## 11/07/2006 6836-75

## UNITED STATES ENVIRONMENTAL PROTECTION AGENC

Mr. Robert Sloan Lonza, Inc. 90 Boroline Road Allendale, NJ 07401

NOV 7 2006

Subject:

Lonza Formulation S-21

EPA Registration No.: 6836-75 Amendment Date: April 21, 2006 EPA Receipt Date: May 11, 2006

Dear Mr. Sloan,

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

Addition of organism, directions, and marketing claims

## Conditions

Revise the label as follows:

- 1) Revise the statement in the last paragraph in the right panel on page 2 so that it is in agreement with PR Notice 2000-5, Mandatory Language, by stating "Caution: Cleaning at 120oF temperature ... necessitate replacement.
- 2) Revise the last statement in the 1<sup>st</sup> paragraph in the left panel on page 5 so that it is in agreement with PR Notice 2000-5, Mandatory Language, by stating "Lonza Formulation S-21 must be limited to areas where compost and mushrooms are not present."
- 3) Revise the list of animal viruses claimed in the right column on page five by deleting "Avian Influenza Virus," because data was not formally submitted to support this organism. Due to recent public health issues surrounding Avian Influenza Virus or Bird Flu, the Agency is requiring data to be submitted to support this virus.
- 4) Delete "Foot spas" from the "Sanitization of Whirlpool Units/Baths" heading on page 7. The Agency is concerned that the reduced contact time is not sufficient to mitigate the microorganisms that may be present in footbaths. If you want to support these directions, you must submit data generated using the Broad Spectrum Performance standard, 91-2(c)(3) and method 91-2(c)(1) of Subdivision G with a one minute contact time. It is felt that the non-food sanitizer method is not a sufficient test to demonstrate an appropriate kill for organisms typically. found in footbaths.
- 5) The statement, "Use 8 oz. per gallon of water to kill Adenovirus Type 5 and type 7" must be added to all disinfection use directions. Revise the following directions accordingly:

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Preparation of Disinfection Use Solution Non Acid Toilet Bowl/Urinal Salon/Barber Instruments and Tools Ultrasonic Bath Disinfection of [Whirlpool] [Units] [Baths] [Footspas] HIV, HBV, and HCV Farm Premise/Veterinary Practice/Poultry Swine Premise/Hatcheries **Dressing Plant** 

- 6) Under "Shoe Bath Sanitizer" directions, delete the phrase, "tracking harmful organisms" and state "to prevent cross contamination into animal areas..."
- 7) The following deodorizing directions on page 10 are unclear as how to apply the product to the surfaces. Revise as follows:
- a) Mopping Solutions, Automatic Scrubbers: Revise the phrase "cleaning solution" to state "water". Also, add the statement, "Allow surfaces to air dry."
- b) Carpets: Revise the phrase "shampooing solution" to state "water."
- c) Cleaning Solutions: "Apply to surfaces using cloth, mop, or sponge. Remove excess liquid or allow surfaces to air dry.'

## **General Comments**

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling 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) and section 4 (a) 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 concerning this letter, please contact Jacqueline McFarlane at (703) 308-6198.

Sincerely.

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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.

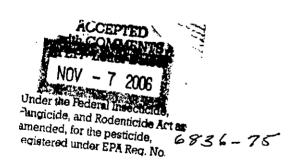
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

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.



## **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 CaCO<sub>3</sub>) 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\*

[Citrus] [Floral] [Fresh] [Lavender] [Lemon] [Lime] [Mint], [Peppermint] [Pine] [Woody] [Scent] [Scented] [Fragrance] (Odor]

## 

## **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. 90 Boroline Road Allendale, NJ 07401

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 majodors.
- 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.
- to clean and disinfect nonporous fire fighting bunker
   / turnout gear; trousers; overcoats, gloves, boots, hoods, helmets, air masks.
- to clean, sanitize and disinfect nonporous personal protective safety equipment: protective headgear, 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 before reuse with clean warm water (about 120°F), and allow to air dry. (Caution: Cleaning at the recommended 120°F temperature will avoid overheating and distortion of the personal safety equipment which would necessitate replacement).

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

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

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

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

Lonza Formulation S-21 leaves a clean fresh scent.

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

## 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] [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

**Boats** 

**Buses** 

Campers

Cars

**Emergency vehicles** 

Mobile homes

Ships

**Taxis** 

Trailers

Trains

Transportation terminals

(TYPES OF SURFACES:)

Use Lonza Formulation S-21 on nonporous

washable hard.

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

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

Shower stalls

[Fiberglass] Shower stalls

[Fiberglass] Sinks [bathroom] [kitchen]

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]

Non-critical medical device surfaces:

Beds [Medical] [Hospital]

Bed frames

Bed rails

Crutches

Non-critical [hospital] [medical]

equipment surfaces

[Medical] Examining tables

[Medical] [Hospital] Lamps

[Medical] [Hospital] Scales

Stands

Stethoscopes

Walkers

Wheel chairs

Other hard nonporous surfaces made

of:

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

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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 Staphylococcus 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 Feline Calicivirus 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 pneumophilia

Norwalk Virus

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]

[Animal Viruses:]

Avian Influenza virus

Avian Infectious Bronchitis Virus

Canine Distemper Virus

Feline Calicivirus

Newcastle's Disease Virus

Pseudorabies Virus

[Fungi:]

Aspergillus niger

Trichophyton mentagrophytes [the Athlete's Foot Fungus]

[A cause of Ringworm]

[A cause of Ringworm of the foot]

Lonza Formulation S-21 EPA Reg. No. 6836-75 EPA Draft Label 4-21-06 (Note to reviewer: Language in [ ] is optional or interchangeable)

#### Dilution:

## **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.

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.

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 At 2 oz. per gallon, LONZA FORMULATION S-21 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.

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] [Use] 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.

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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 [/VIRUCIAL\*] DIRECTIONS:

Use LONZA FORMULATION S-21 to disinfect hard nonporous noncritical 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]] [UNIT[S]] [FOOT SPASI:

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 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]] [UNIT[S]] [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 [/ VIRUCIAL\*] 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 usesolution 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.

#### **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-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.

## POULTRY AND SWINE PREMISE DISINFECTION [/ VIRUCIAL\*] 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: 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.

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 SANITIZER DIRECTIONS:

To prevent cross contamination into animal areas, apply a foam layer approximately ½ to 2 inches thick made from a solution of 2 oz. of LONZA FORMULATION S-21 per 2-5 ½ 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.

## FOGGING DEVICE HATCHERY ROOM 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. 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.

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

#### **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 solled 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

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.

# WATER DAMAGE RESTORATION SANITIZER 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 to sanitize against odor causing bacteria on the following porous and semi-porous materials: carpets, carpet cushions, subfloors, drywall, 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, 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 / Sanitizing 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 / sanitizing. 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.

Lonza Formulation S-21 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, Farms, 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-21 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 Backup, Water Damage: 4 – 8 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.

(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 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 filth 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.

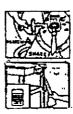
4. WAIT:

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.

LOCK / STORE:

Slide the Trigger Stop to the "LOCK" position.





## PACKET LABEL TO BE USED WITH MASTER CONTAINER LABEL

## 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-21**

EPA. Reg. No. 6836-75. EPA. Est. No. (insert EPA Est. No. here) Net Contents:

Active Ingredients:	
Octyl decyl dimethyl ammonium chloride	1.65%
Dioctyl dimethyl ammonium chloride	
Didecyl dimethyl ammonium chloride	0.99%
Alkyl (C <sub>14</sub> , 50%; C <sub>12</sub> , 40%; C <sub>16</sub> , 10%)	
dimethyl benzyl ammonium chloride	2.20%
Other Ingredients:	
Total:	

## 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 5.]

Lonza Formulation S-21 EPA Reg. No. 6836-75 EPA Draft Label 4-21-06 (Note to reviewer: Language in [ ] is optional or interchangeable)