food processing equipment by immersion.

**TO SANITIZE BEVERAGE DISPENSING EQUIPMENT:**

1. Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing.
2. Fill equipment with a solution of 1/2 oz. [to 1 1/2 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 1/2 oz. [to 1 1/2 oz.] of **Lonza Formulation S-38F** per gallon of water (or equivalent dilution) (150 ppm [to 400 ppm] active) for final washer and rinser applications. Allow surfaces to remain wet for at least 60 seconds. Drain thoroughly before reuse and allow to air dry.



**TO SANITIZE BEER FERMENTATION AND STORAGE TANKS:**

Wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing. Prepare a use-solution of 1/2 oz. [to 1 1/2 oz.] of **Lonza Formulation S-38F** per gallon of water (or equivalent dilution) (150 ppm [to 400 ppm] active) for mechanical or automated systems. Allow surfaces to remain wet for at least 60 seconds. Drain thoroughly and allow to air dry before reuse.

**TO SANITIZE EGG SHELLS INTENDED FOR FOOD:**

To sanitize previously cleaned food-grade eggs in shell egg and egg product processing plants, spray with a use-solution of 1/2 oz. [to 1 1/2 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.

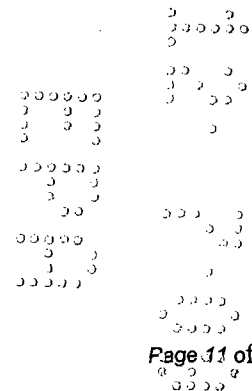
**U.S. PUBLIC HEALTH SERVICE  
FOOD SERVICE SANITIZATION  
RECOMMENDATIONS**

**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 1 1/2 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 1 1/2 oz.] of **Lonza Formulation S-38F** per gallon of water (150 ppm [to 400 ppm] active quat) (or equivalent dilution) by rinsing, spraying or swabbing until thoroughly wet.
5. Allow sanitized surface to drain and air dry. Do not rinse.

**TO SANITIZE BEVERAGE DISPENSING EQUIPMENT:**

1. Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing.
2. Fill equipment with a solution of 1/2 oz. [to 1 1/2 oz.] **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: 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)

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)

**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.

**(For 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.

