

6836-78

09/30/2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY


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

SEP 30 2004

 OFFICE OF
 PREVENTION, PESTICIDES
 AND TOXIC SUBSTANCES

 Robert Sloan
 Sr. Regulatory Services Associate
 Lonza Inc.
 17-17 Route 208
 Fair Lawn, NJ 07410

 Subject: R-82
 EPA Reg. No. 6836-78
 Application Dated: September 2, 2004
 Receipt Date: September 3, 2004

Dear Mr. Sloan,

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

Proposed Notification

- Restore the statement: **At ½ oz. Per gallon, LONZA FORMULATION R-82F will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, nonporous surfaces. Follow disinfection instructions under the Disinfection/Virucidal/Fungicidal/Mold and Mildew Control Directions.** Referencing the label dated 4/26/2001.
- Restore the statement: **Leave surface wet for 1 minute (60) seconds.....with ½ oz. per gallon use - solution located under the Special Instructions for Cleaning and Decontamination against HIV-1 HBV or HCV on Surfaces / Objects Soiled with Blood/ Body Fluids.** Referencing the label dated 4/26/2001.

Comments

Based on a review of the material submitted, the following comments apply:

This application for notification to restore the statement: **At ½ oz. Per gallon, LONZA FORMULATION R-82F will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, nonporous surfaces. Follow disinfection instructions and restore the statement: Leave surface wet for 1 minute (60) seconds.....with ½ oz. per gallon use - solution** is accepted. A copy has been placed in our records for future reference.

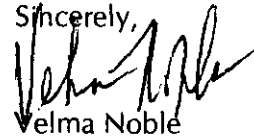
CONCURRENCES							
SYMBOL	7510 C						
SURNAME	D. Smith						
DATE	09-30-04						

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble

Product Manager (31)
Regulatory Management Branch1
Antimicrobial Division (7510c)0

CONCURRENCES

SYMBOL	7510C							
SURNAME	D. Smith							
DATE	09-30-04							

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. EPA
Room 266A, Crystal Mall 2
1801 S. Bell Street
(Formerly: 1921 Jefferson Davis Highway)
Arlington, VA 22202

Lonza Inc
17-17 Route 208
Fair Lawn, NJ 07410, USA

Robert J. Sloan
Performance Chemicals
Regulatory Services

Phone: (201) 794-2610
Fax: (201) 696-3569
bob.sloan@lonza.com

Attention: Velma Noble (PM-31)

September 2, 2004

Lonza Formulation R-82
EPA Reg. No. 6836-78

NOTIFICATION PER PR NOTICE 98-10
THIS SUBMISSION IS NOT SUBJECT TO FEES UNDER PRIA

Dear Ms. Noble,

In order to respond to deficiencies noted in the subject label by California DPR, Lonza is submitting a **Notification per PR Notice 98-10**. The proposed changes are:

1. **DISINFECTION / VIRUCIDAL* / FUNGICIDAL / MOLD AND MILDEW CONTROL**
DIRECTIONS: For mold and mildew.
 - ◆ **Add** the following, which was mistakenly deleted from the 10/18/02 and subsequent EPA Stamped labels: *At ½ oz. per gallon, LONZA FORMULATION R-82F 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...*
2. **SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OR HBV OR HCV ON SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS.**
Contact time:
 - ◆ **Restore** the use solution information, which was mistakenly deleted from the 10/18/02 and subsequent EPA Stamped labels: *Leave surface wet for 1 minute (60 seconds) ... with ½ oz. per gallon use-solution.*

September 2, 2004
Lonza Formulation R-82
EPA Reg. No. 6836-78

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NOTIFICATION PER PR NOTICE 98-10
THIS SUBMISSION IS NOT SUBJECT TO FEES UNDER PRIA

In support of this Notification, enclosed are the following:

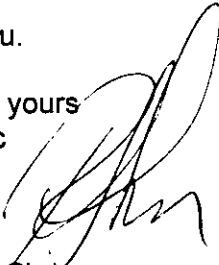
1. EPA Form 8570-1, Application for Pesticide Amendment, OPP ID No. 296536
2. Three copies of the revised label with one copy highlighted for ease of review.

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

If you have any questions, please call me at 1-800-777-1875, ext. 2610.

Thank you.

Sincerely yours
Lonza Inc



Robert J. Sloan
Sr. Regulatory Services Associate



Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0080, Approval expires 2-28-95

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United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

296536

Application for Pesticide - Section I

1. Company/Product Number 6836-78	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Lonza Formulation R-82	PM# Team 31	
5. Name and Address of Applicant (Include ZIP Code) LONZA, Inc. 17-17 Route 208 Fair Lawn, NJ 07410 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

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

NOTIFICATION PER PR NOTICE 98-10
THIS SUBMISSION IS NOT SUBJECT TO FEES UNDER PRIA

Section - III

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

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Robert J. Sloan		Title Sr. Regulatory Services Associate		Telephone No. (Include Area Code) (201) 794-2610	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Sr. Regulatory Services Associate			
4. Typed Name Robert J. Sloan		5. Date 9/2/84			

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and protective (rubber or chemical resistant) gloves. Harmful if swallowed and / or if 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.

(If container size is 5 gallons or larger, use the following Environmental Hazards statement.)

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 R-82

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_3) 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.....	6.510%
Dioctyl dimethyl ammonium chloride	2.604%
Didecyl dimethyl ammonium chloride	3.906%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₀ , 10%) dimethyl benzyl ammonium chloride.....	8.680%
(Other) (Inert) Ingredients:.....	78.300%
Total	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER (PELIGRO)

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

EPA Reg. No. 6836-78
EPA Est. No. (as indicated on container)
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 R-82:

- 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 R-82** has been formulated to aid in the reduction of cross-contamination not only in hospitals, but in schools, institutions and industry.

Use Lonza Formulation R-82

- 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.

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

(AREAS OF USE:)

Use **Lonza Formulation R-82** in:

Bathrooms
Homes (households)
Kitchens

Dental offices
Health Care Facilities
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 Salons

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 R-82** on washable hard, nonporous surfaces of:

Appliances, exteriors of
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 of
Outdoor furniture
Refrigerators, exteriors of
Refrigerated storage and display equipment

Showers
Shower stalls (Fiberglass)
Sinks (**bathroom**) (**kitchen**) (**Fiberglass**)
Stoves (stovetops)
Tables, (picnic tables) Non-wooden picnic tables and Outdoor (patio) furniture except cushions and wood frames.
Tanning beds
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 R-82 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 R-82** 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 R-82** should be limited to areas where compost and mushrooms are not present.

LONZA FORMULATION R-82 is a sanitizer for hard nonporous non-food contact surfaces at 1:1024 dilution (200 ppm active, ½ oz. per 4 gallons) 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 R-82 eliminates 99.9% of *Staphylococcus aureus* and *Klebsiella pneumoniae* in 60 seconds.

LONZA FORMULATION R-82 is effective against Citrus Canker Disease (*Xanthomonas axonopodis* pv. *citri*) at 2000-ppm active quat.

LONZA FORMULATION R-82 is effective against:

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

LONZA FORMULATION R-82 is a mildewstat at 1:256 dilution (½ 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 R-82 is a (one-step) (Hospital Use) disinfectant at 1:256 dilution (1/2 oz. per gallon of water), Bactericidal according to the current AOAC Use-Dilution Test Method 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
Brevibacterium ammoniagenes (*Brevibacterium*)
Campylobacter jejuni
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 (*Serratia*)
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 at 1:64 dilution (2 oz. per gallon of water)
*Hepatitis B Virus (HBV)
*Hepatitis C Virus (HCV)
*Herpes Simplex Virus Type 1
*Herpes Simplex Virus Type 2
*HIV-1 (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:)

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

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Dilution:

Disinfection (1:256).....½ oz. per gallon of water
..... (886 ppm active)
Sanitizer (1:1024) ½ oz. per 4 gallons of water
..... (200 ppm active quat)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Before use in federally inspected meat and poultry food processing plants and dairies, food products and packaging materials must be removed from the room or carefully protected.

Preparation of Use-Solution:

(Add) (Mix) ½ oz. per gallon of water (1:256).
For heavy duty use, (add) (mix) 2 oz. per gallon of water (1:64).

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

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

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

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

For fungicidal activity, Lonza Formulation R-82 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 R-82 is a one-step fungicide at ½ oz. per gallon in 250 ppm hard water and 5% serum.

At ½ oz. per gallon in 400 ppm hard water, Lonza Formulation R-82 must be used on precleaned surfaces.

For mold and mildew, At ½ oz. per gallon, **LONZA FORMULATION R-82** 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.

(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.)

(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: 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) ½ oz. of Lonza Formulation R-82 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 ½ oz. to the bowl and mix. Brush over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.

From Use Solution:

Empty toilet bowl or urinal and apply ½ oz. per gallon use-solution to exposed surfaces and under the rim with a cloth, mop, sponge or mechanical spray. Brush or swab thoroughly, allow to stand for 10 minutes and flush.

For Heavy Duty Use:

Empty toilet bowl or urinal and apply 2 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 R-82** at 1/2 oz. per gallon. Apply with a damp mop or autoscrubber. Allow surface to remain wet for 10 minutes. Wipe or allow to air dry. Do not use on floor finish at 2 oz. per gallon.

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

Mix 1 oz. (30 ml) of **LONZA FORMULATION R-82** per gallon of water (1/4 oz. [7.5 ml] of **LONZA FORMULATION R-82** 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 R-82** to disinfect hard nonporous, non-critical objects compatible with Ultrasonic cleaning units.

Pour fresh use-solution of 1/2 oz. per gallon of water (1:256) directly into bath chamber. Preclean heavily soiled objects. Place objects into unit and operate for a minimum of 10 minutes, according to the manufacturer's directions. Remove objects and wash with sterile water (sterile water for injection) or allow to air dry. Prepare fresh solution for each use.

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

After using the [whirlpool (unit) (bath)] [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 1/2 oz. of **Lonza Formulation R-82** for each gallon of fresh water added. Start the pump to circulate the solution. Wash down the sides, [(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. Treated surfaces must remain wet for 10 minutes. After the (unit) (bath) (foot spa) has been thoroughly disinfected, drain the solution from the (unit) (bath) (foot spa) and rinse the disinfected 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 (unit) (bath)] [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 1/2 oz. of **Lonza Formulation R-82** for each 4 gallons of fresh water added. Start the pump to circulate the solution. Wash down the sides, [(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. Treated surfaces must remain wet for at least (60 seconds) (one minute). After the (unit) (bath) (foot spa) has been thoroughly sanitized, drain the solution from the (unit) (bath) (foot spa). Wipe dry with a clean sponge or cloth or allow to air dry. Repeat for heavily soiled units.

***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 or HBV or HCV must be thoroughly cleaned from surfaces and objects before application of **LONZA FORMULATION R-82**.

Contact time: Leave surface wet for 1 minute (60 seconds) for HIV-1 and 10 minutes for HBV and HCV with 1/2 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) 1/2 oz. of **Lonza Formulation R-82** per 4 gallons 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. Do not use in food preparation, food handling and food storage areas. This product is not to be used on glassware, dishware, cookware or utensils.

TO SANITIZE BARBER / SALON INSTRUMENTS AND TOOLS:

Immerse precleaned barber / salon instruments and tools such as combs, brushes, razors, scissors, blades and manicure instruments in a use-solution of ½ oz. of Lonza Formulation R-82 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 feeding or watering animals, 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 ½ oz. of **LONZA FORMULATION R-82** per gallon of water (or equivalent dilution) for a period of 10 minutes. Wipe or allow to air dry. Immerse all animal handling and restraining equipment as well as forks, shovels, and scrapers used to remove litter and manure. Rinse all surfaces that come in contact with food, including equipment used for feeding or watering, with potable water before reuse. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

FARM PREMISE USE:

Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with a use-solution of 1/2 oz. of **LONZA FORMULATION R-82** 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, boats and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

POULTRY AND SWINE PREMISE DISINFECTION DIRECTIONS:

Remove all animals and feeds from premises, vehicles and enclosures such as coops and crates. Remove all litter, droppings and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Use ½ oz. of **LONZA FORMULATION R-82** 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, coops and other closed spaces. Do not house animals 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.

Hatcheries: Use ½ oz. of **LONZA FORMULATION R-82** per gallon of water to treat hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard nonporous 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 R-82**. Use ½ oz. of **LONZA FORMULATION R-82** 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 1/2 oz. per 4 gallons of water use-solution for 60 seconds prior to entering area. Change the solution in the bath daily or when solution appears diluted or soiled.

Shoe Foam Sanitizing Directions:

To prevent cross contamination into animal areas and the packaging and storage areas of food plants. Apply a foam layer approximately 1/2 to 2 inches thick made from a solution of 1/2 oz. of **LONZA FORMULATION R-82** 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 1/2 oz. 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 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 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).

FOGGING DEVICE INCUBATOR AND HATCHER SANITIZER DIRECTIONS:

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 1/2 oz. of **Lonza Formulation R-82** 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, pre-clean 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 1 oz. of **Lonza Formulation R-82** per gallon of water. Heavily soiled areas may require repeated cleaning before treatment.

DO NOT APPLY USE-SOLUTION TO THE MUSHROOM CROP, COMPOST OR CASING. Rinse treated surfaces with potable water before they contact the crop, compost or casing.

CITRUS CANCER DISEASE CONTROL:

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

Thoroughly clean all hard nonporous surfaces with soap or detergent and rinse with water. Then saturate surfaces with a 1:109 use-dilution. (1.2 oz. of Lonza Formulation R-82 per gallon of water or 6 oz. of Lonza Formulation R-82 per 5 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 the container size 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.