

6836-75

7/6/2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 6 2004

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

Subject: Lonza Formulation S-21
EPA Registration No. 6836-75
Amendment Date: January 6, 2004
EPA Receipt Date: January 8, 2004

Dear Mr. Sloan,

The amendment submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable with the conditions below.

- Addition of Bacterial Stability Claim
- Addition of Organisms

Conditions

Revise the label as follows:

1. Page 3: Specify that the picnic tables and Outdoor (patio) furniture are hard nonporous surfaces by stating *Non-wooden picnic tables and "Outdoor (patio) furniture except cushions and wood frames.*
2. Page 4: Since Ringworm is caused by several different fungi, revise the claim to read as *"Trichopyton mentagrophytes (A cause of ringworm) or (A cause of ringworm of the foot).*
3. Page 5: Delete the Bacterial Stability of Use-Dilution directions. (Refer to acceptable data section)
4. Page 7: Revise the "Fogging Device Hatchery Room Sanitizer" and "Fogging Device Incubator and Hatcher Sanitizer" directions are incomplete. It would seem they needed to merged for completeness. It must read as follows:

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,

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racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap and detergent and rinse with water. Close room off so fog is confined to room to be treated.

[For Hatchery Room: Mix four parts of product to three parts water (2 gallons to 1.5 gallons 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. Do not enter until fog has settled approx. 30-60 minutes after fogging is completed. Thoroughly scrub all treated feed racks, mangers, troughs, and rinse with potable water before reuse.

Note: Text is acceptable as presented.

- 5. Page 9: Revise the "Shoe Foam Directions" heading to read "Shoe Foam Sanitizer Directions." Also, revise the phrase, "to prevent tracking of harmful bacteria into animal areas" to state "to prevent cross contamination into animal areas..."
- 6. Typographical Errors
 - Page 8: Under Citrus Canker Disease Control," revise phrase "though treatment" to read "through treatment."

Acceptable Data

Data Requirement	Means of Support	Status
Virucidal Effectiveness Test - Human Coronavirus	Submitted study, MRID 460507-04	Acceptable
AOAC Use Dilution Method - Legionella pneumophila	Submitted study, MRID 460507-06	Acceptable
Bacterial Stability Use-Dilution Testing - P. aeruginosa	Submitted study, MRID 460507-07	Unacceptable
Bacterial Stability Use-Dilution Testing - S. aureus	Submitted study, MRID 460507-08	Unacceptable
Bacterial Stability Use-Dilution Testing- S. choleraesuis	Submitted study, MRID 460507-09	Unacceptable

The Bacterial Stability data in MRID Nos. 460507-07 thru 460507-09 is unacceptable because the data does not reflect testing conducted with 400 ppm hard water tolerance level since

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the product tested was a ready-to-use formulation. You will need to submit additional information about how the tested product was prepared before this data is accepted

General Comments

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

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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

Sincerely



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

Enclosure: Stamped Label
Efficacy Data Evaluation

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**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), protective (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 trandicate 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:
JUL 6 2004**

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 6836-75**

LONZA FORMULATION S-21

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

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

For use in federally inspected meat and poultry plants

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

Active Ingredients:

Octyl decyl dimethyl ammonium chloride	1.65%
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%

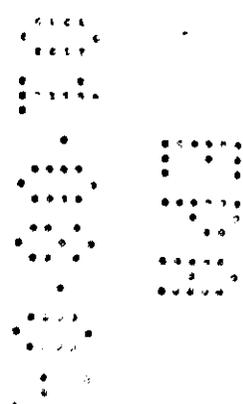
KEEP OUT OF REACH OF CHILDREN

DANGER (PELIGRO)

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

EPA Reg. No. 6836-75
EPA Est. No. (insert EPA Establishment No. here)
Net Contents (insert container size here)

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



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-21:

- 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 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).
- 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.

Cross-contamination is of major housekeeping concern. **Lonza FORMULATION S-21** 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-21

- in federally inspected Meat & Poultry Plants as a disinfectant or non-food contact sanitizer on all surfaces in inedible product processing areas, nonprocessing areas and / or exterior areas. This product was authorized by USDA as category D1 under the prior authorization program and its formula has not been changed.
- 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.

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

(AREAS OF USE:)

Use **Lonza Formulation S-21** in:

- Bathrooms
- Homes (households)
- Kitchens

- Dental offices
- Hospitals
- Medical Offices
- Nursing homes

- Day care centers
- Nurseries

- Bars
- Cafeterias
- Convenience stores
- Food processing plants
- 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)

- Camp grounds
- Play ground equipment

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

- Airplanes
- Boats
- Buses
- Campers
- Cars
- Emergency vehicles
- Mobile homes
- Ships
- Taxis
- Trailers
- Trains
- Transportation terminals

(TYPES OF SURFACES:)

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

- Appliances, exteriors
- 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
- Floors
- Foot Spas
- Garbage cans
- Highchairs
- Kennel runs
- Microwave ovens, exteriors
- Outdoor furniture
- Refrigerators, exteriors
- Refrigerated storage and display equipment
- Showers
- Shower stalls
- (Fiberglass) Shower stalls
- (Fiberglass) Sinks (bathroom, kitchen)
- Sinks (bathroom, kitchen)
- Stoves (stovetops)

- Tables, (picnic tables)
- Telephones
- Toilets
- Toilet bowls
- Toilet bowl surfaces
- Tubs (Fiberglass)
- Tiles, glazed
- Ultrasonic baths
- Urinals
- Walls
- Whirlpool bathtubs

- 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.

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

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

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

LONZA FORMULATION S-21 is effective against:

- Avian Infectious Bronchitis Virus
- Avian Influenza Virus
- Canine Distemper Virus
- Newcastle's Disease Virus
- Pseudorabies Virus

LONZA FORMULATION S-21 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.

LONZA FORMULATION S-21 is a (one-step) (Hospital use) disinfectant at 1:64 dilution (2 oz. per gallon of water), 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 choleraesuis (Salmonella)

- Acinetobacter baumannii (Acinetobacter)
- Brevibacterium ammoniagenes (Brevibacterium)
- Campylobacter jejuni (Campylobacter)
- 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)
- Vibrio cholerae

(Viruses:)

- *Adenovirus Type 5 (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)
- *Respiratory Syncytial Virus (RSV)
- *Vaccinia (Pox Virus)

(Animal Viruses:)

- Avian Influenza virus
- Avian Infectious Bronchitis Virus
- Canine Distemper Virus
- Newcastle's Disease Virus
- Pseudorabies Virus

(Fungi:)

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

Dilution:

Disinfection (1:64) 2 oz. per gallon of water
Sanitizer (1:256) 2 oz. per 4 gallons of water
.....(200 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-21 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-21 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-21 must be used on precleaned surfaces.

For mold and mildew 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.

(Note to reviewer: Only one of the following two statements will be used. Supplemental registrants will pick only one time frame for their label up to one year.)

BACTERICIDAL STABILITY OF USE-DILUTION: Tests confirm that the use solution of Lonza Formulation S-21 remains effective against Pseudomonas aeruginosa, Staphylococcus aureus and Salmonella choleraesuis for (up to 7 days) (up to one week) (up to one month) (up to 2 months) (up to 3 months) (up to 4 months) (up 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) 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.

(or)

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

(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 preclean 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-21** 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.

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

Mix 4 oz. (120 mL) of **LONZA FORMULATION S-21** per gallon of water (1 oz. [30 mL] of **Lonza Formulation S-21** per quart of water) 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. 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 DIRECTIONS:

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

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

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

DISINFECTION OF [WHIRLPOOL (BATH(S) (UNITS)) [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. After use (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)) [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 ounces of **Lonza Formulation S-21** 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) (foot spa) 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-21**.

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 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-21** per 4 gallons of water (1/2 oz. of **Lonza Formulation S-21** 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.

TO SANITIZE BARBER / SALON INSTRUMENTS AND TOOLS:

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

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 2 oz. of LONZA FORMULATION S-21 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.

RM 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-21 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.

BROODERY 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 2 oz. of LONZA FORMULATION S-21 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 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-21 per gallon of water to treat the following hard nonporous surfaces: hatches, 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.

FOGGING DEVICE HATCHERY ROOM 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. Use LONZA FORMULATION S-21 undiluted. Insert the nozzle of the fogger through a suitable opening into the room. With the setting in maximum output, for one minute for each 4000 cubic feet of space in the room. Do not allow people to contact or breathe this fog and do not enter until the fog has settled (30 - 60 minutes after fogging is completed).

FOGGING DEVICE INCUBATOR AND HATCHER SANITIZER DIRECTIONS:

Mix 48 ounces LONZA FORMULATION S-21 to 80 ounces water (or equivalent dilution). Fog 3 - 8 ounces of this into setters and hatchers immediately after transfer. Repeat daily in setters and every 12 hours in hatchers. Discontinue hatchers treatments at least 24 hours prior to pulling the hatch. It is acceptable to fog setters and hatchers with a 4 ounce per gallon (or equivalent dilution) solution of LONZA FORMULATION S-21 on an hourly or every other hour basis. If this is done, fog for 30 - 90 seconds once per hour or once every two hours. When fogging is completed, ventilate buildings, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed 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. Do not allow people to contact or breathe this fog and do not enter until the fog has settled (30 - 60 minutes after fogging is completed).

NOTE: The fog generated is irritating to the eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has settled (30-60 minutes after fogging is completed). If the building must be entered, then the individuals entering the building must wear a self contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long pants.

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-21. Use 2 oz. of LONZA FORMULATION S-21 per gallon of water to treat all vehicles. 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 tracking harmful organisms into animal areas, shoe baths containing one inch of freshly made solution should be placed at all entrances to buildings and hatcheries. Scrape waterproof work boots and place in a 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 DIRECTIONS:

To prevent tracking harmful organisms 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-21** 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-21 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-21** per gallon of water (or equivalent dilution). Apply use solution with a cloth, mop, sponge, sprayer or by immersion to thoroughly wet the surfaces. Treated surfaces should be allowed to remain wet for 10 minutes. Wipe or allow to air dry. For heavily soiled areas, preclean first. Prepare 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-21** 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 CANKER 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-21 per gallon of water) (19 oz. of Lonza Formulation S-21 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 should be either rinsed or laundered before reuse. Footwear should be rinsed 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 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 USE WITH BOWL CLEANING TOOL:

Specially formulated for daily and light cleaning of toilet bowls and urinals. Dispensed from the Bowl Cleaning Tool, this 8 ounce container cleans more toilets than a full quart of regular bowl cleaner.

Concentrated - Cleans up to 37 toilets.

Cost Efficient - Metered dispensing combined with concentrated cleaner.

Disinfectant - Broad-spectrum antimicrobial agent or disinfectant for use on inanimate hard surfaces.

Deodorizer - Deodorizes as it disinfects by controlling malodors produced by microorganisms found in such areas as urinals and toilet bowls.

This product has been designed specifically for hospitals, nursing homes, schools, and other institutions where housekeeping is of prime importance. It deodorizes as it cleans by killing microorganisms in urinals and toilet bowls. Efficacy tests have demonstrated that this product, when used as directed, is a proven "one step" bactericide and virucide in water up to 400 ppm hardness in the presence of organic soil (5% blood serum). Gross and heavy soil must be removed prior to application of the product. This product is recommended for use on hard nonporous surfaces (toilet bowls and urinals) and is to be dispensed only out of the Cleaning Tool.

To Disinfect, Deodorize and Clean:

1. REMOVE WATER
Force water into the bowl or urinal trap with the Bowl cleaning Head.
2. APPLY CLEANER:
Prior to application of the product, remove gross filth and heavy soil. Slide Trigger Stop to the "ON" position. Squirt concentrated bowl cleaner under and around the rim a minimum of 3 squirts to thoroughly wet exposed surfaces for toilet bowls and urinals.
3. CLEAN:
Wipe all surfaces with the swab portion of the head so as to wet thoroughly. Scour with the scrub pad under the flush ring to remove stubborn stains.
WAIT:
Allow to remain wet for 10 minutes. Flush. Rinse cleaning head in flush water. Drain head and shake off excess water. Repeat cleaning if necessary.
5. LOCK / STORE
Slide the Trigger Stop to the "LOCK" position.

