

6836-140

8/14/2007

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

AUG 14 2007

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Georgia Anastasiou
Agent for Lonza
Lewis & Harrison
122 C Street, NW Suite 740
Washington, DC 20001

Subject: Lonza Formulation S - 21F
EPA Registration No. 6836-140
Amendment Dated: April 20, 2007
EPA Received Date: April 25, 2007

Dear Georgia Anastasiou

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, is acceptable with comments.

Proposed Amendment

Revised Label
Adding Marketing Text
Adding Claims for Avian influenza (H2N2) and Clostridium Difficile-Vegetative

Label Comments

1. Pg 2, Right column, ninth bullet item, Revise the words "can be" to "must be" to reflect the mandatory language in PR Notice 2000-5.
2. Pg. 3, Revise the words "can be and may be" located in the 2nd, 3rd, 4th, and 5th sentences to reflect the mandatory language of PR Notices 2000-5.
3. For example: "Lonza Formulation S-18F is for use in the laundry to control....."
4. Pg. 3, Revise the last statement in the 12th claim to be in compliance with PR Notice 2000-5 by deleting the term, "recommended."
5. Pg. 4, Correct the typographical error from the use site "Doorknobs (hahdles)" to read "Doorknobs (handles)".

CONCURRENCES

| | | | | | | | |
|---------|--------|--|--|--|--|--|--|
| SYMBOL | 7570C | | | | | | |
| SURNAME | | | | | | | |
| DATE | 8-9-07 | | | | | | |

6. Pg. 5, Top paragraph, delete the use site "automatic washing systems", you must submit directions for use.
7. Pg. 5, and 6, Delete the dilution rate and contact time from the label claims such that they are considered incomplete directions for use. Alternatively, these listings of organisms and claims must be moved to the "Directions for Use" section of the label. Also, delete the dilution rate for Adenovirus Type 5 and Type 7.
8. Pg. 5, Right column, bottom paragraph delete the word "may be" from the statement "Application of effective sanitizing procedures reduces the number of those organisms which may be present to...." To read "*Application of effective sanitizing procedures reduces the number of those organisms present ...*" to reflect the mandatory language of PR Notice 2000-5.
9. Pg. 5, The Agency will no longer accept claims against the bacterium, **Clostridium difficile-vegetative**, If you wish to support a *C. difficile* claim, you must conduct the data on the *C. difficile* spore using sporicidal test method.
10. Pg. 7, Move the heading, "DIRECTIONS FOR USE" and misuse statement, "It is a violation of Federal Law....." to appear above the dilution chart.
11. Pg. 7, Revise the last statement located in the Disinfection/Virucidal/Fungicidal/Mold and Mildew Control directions section to read "*For heavily soiled areas, a preliminary cleaning is **required***" to reflect the mandatory language of PR Notice 2000-5 and move this statement before the Fungicidal Activity section.
12. Pg. 8, Revise the "Disinfection of [Whirlpool (Bath) (Units)] [Foot Spas] heading and directions by deleting "Foot spas." You must add the following directions to support foot spas disinfection directions:
 13. Disinfection of Pedicure Foot Spas: For heavily soiled units, drain the water and thoroughly clean all hard nonporous surfaces with soap or detergent. After using pedicure foot spa, drain and refill with fresh water to cover the intake valve or highest jet by 2 inches. Add 1oz. of product per gallon of fresh water. Start pump to circulate the solution. Turn the pump off to allow the solution to sit for 10 minutes. Wash down the unit sides and seat with a clean swab, brush, or sponge such that these surfaces remain wet for a 10 minute contact time, drain the solution from the pedicure foot spa and rinse with fresh water.
14. Pg. 8, Qualify "rollers" as a use site by stating "plastic rollers".
15. Pg. 8, Under the Salon/ Barber Instruments and Tools Disinfection...section, the last sentence in this paragraph "**Fresh solution should be prepared**" must be revised to read "**Fresh solution must be prepared**" to be in compliance with PR Notice 2000-5.
16. Pg. 8, Revise the first sentence under "Personal Protection" in the HIV/HBV/HCV directions to read, "Clean up *must* always be done wearing protective gloves....." such that it is in agreement with mandatory language of PR Notice 2000-5.
17. Pg. 9, Under the "Poultry and Swine Premise Disinfection [Virucidal] Directions, delete the word "recommended" located in the 6th statement, "Saturate surfaces with the disinfecting solution for 10 minutes" to be in compliance with PR Notice 2000-5.

18. Pg. 10, Revise the following statement under "Mushroom Farm Premise" directions to reflect the mandatory language of PR Notice 2000-5.
19. *"The first step in any ongoing sanitation program should be..." to read "The first step in any ongoing sanitation program must be..."*
20. *"This may be accomplished by using a shovel, broom... to read "This is accomplished by using a shovel, broom, vacuum..."*
21. Pg. 10, In the Citrus Canker Disease Control, revise the statement *"Treatments can be applied to trucks, attached trailers."* to read *"Treatments must be applied to trucks, attached trailers..."* to be in compliance with PR Notice 2000-5.
22. Pg. 11, Delete the following directions under "deodorizing" "Carpets" and Sewage Backup, Water Damage" because the appropriate directions for these sites are located in the right column.
23. Pg. 12, Revise the dilution chart, left column, such that it is in agreement with 40CFR 180.940 (a) and (c):

| |
|---|
| For Food Contact Surfaces, Food Processing Equipment and Utensils in Dairies and Public Eating Establishments(40 CFR 180.940(a)) |
| 1 oz. Lonza Formula S-18F per 4-5 ½ gallons of water (150-200 ppm active quat) (or equivalent dilution) |
| For Food Contact Surfaces, Food Processing Equipment and Utensils in Food Processing Plants (40 CFR 180.940(c)) |
| 1 oz. Lonza Formula S-18F per 2¾-5 ½ gallons of water (150-300 ppm active quat) (or equivalent dilution) |
| 1 oz. Lonza Formula S-18F per 2-5 ½ gallons of water (150-400 ppm active quat) (or equivalent dilution) |
| 1 oz. Lonza Formula S-18F per 2¾-4 gallons of water (200-300 ppm active quat) (or equivalent dilution) |
| 1 oz. Lonza Formula S-18F per 2-4 gallons of water (200-400 ppm active quat) (or equivalent dilution) |

24. Pg. 12, Add "150-200 ppm active quat" directly after the header "To Sanitize Food Processing Equipment and other Hard Surfaces in Food Processing Locations such as Dairies, Restaurants and Bars to clarify the appropriate dilution rate for the user.
25. Pg.12, Revise the first statement in the third paragraph under "To Sanitize Food Contact Surfaces" by adding "150-200 ppm active quat" such that it reads "Apply a use-solution of [insert appropriate dilution here] (150-200ppm of active quat)".
26. Pg.12, Revise the directions, "To Sanitize Beverage Dispensing Equipment" by providing a use dilution rate, "fill equipment with a solution of 0.2 ounces," and acceptable parts per million range (150-200ppm active quat).

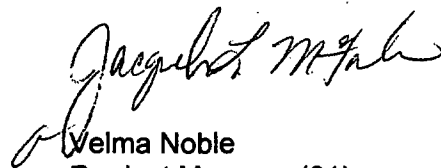
27. Pg. 12, Revise the 3rd statement in the "To Sanitize Ice Machines" to read "Apply a solution of 0.3 ounces by mechanical spray, directly pouring, or by recirculating through the system.
28. Pg. 12, Revise 2nd statement, under the "To Sanitize Sanitary Filling Equipment" to read "Prepare a use-solution of [insert appropriate dilution here] (150-400ppm active quat)
29. Pg. 13, Revise the "To Sanitize Beer Fermentation and Storage Tanks" and "To Sanitize Egg Shells Intended for Food" directions by adding the acceptable parts per million range "(150 – 200pp active quat)," after the use dilution rate.
30. Pg.13, Revise the 4th statement locate in the Cleaning and Sanitizing section, to read "For equipment and utensils by immersion, apply a use-solution of 0.3 ounces (150-200 ppm active quat) by rinsing, spraying or swabbing until thoroughly wet"
31. Pg.13, Revise the 4th statement under "Wisconsin State Board of Health Directions for Eating Establishments" to read "Sanitize in a use solution if 0.4 ounces (150-200ppm active quat)...."
32. Pg. 13, Delete the "To Sanitize Beverage Dispensing Equipment" directions because it already appears on page 12 of your label.

General Comments

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

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
Antimicrobial Division (7510c)

**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 (rubber or chemical resistant) gloves and protective clothing. Harmful if swallowed or absorbed through the skin. 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 14 2007

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 5813-91

**5 8 18
LONZA FORMULATION S-21F**

One-Step Disinfectant

Cleaner - Sanitizer - Fungicide
Mildewstat - Virucide* - Deodorizer
for Homes, Hospitals, Institutional and Industrial Use

Effective in hard water up to 400 ppm hardness
(calculated as CaCO₃) in the presence of 5% serum
contamination

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..... | 1.65% |
| Dioctyl dimethyl ammonium chloride..... | 0.66% |
| Didecyl dimethyl ammonium chloride..... | 0.99% |
| Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride..... | 2.20% |
| Other Ingredients: | 94.50% |
| Total: | 100.00% |

KEEP OUT OF REACH OF CHILDREN

DANGER (PELIGRO)

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

EPA Reg. No. 6836-140

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

Net Contents (insert container size here)

Manufactured by:
LONZA INC., 90 Boroline Road, Allendale, NJ 07401

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

Lonza Formulation S-21F:

- 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) 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 even in the presence of hard water).
- will not leave grit or soap scum.
- is a (versatile) disinfectant and sanitizer for hard, nonporous 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).
- 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 and Hepatitis B Virus and Hepatitis C 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 EPA Sanitizer Test standards for non-food contact sanitizers.
- is a proven one-step disinfectant - cleaner - sanitizer - fungicide - mildewstat - virucide* which is effective in water up to 400 ppm hardness in the presence of 5% serum contamination.
- meets AOAC Germicidal & Detergent standards for previously cleaned food-contact surfaces.
- has been cleared by 40 CFR 180.940(a) and (c) for use on food processing equipment, utensils and other food-contact articles.

Cross-contamination is of major housekeeping concern. **LONZA FORMULATION S-21F** 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-21F:

- 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.
- 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 showers and tubs, shower doors and curtains, 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, Egg Holding Area; Setter Room, Tray Dumping Area, Trays, Buggies, Racks, Egg Flats, Chick Holding Room, Hatchery Room, Chick Processing Area, Chick Loading Area, Poultry Buildings, Ceilings, Sidewalls and Floors, Drinkers and other Poultry House related equipment, and all other hard, nonporous surfaces in the Hatchery environment.
- for Swine Premise Sanitation: Waterers and Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns and areas, Nursery blocks, Creep area, Chutes.
- for Farm Premise Sanitation of hard nonporous surfaces: floors, walls, feed racks, mangers, troughs, automatic feeders, fountains and waterers, forks, shovels, scrapers and other nonporous surfaces in barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals.

Lonza Formulation S-21F is effective at controlling mold and mildew odor on mattresses, pillows and shower curtains.

Lonza Formulation S-21F can be used in the laundry to control odors on musty bedding and linens. Test on a small inconspicuous area before using.

Lonza Formulation S-21F may be used on mildew stains in damp areas such as bathrooms, showers, kitchens, basements and laundry rooms.

Lonza Formulation S-21F may be used in work areas such as tool rooms and garages for odor control and light duty cleaning.

Lonza Formulation S-21F may be used to remove odors caused by flooding and smoke from fires.

Lonza Formulation S-21F leaves a clean fresh scent.

Lonza Formulation S-21F provides long lasting freshness against tough (pet) odors such as odors from litter boxes and pet accidents.

Lonza Formulation S-21F (Kills) (Eliminates) (Removes)
(Destroys) avian influenza A (H3N2) on pre-cleaned environmental surfaces

Lonza Formulation S-21F (Kills) (Eliminates) (Removes)
(Destroys) *[Insert pathogen or pathogens from lists on pages 5 or 6]* on pre-cleaned environmental surfaces

Lonza Formulation S-21F (Kills) (Eliminates) (Removes)
(Destroys) Germs) (Bacteria) (Viruses*) (on pre-cleaned environmental surfaces)

Use [on] [to clean and disinfect] nonporous athletic mats, wrestling mats, gymnastic mats, exercise equipment and training tables.

Use [on] [to clean and disinfect] nonporous personal protective safety equipment, wrestling headgear, boxing headgear, protective headgear, athletic helmets, hard hats, half mask respirators, full face breathing apparatus, gas masks, goggles, spectacles, face shields, hearing protectors, and ear muffs. Rinse all equipment that comes in prolonged contact with skin with warm water and allow to air dry before reuse. [Caution: Cleaning at the recommended 120°F. temperature will avoid overheating and distortion of the personal safety equipment that would necessitate replacement.]

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

(AREAS OF USE:)

Use Lonza Formulation S-21F 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
Food processing plants
Food preparation areas
Food storage areas
Institutional kitchens
Restaurants
USDA inspected food processing facilities

Athletic facilities
Barber shops
Business and office buildings
Colleges
Correctional facilities
Dressing rooms
Exercise facilities
Factories
Hotels
Institutional facilities
Institutions
Locker rooms
Motels
Prisons
Public facilities
Public rest rooms
Schools
Shower and bath areas
Salons [Beauty] [Tanning]

Camp grounds
Play ground equipment

Animal laboratories
Dairy farms
Farms
Hog farms
Kennels
Mushroom Farms
Poultry farms
Pet animal quarters
Pet shops
Turkey farms
Zoos

Airplanes
Airports
Ambulances
Boats
Buses
Campers
Cars
Emergency (Police) (EMS) (Fire)
(Rescue) vehicles
Mobile homes
Railcars
Ships
Taxis
Trailers
Trains
Transportation terminals
Trucks (Box Trucks)

(TYPES OF SURFACES:)

Use Lonza Formulation S-21F on washable
hard, nonporous surfaces of:

Appliances, exteriors
Bathroom fixtures
Bathtubs [fiberglass]
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
Foot Spas
Garbage cans
Highchairs
Kennel runs
Microwave ovens, exteriors
Outdoor (patio) furniture except cushions and
wood frames
Refrigerators, exteriors
Refrigerated storage and display equipment
Showers
(Fiberglass) Shower stalls
(Fiberglass) Sinks (bathroom, kitchen)
Stoves (stovetops)
Tables [Non-wooden picnic tables]
Telephones
Toilets
Toilet bowls
Toilet bowl surfaces
Tubs (Fiberglass)
Tiles, glazed
Ultrasonic baths
Urinals
Walls
Whirlpool [bathtubs] [tubs] [units]

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
Ice Machines
Kitchen equipment
Refrigerator bins used for meat, fruit,
vegetables and eggs
Silverware
Slurpy Machines
Tupperware®

Non-critical medical device surfaces
[Medical] [Hospital] Beds
Bed frames
Bed rails
Crutches
Defibrillators
Gurneys
Non-critical [hospital] [medical] equipment
surfaces
[Medical] Examining tables
[Medical] [Hospital] Lamps
Rescue tools
Resuscitators
[Medical] [Hospital] Scales
Stands
Stretchers
Stethoscopes
Walkers
Wheel chairs

Other hard nonporous surfaces made of:
Formica®
Glazed ceramic
Glazed enameled surfaces
Glazed porcelain
Laminated surfaces
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.

Use Lonza Formulation S-21F

- 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-21F** may be applied through automatic washing systems, immersion tanks, foaming apparatus and low-pressure sprayers.

Lonza Formulation S-21F 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-21F** 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-21F** should be limited to areas where compost and mushrooms are not present.

LONZA FORMULATION S-21F is a sanitizer for hard nonporous non-food contact surfaces at 1:256 dilution (200 ppm active, 2 oz. per 4 gallons of water) according to the method for Sanitizers - Non-Food Contact Surfaces, modified in the presence of 500 ppm hard water plus 5% organic serum in 60 seconds against:

Klebsiella pneumoniae *Staphylococcus aureus*

LONZA FORMULATION S-21F eliminates 99.9% of *Staphylococcus aureus* and *Klebsiella pneumoniae* in 60 seconds.

LONZA FORMULATION S-21F is effective against Citrus Canker Disease (*Xanthomonas axonopodis* pv. *citri*) at 2000-ppm active quat.

LONZA FORMULATION S-21F is a mildewstat at 1:64 dilution (2 oz. per gallon) and will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard nonporous surfaces.

(Note to reviewer: only one of the two use-dilution ranges will be used on a container label)

LONZA FORMULATION S-21F is an effective sanitizer for use on pre-cleaned food contact surfaces at 2 oz. per 4 – 5 1/2 gallons of water (200 – 150 ppm active quat) (or) [2 oz. per 2 – 5 1/2 gallons of water (150 – 400 ppm active quat)] in waters up to 500 ppm hardness in 60 seconds against:

Campylobacter jejuni
Escherichia coli
Staphylococcus aureus

LONZA FORMULATION S-21F is an effective sanitizer for use on pre-cleaned food contact surfaces at [2 oz. per 4 gallons of water (200 active quat)] (or) [1 oz. per 1– 2 gallons of water (200 – 400 ppm active quat)] in waters up to 500 ppm hardness in 60 seconds against:

Campylobacter jejuni
Escherichia coli
ESBL *Escherichia coli* – (Extended spectrum beta-lactamase producing *E. coli*)
Shigella sonnei
Staphylococcus aureus
Vibrio cholerae
Yersinia enterocolitica

LONZA FORMULATION S-21F is an effective sanitizer for use on pre-cleaned food contact surfaces at [3/4 oz. per gallon of water (300 active quat)] (or) [1 oz. per 1 – 1 1/3 gallons of water (3/4 – 1 oz. per gallon of water) (400 – 300 ppm active quat)] in waters up to 500 ppm hardness in 60 seconds against:

Campylobacter jejuni
Escherichia coli
ESBL *Escherichia coli* – (Extended spectrum beta-lactamase producing *E. coli*)
Salmonella enterica
Shigella sonnei
Staphylococcus aureus
Vibrio cholerae
Yersinia enterocolitica

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 organisms which may be present on equipment and utensils after cleaning, and reduces the potential for the transfer, either directly through tableware such as glasses, cups and flatware or indirectly through food.

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

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

Articles that can be immersed in solution must remain in solution for 60 seconds.

Articles or surfaces too large for immersing must be thoroughly wetted or flooded by rinsing, spraying or swabbing.

Allow all sanitized surfaces to drain thoroughly (and air dry).

LONZA FORMULATION S-21F fulfills the criteria of Appendix F of the Grade "A" Pasteurized Milk Ordinance 1999 Recommendations of the U.S. Public Health Services in waters up to 500 ppm of hardness calculated as CaCO_3 when evaluated by the AOAC Germicidal and Detergent Sanitizer Method.

LONZA FORMULATION S-21F is effective against:

(Animal Viruses :)

Avian Infectious Bronchitis Virus
Avian Influenza Virus
Avian Influenza (H3N2)
Canine Distemper Virus
Feline Calicivirus
Newcastle's Disease Virus
Pseudorabies Virus

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

LONZA FORMULATION S-21F is a (one-step) (Hospital use) disinfectant at 1:64 dilution (2 oz. per gallon), Bactericidal according to the current AOAC Use-Dilution Test Method, Fungicidal according to the AOAC Fungicidal Test and Virucidal* according to the virucidal qualification modified in the presence of 400 ppm hard water plus 5% organic serum against:

(Bacteria:)

Pseudomonas aeruginosa (*Pseudomonas*)
Staphylococcus aureus (*Staph*)
Salmonella enterica (*Salmonella*)
Acinetobacter baumannii (*Acinetobacter*)
Brevibacterium ammoniagenes (*Brevibacterium*)
Campylobacter jejuni (*Campylobacter*)
Clostridium Difficile - vegetative
Enterobacter aerogenes
Enterococcus faecalis (*Enterococcus*)
Enterococcus faecalis - Vancomycin resistant (VRE)
Escherichia coli (*E. coli*)
ESBL *Escherichia coli* - (Extended spectrum beta-lactamase producing *E. coli*)
Klebsiella pneumoniae (*Klebsiella*)
Legionella pneumophila
Pseudomonas cepacia (*Pseudomonas*)
Salmonella schottmuelleri (*Salmonella*)
Salmonella typhi (*Salmonella*)
Serratia marcescens
Shigella dysenteriae (*Shigella*)
Staphylococcus aureus Methicillin-Resistant (MRSA)
Staphylococcus aureus Multi-Drug Resistant
Staphylococcus aureus - Vancomycin Intermediate Resistant - (VISA)
Streptococcus pyogenes (*Strep*) [a cause of scarlet fever]
Vibrio cholerae

(Viruses:)

*Adenovirus Type 5 (Adenovirus) at 1:16 dilution
(8 oz. per gallon of water)
*Adenovirus Type 7 (Adenovirus) at 1:16 dilution
(8 oz. per gallon of water)
*Hepatitis B Virus (HBV)
*Hepatitis C Virus (HCV)
*Herpes Simplex Virus Type 1 (Herpes)
*Herpes Simplex Virus Type 2 (Herpes)
*HIV-1 (the AIDS Virus)
*Human Coronavirus
*Influenza Type A / Brazil (Influenza)
*Norwalk Virus [Norovirus]
*Respiratory Syncytial Virus [RSV]
*SARS Associated Coronavirus [SARS] [cause of Severe Acute Respiratory Syndrome]
*Vaccinia [Pox Virus]

(Fungi:)

Trichophyton mentagrophytes (the Athlete's Foot Fungus)
(A cause of Ringworm)
(A cause of Ringworm of the foot)
Aspergillus niger

Dilution:

| | |
|---------------------|------------------------------------|
| Disinfection (1:64) | 2 oz. per gallon of water |
| Disinfection (1:16) | 8 oz. per gallon of water |
| Sanitizer (1:175) | 4 oz. per 4 gallons of water |
| | (2 oz. per 2 gallons of water) |
| | (1 oz. per gallon of water) |
| | (400 ppm active) |
| Sanitizer (1:171) | 3 oz. per 4 gallons of water |
| | (1 oz. per 1 1/3 gallons of water) |
| | (3/4 oz. per gallon of water) |
| | (300 ppm active) |
| Sanitizer (1:138) | 2 oz. per 4 gallons of water |
| | (1 oz. per 2 gallons of water) |
| | (1/2 oz. per gallon of water) |
| | (200 ppm active) |
| Sanitizer (1:352) | 2 oz. per 5 1/2 gallons of water |
| | (1 oz. per 2 3/4 gallons of water) |
| | (3/8 oz. per gallon of water) |
| | (150 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 Disinfectant Use-Solution:

Add (mix) 2 oz. per gallon of water (1:64).

For heavy duty use, add (mix) 8 oz. per gallon of water (1:16).

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

Apply use-solution to hard, nonporous surfaces, thoroughly wetting the 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.

For sprayer applications, use a coarse spray device. Spray 6 - 8 inches from surface; rub with brush, sponge or cloth. Avoid breathing spray.

For fungicidal activity, Lonza Formulation S-21F is an effective fungicide against Trichophyton mentagrophytes (the athlete's foot fungus) in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities.

Lonza Formulation S-21F is a one-step fungicide at 2 oz. per gallon in 250 ppm hard water and 5% serum.

At 2 oz. per gallon in 400 ppm hard water, Lonza Formulation S-21F must be used on precleaned surfaces.

For mold and mildew At 2 oz. per gallon, **LONZA FORMULATION S-21F** will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, nonporous surfaces. Follow disinfection instructions. Repeat treatment every seven days, or more often if new growth appears.

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.

(Note to reviewer: E OF the following two statements will be used:)

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

(or)

BACTERICIDAL STABILITY OF USE-DILUTION: Tests confirm that Lonza Formulation S-21F, when diluted in [water up to 400 ppm of hardness] [soft water] [via use of automatic dispensing devices], remains effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella enterica* for [up to 7 days] [[up to one week] [for up to one month] [up to 2 months] [up to 3 months] [to 4 months] [to 5 months] [up to 6 months] [up to 7 months] [up to 8 months] [up to 9 months] [up to 10 months] [up to 11 months] [up to 12 months] [up to one year] [up to two years] when stored in a sealed container such as a spray bottle. If product becomes visibly dirty or contaminated, the use-dilution must be discarded and fresh product prepared. Always use clean, properly labeled containers when diluting this product. Bactericidal stability of the use-dilution does not apply to open containers such as buckets or pails.

(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. (optional language:) 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 2 oz. per gallon of water to clean and deodorize surfaces. Apply using a cloth, mop, sponge or sprayer. Wipe or allow to air dry.

NON-ACID TOILET BOWL (AND) (URINAL) DISINFECTANT / CLEANER DIRECTIONS:

Remove gross filth prior to disinfection.

From Concentrate:

Add 2 oz. to the bowl. Thoroughly brush or swab over exposed surfaces and 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 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-21F** at 2 oz. per gallon. Apply with a damp mop or autoscrubber. Allow surface to remain wet for 10 minutes. Wipe or allow to air dry. Do not use on floor finish at 8 oz. per gallon.

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

Mix 4 oz. (120 mL) of LONZA FORMULATION S-21F per gallon of water (1 oz. [30 mL] of Lonza Formulation S-21F per quart of water) to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, razors, scissors, blades, rollers, manicure and other salon instruments and tools for 10 minutes. Use 8 oz per gallon of water to kill Adenovirus Type 5 and type 7. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Fresh solution should be prepared 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 [/ VIRUCIDAL*]
DIRECTIONS:**

Use LONZA FORMULATION S-21F to disinfect hard nonporous non-critical objects compatible with Ultrasonic cleaning units.

Pour fresh use-solution of 2 oz. of Lonza Formulation S-21F per gallon of water directly into bath chamber. Use 8 oz per gallon of water to kill Adenovirus Type 5 and type 7. Pre-clean heavily soiled objects. Place objects into unit and operate for a minimum of 10 minutes, according to the manufacturer's directions.

Remove objects and wash with sterile water (sterile water for injection) or allow to air dry. Prepare fresh solution for each use.

DISINFECTION OF [WHIRLPOOL (BATH(S) (UNITS)) [FOOT SPAS]:

After using the [whirlpool (bath) (unit)] [foot spa], drain and refill with fresh water to (just cover the intake valve) (cover the highest jet) (2 inches above the highest jet). Add 2 oz. of Lonza Formulation S-21 for each gallon of fresh water added. Start the pump to circulate the solution. Wash down [the (deck) (seat of chair lift) (any related equipment)] any uncovered surfaces on the (bath) (unit) (foot spa) with a clean swab, brush or sponge with the solution. Treated surfaces must remain wet for 10 minutes. Use 8 oz per gallon of water to kill Adenovirus Type 5 and type 7.

After the (bath) (unit) (foot spa) has been thoroughly disinfected, drain and rinse surfaces with fresh water. Wipe dry with a clean sponge or cloth or allow to air dry. Repeat for heavily soiled units.

SANITIZATION OF WHIRLPOOL (BATH(S) (UNITS):

After using the whirlpool (bath) (unit), drain and refill with fresh water to (just cover the intake valve) (cover the highest jet) (2 inches above the highest jet). Add 2 ounce of Lonza Formulation S-21F for each 2 - 4 gallons of fresh water added. Start the pump to circulate the solution. Wash down the [(deck) (seat of chair lift) (any related equipment) and] any uncovered surfaces on the (bath) (unit) with a clean swab, brush or sponge with the solution. Treated surfaces must remain wet for at least 60 seconds. Drain bath and wipe dry with a clean sponge or cloth or allow to air dry.

***KILLS HIV AND HBV AND HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS** in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces / objects with blood or body fluids, and in which the surfaces / objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS) or Hepatitis B Virus (HBV) or Hepatitis C Virus (HCV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OR HBV OR HCV ON SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS:

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

CLEANING PROCEDURE: Blood and other body fluids containing HIV-1 or HBV or HCV must be thoroughly cleaned from surfaces and objects before application of LONZA FORMULATION S-21F.

CONTACT TIME: Leave surface wet for 1 minute (60 seconds) for HIV-1 and 10 minutes for HBV and HCV with a 2 oz. per gallon use-solution. Use 8 oz per gallon of water to kill Adenovirus Type 5 and type 7. Use a 10-minute contact time for disinfection against all other viruses, bacteria and fungi claimed.

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.

TO SANITIZE NON-FOOD CONTACT SURFACES:

Add (mix) 2 oz. of Lonza formulation S-21F per 4 gallons of water (1/2 oz. of Lonza Formulation S-21F per gallon of water) to sanitize hard nonporous surfaces. Treated surfaces must remain wet for 60 seconds. Wipe dry with a sponge, mop or cloth or allow to air dry.

(Note to reviewer: If this product is to be used as a sanitizer solely on non-food contact surfaces, the following statement must be included:)

Do not use in food preparation, food handling and food storage areas. This product is not to be used on glassware, dishware, cookware or utensils.

TO SANITIZE BARBER / SALON INSTRUMENTS AND TOOLS:

Immerse precleaned barber / salon instruments and tools (such as combs, brushes, razors, scissors, blades, rollers and manicure instruments) in a use-solution of 2 oz. of Lonza Formulation S-21F per 4 gallons 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.

LONZA FORMULATION S-21F is effective against:

(Animal Viruses:)

Avian Infectious Bronchitis Virus

Canine Distemper Virus

Feline Calicivirus

Newcastle's Disease Virus

Pseudorabies Virus

["SPECIAL INSTRUCTIONS FOR INACTIVATING AVIAN INFLUENZA A" AND OTHER ANIMAL VIRUSES LISTED ON THIS LABEL]

[VETERINARY], [ANIMAL CARE] and [ANIMAL LABORATORY] FACILITIES/ [ZOOS] / [PET SHOPS] / [KENNELS] AND [FARM PREMISE] DISINFECTION / [VIRUCIDAL] DIRECTIONS:

For cleaning and disinfecting hard nonporous surfaces: equipment used for feeding or watering animals, utensils, instruments, cages, kennels, stables, catteries pens, stalls and etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, pens, stalls and 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 2 oz. of **LONZA FORMULATION S-21F** per gallon of water [or equivalent dilution] for a period of 10 minutes. Use 8 oz per gallon of water to kill Adenovirus Type 5 and type 7. Wipe or allow to air dry. Immerse all animal handling and restraining equipment as well as forks, shovels, and scrapers used to remove litter and manure. Thoroughly scrub all treated surfaces, then rinse all surfaces that come in contact with food, including equipment used for feeding or watering, with potable water before reuse. Ventilate buildings, animal enclosures, [vehicles] and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

VETERINARY PRACTICE / ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP / KENNELS DISINFECTION [VIRUCIDAL*] 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 2 oz. of **LONZA FORMULATION S-21F** per gallon of water (or equivalent dilution) for a period of 10 minutes. Use 8 oz per gallon of water to kill Adenovirus Type 5 and type 7. 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 2 oz. of **LONZA FORMULATION S-21F** per gallon of water (or equivalent dilution) for a period of 10 minutes. Use 8 oz per gallon of water to kill Adenovirus Type 5 and type 7. 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

[VIRUCIDAL*] 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 2 oz. of **LONZA FORMULATION S-21F** per gallon of water. Saturate surfaces with the recommended disinfecting solution for 10 minutes. Use 8 oz per gallon of water to kill Adenovirus Type 5 and type 7. Immerse all halters, ropes and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings, cars, trucks, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

Hatcheries: Use 2 oz. of **LONZA FORMULATION S-21F** per gallon of water to treat the following hard nonporous surfaces: hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces wet for 10 minutes or more. Wipe dry with a clean cloth or sponge or allow to air dry.

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**FOGGING DEVICE HATCHERY M SANITIZER / FOGGING
DEVICE INCUBATOR AND HATCHER SANITIZER
DIRECTIONS:**

Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of the room to be treated. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Close room off so fog is confined to room to be treated.

[For Hatchery Room: Mix two parts of product to one part water (2 gallons to 1 gallon of water). Insert nozzle of fogger through suitable opening to room. With the setting in maximum output, for one minute for each 4000 cubic feet of space in the room.]

[For Incubator and Hatcher: Mix 24 oz per 104 oz of water. Fog 3-8 oz into setters and hatchers immediately after transfer. Repeat daily in setters and every 12 hours in hatchers. Discontinue hatchers treatment at least 24 hours prior to pulling the hatch. It is acceptable to fog setters and hatchers with 2 oz per gallon on an hourly or every other hourly basis. If this solution is used, fog for 30-90 seconds once per hour or once every 2 hours.]

When fogging is completed, ventilate buildings, and other closed spaces. Do not allow people to contact or breathe this fog. Do not house livestock or employ equipment until treatment has been absorbed or dried. Vacate the area of all personnel for a minimum of 2 hours. Thoroughly scrub all treated feed racks, mangers, troughs, and rinse with potable water before reuse.

**FOGGING IS TO BE USED AS AN ADJUNCT TO
ACCEPTABLE MANUAL CLEANING AND DISINFECTING
FOR ROOM AND MACHINE SURFACES.**

Vehicles: Treat all vehicles including mats, crates, cabs and wheels with water and LONZA FORMULATION S-21F. Use 2 oz. of LONZA FORMULATION S-21F per gallon of water to treat all vehicles. Use 8 oz per gallon of water to kill Adenovirus Type 5 and type 7. Leave all treated surfaces wet for 10 minutes or more. Wipe dry with a clean cloth or sponge 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 should be placed at all entrances to buildings and hatcheries. Scrape waterproof work boots and place in a 2 oz. per 4 gallons 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.

SHOE FOAM SANITIZER DIRECTIONS:

To prevent cross contamination into animal areas and the packaging and storage areas of food plants. Apply a foam layer approximately 1/2 to 2 inches thick made from a solution of 2 oz. of LONZA FORMULATION S-21F per 2 - 5 1/2 gallons of water (400 - 150 ppm active quat) (or equivalent dilution), at all entrances to buildings, hatcheries, production and packaging rooms by using a foam generating machine or aerator to apply the foam layer. Follow the foaming directions as specified by the manufacturer of the foam generator or aerator. Scrape waterproof work boots (shoes). Stand or walk through foamed area for 60 seconds prior to entering area. Wash and replace Foam Area at least daily or more often if the Foam Area 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 2 oz. of Lonza Formulation S-21F per gallon of water solution. 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 2 oz. of Lonza Formulation S-21F 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 8 oz. of Lonza Formulation S-21F 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.

CITRUS CANCER DISEASE CONTROL:

For prevention of Citrus Canker Disease through treatment of precleaned equipment. Effective against *Xanthomonas axonopodis* pv. *citri* (Citrus Canker Disease) at 2000 ppm active quat. Treatments can be applied to trucks, attached trailers, field harvesting equipment including cargo area, wheels, tires, undercarriage, hood, roof, fenders, and any other hard nonporous part of the equipment that can be taken into infested areas.

Thoroughly clean all surfaces with soap or detergent and rinse with water. Then saturate surfaces with a 1:27.5 use-dilution (4 3/4 oz. of Lonza Formulation S-21F per gallon of water or 19 oz. of Lonza Formulation S-21F per 4 gallons of water) (or equivalent dilution) (2000 ppm active quat) for a period of 10 minutes. Allow to air dry. All surfaces that come in contact with food or crop must be rinsed with potable water before reuse. To prevent the spread of Citrus Canker Disease by this artificial means of transportation, treatments are made by trigger spraying, dipping or brushing. Clothing must be either rinsed or laundered before reuse. Footwear must be rinsed before reuse.

Lonza Formulation S-21F is effective at eliminating odors on porous surfaces such as upholstery, drapes, carpets, bedding, shower curtains, mattresses and non-porous surfaces such as walls and floors. Excellent for fire restoration.

Other suggested Uses: Homes, Veterinary Clinics, Fish Markets, Kennels, Trash Compactors, Offices, Beauty Salons, Locker Rooms, Health Spas, Conference rooms, Elevators, Smoking Areas, Lounges, Day Care Centers, Dry Cleaners, Theaters, Fairs, Auditoriums and Churches.

Deodorizing directions:

Nursing Homes, Hospitals, Hotels, Schools, Restaurants: 2 - 4 oz. in chemical toilets, waste receptacles, bed pans, drainage bottles, diaper pails, hampers, disposals, commodes and air conditioner pans will eliminate odors.

Mopping Solutions, Automatic Scrubbers: 2 - 4 oz. per gallon of cleaning solution eliminates undesirable odors.

Laundry: 2 oz. per load added during the final rinse cycle deodorizes all offensive odors.

Air Freshener/Automotive Uses: 8 ounces per gallon of water or desired concentration will effectively neutralize damp musty odors caused by mildew in storage areas, basements, closets and bathrooms. Effective on smoking and cooking odors (garlic, fish, onions, etc.). Automobile odors from tobacco, musty carpet smell and beverage smells will be eliminated.

Carpets: 2 - 4 oz. per gallon of shampoo solution eliminates odors associated with urine, vomit, smoke, and mildew. Reapply after cleaning for freshening effects. Allow to dry.

RV Holding Tanks: Toilet waste: cover bottom of holding tank with water and add 2 - 4 oz. If odors return before time to empty, simply add 2 - 4 oz. to the tank. Kitchen waste: 2 - 4 oz. of Lonza Formulation S-21F to gray water tank as needed to control malodors created by dirty dish water.

Pet Odors: Use 8 - 12 oz. per gallon of water or desired concentration, for urine, feces, and vomit, in carpet and upholstery. Clean prior to application then spray onto affected areas. Test hidden area for colorfastness. Allow 10 minutes contact time. Then blot with clean cloth. Allow to dry. Also effective on pet bedding and litter boxes.

Sewage Back Water Damage: 2 - 4 oz. per gallon of water or desired concentration. Spray over affected areas before and after cleaning and extraction. Allow ten minutes contact time. Use proper ventilation; open windows.

Cleaning Solution: Dilute 2 - 4 oz. per gallon of water for cleaning of kitchen counters, tables, walls, bathrooms, toilet seats, mopping floors and large routine applications.

WATER DAMAGE RESTORATION AGAINST ODOR-CAUSING BACTERIA AND FUNGI FOR HOME, INSTITUTIONAL, INDUSTRIAL AND HOSPITAL USE:

This product is particularly suitable for use in water damage restoration situations against odor causing bacteria on the following porous and semi-porous materials: carpets, carpet cushions, subfloors, drywall, concrete, brick, trim and frame lumber, tackless strip and paneling. Using appropriate dilution, saturate the affected materials with enough product to remain wet for at least 10 minutes.

Sewer Backup and River Flooding: During mitigation procedures, dilute 2 - 4 oz. of the concentrate per gallon of water, allowing for the diluting effect of absorbed water within saturated materials. Remove gross filth or heavy soil along with non-salvageable materials. Saturate all affected areas with a coarse spray device before and after cleaning and extraction.

Carpets, Carpet Cushions and Other Porous Materials such as Subfloors, Drywall, Concrete, Brick, Trim and Frame Lumber, Tackless Strip and Paneling: For water damage from a clean source, extract excess water. Test hidden area for colorfastness. Dilute 2 - 4 oz. of the concentrate per gallon of water, allowing for the diluting effect of absorbed water within saturated materials. Remove gross filth or heavy soil. Saturate all affected areas with a coarse spray device. Roll, brush or agitate into the materials and allow materials to remain wet for 10 minutes. Follow with a thorough extraction. Dry rapidly and thoroughly.

Special instructions For Cleaning Carpet Against Odor Causing Bacteria: Use this product in industrial and institutional areas such as homes, motels, hotels, nursing homes, schools, and hospitals. Use on wet-cleanable synthetic fibers. Do not use on wool. Vacuum carpet thoroughly prior to cleaning. Test fabric for colorfastness. **For portable extraction units:** Mix 2 oz. of concentrate per gallon of water. **For truck mounted extraction machines:** Mix 2 - 4 oz. of concentrate per gallon of water and meter at 4 gallons per hour. **For rotary floor machines:** Mix 2 oz. of concentrate per gallon of water and apply at the rate of 300 - 500 sq. ft. per gallon. Do not mix this product with other cleaning products. Follow the cleaning procedures specified by the manufacturer of the cleaning equipment. After using the product, set the carpet pile and protect the carpet from furniture legs and bases while drying. Do not over-wet. If applied to stain resistant nylon carpet, apply a fabric protector according to the manufacturer's directions.

(Note to reviewer. On a final printed label, only one of the following dilution rates will be used in the sanitization sections below)

For Food Contact Surfaces, Food Processing Equipment and Utensils in Dairies and Public Eating Establishments (40 CFR 180.940 (a)) and For Food Contact Surfaces, Food Processing Equipment and Utensils in Food Processing Plants (40 CFR 180.940 (c)):

2 oz. Lonza Formulation S-21F per 5 1/2 gallons of water (150 ppm active quat) (or equivalent dilution)

(or)

2 oz. Lonza Formulation S-21F per 4 gallons of water (200 ppm active quat) (or equivalent dilution)

(or)

3 oz. Lonza Formulation S-21F per 4 gallons of water (300 ppm active quat) (or equivalent dilution)

(or)

4 oz. Lonza Formulation S-21F per 4 gallons of water (400 ppm active quat) (or equivalent dilution)

(or)

2 oz. Lonza Formulation S-21F per 4 - 5 1/2 gallons of water (150-200 ppm active quat) (or equivalent dilution)

(or)

1 oz. Lonza Formulation S-21F per 1 1/3 - 2 3/4 gallons of water (150-300 ppm active quat) (or equivalent dilution)

(or)

1 oz. Lonza Formulation S-21F per 1 - 2 3/4 gallons of water (150-400 ppm active quat) (or equivalent dilution)

(or)

1 oz. Lonza Formulation S-21F per 1 1/3 - 2 gallons of water (200-300 ppm active quat) (or equivalent dilution)

(or)

1 oz. Lonza Formulation S-21F per 1 - 1 1/3 gallons of water (200-400 ppm active quat) (or equivalent dilution)

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-21F 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 *[insert appropriate dilution here]* (or equivalent dilution) 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 or 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 *[insert appropriate dilution here]* (or equivalent dilution).
3. Allow solution to remain in equipment for at least 60 seconds.
4. Drain thoroughly before reuse and allow to air dry.

TO SANITIZE ICE MACHINES:

1. Turn off refrigeration
2. Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing.
3. Apply a solution of *[insert appropriate dilution here]* (or equivalent dilution) y mechanical spray, directly pouring, or by recirculating through the system.
4. Allow surfaces to remain wet or solution to remain in equipment for at least 60 seconds.
5. 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 *[insert appropriate dilution here]* (or equivalent dilution) 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 *[insert appropriate dilution here]* (or equivalent dilution) 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 *[insert appropriate dilution here]* (or equivalent dilution). 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-21F 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 *[insert appropriate dilution here]* (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 *[insert appropriate dilution here]* (or equivalent dilution) by rinsing, spraying or swabbing until thoroughly wet.
5. Allow sanitized surface to drain and air dry. Do not rinse.

WISCONSIN STATE BOARD OF HEALTH DIRECTIONS FOR EATING ESTABLISHMENTS

1. Scrape and pre-wash utensils and glasses whenever possible.
2. Wash with a good detergent or compatible cleaner.
3. Rinse with clean water.
4. Sanitize in a use-solution of *[insert appropriate dilution here]* (or equivalent dilution). Immerse all utensils for at least two minutes or for contact time specified by governing sanitary code.
5. Place sanitized utensils on a rack or drain board to air-dry

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 *[insert appropriate dilution here]* (or equivalent dilution).
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.

FOR DISINFECTION

Note to reviewer: the following will be used for 1/2 oz of concentrate:
MIX EACH PACKET WITH [1 QUART] OF WATER

Note to reviewer: the following will be used for 4 oz of concentrate:
MIX EACH PACKET WITH [2 GALLONS] OF WATER

Note to reviewer: the following will be used for 8 oz of concentrate:
MIX EACH PACKET WITH [4 GALLONS] OF WATER

Note to reviewer: the following will be used for 16 oz of concentrate:
MIX EACH PACKET WITH [8 GALLONS] OF WATER

LONZA FORMULATION S-21F

EPA. Reg. No. 6836-140
EPA. Est. No. (insert EPA Est. No. here)
Net Contents:

Active Ingredients:

| | |
|---|---------|
| Octyl decyl dimethyl ammonium chloride..... | 1.65% |
| Dioctyl dimethyl ammonium chloride | 0.66% |
| Didecyl dimethyl ammonium chloride | 0.99% |
| Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride..... | 2.20% |
| Other Ingredients: | 94.50% |
| Total: | 100.00% |

KEEP OUT OF REACH OF CHILDREN

DANGER

See outer container for Precautionary Statements and Use directions

Disposal: Do not reuse packet. Wrap and put in trash.

Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

[IF OTHER PACKET SIZES ARE DESIRED, NEW PACKET LABEL WILL BE IDENTICAL AND THE ONLY THINGS THAT WILL VARY ARE THE NET CONTENTS, AMOUNT OF WATER TO DILUTE WITH AND PPM ACTIVE QUAT. THOSE 3 ITEMS WILL HAVE TO MATCH OR BE EQUIVALENT TO THE DILUTION CHART THAT IS SHOWN ON PAGE 6.]