ED STATES ENVIRONMENTAL PROTEC

APR - 4 2003

Ms. Ana Rodriguez-Koster Agent for Lonza, Inc. Lewis & Harrison 122 C Street, NW Ste. 740 Washington, DC 20002

Subject:

Lonza Formulation S-38F

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EPA Registration No. 6836-138

Amendment Date: November 22, 2002 EPA Receipt Date: November 25, 2002

Dear Ms. Koster.

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

Response to Agency letter dated October 24, 2002

Conditions

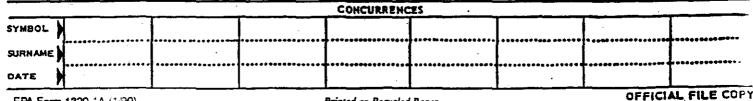
Revise the label as follows:

- 1. Page 1: Under the "Precautionary Statements," revise the phrase, "protective gloves" to read either "protective (rubber or chemical resistant) gloves" or "rubber or chemical resistant gloves."
- 2. Page 4: Add the use site, "laundries," since you have directions.
- Page 5: You must add the following food contact sanitizing claim: 3.

Lonza Formulation S38F is an effective sanitizer for use on food contact surfaces in 60 seconds at 150 ppm active against:

Escherichia coli Staphylococcus aureus

Please Note: The food contact sanitization claim has been accepted on this label since its registration on June 18, 1990. Therefore, we are not asking that it be deleted. However, we would like some clarification as to what data was submitted to support this claim.



EPA Form 1320-1A (1/90)

Printed on Recycled Paper

4. Page 6: Revise the "Dilution" table by distinguishing the 1:64 disinfection use solution as "Medical" and the 1:128 disinfection use solution as "Nonmedical." It should look exactly like the "Preparation of Use Solution" table.

General Comments

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

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

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

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

Sincerely

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510C)

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and protective gloves. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5 minutes, then continue rinsing eye.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

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

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling poison control center or doctor or going for treatment.

(Note to reviewer: If container size is 5 gallons or larger, the following Environmental Hazards statements will be used:)

ENVIRONMENTAL HAZARDS

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 Wesp TED and or Regional Office of the EPA.

with COMMENTS
in EPA Letter Dated:

APR 4 - 2003

Under the Federal Insecticide,
Funcicide, and Rodenticide Act as
amended, for the perticide,
registered under EPA Reg. No. & 836 - 138

LONZA FORMULATION S-38F

One-Step Disinfectant

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

Acid-Free Cleaner Acid-Free Disinfectant

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

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

For use in federally inspected meat and poultry plants

An effective sanitizer for use on food contact surfaces

Staphylocidal • Pseudomonacidal • Bactericidal
 Salmonellacidal • Fungicidal • Virucidal*

Active Ingredients:

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

KEEP OUT OF REACH OF CHILDREN

DANGER (PELIGRO)

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

EPA Reg. No. 6836-138
EPA Est. No. (<u>insert EPA Establishment No. here</u>)
Net Contents (<u>insert container size here</u>)

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

LONZA FORMULATION S-38F EPA Reg. No. 6836-138 EPA draft label 11-19-02 (Note to reviewer: Language in () is optional or interchangeable)

Page 1 of 10

Resubmission of Label in Response to Agency Letter Dated 10-24-02

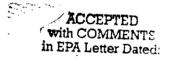
(Note to reviewer: The following is considered optional marketing language.)

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

Lonza Formulation S-38F

- delivers non-acid disinfectant and cleaning performance in an economical concentrate.
- is effective yet economical.
- is an economical concentrate (that can be diluted for use) (with a mop and bucket, trigger sprayers, sponge or by soaking).
- (is a heavy duty disinfectant cleaner that) (is an alkaline pH disinfectant cleaner that) cleans, disinfects and deodorizes in one labor saving step.
- deodorizes by killing microorganisms that cause offensive odors.
- (improves labor results by) effectively controls (controlling) malodors.
- will disinfect, clean and deodorize surfaces in rest rooms and toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause malodors.
- is formulated for use in daily maintenance programs with a balance of detergents, biocides and malodor counteractants that deliver effective cleaning, disinfecting and malodor control.
- is a complete, chemically balanced disinfectant (and sanitizer) (that provides clear use solutions).
- will not leave grit or soap scum.
- is a (versatile) disinfectant and sanitizer for hard, nonporous nonfood contact surfaces in Veterinarian, Animal care and Farm Premise applications.
- is a (versatile) cleaner and broad spectrum disinfectant formulated for use only on non-critical instruments in Ultrasonic Baths (Ultrasonic cleaning units).
- Cleans, shines, deodorizes and disinfects nonporous household surfaces.
- Inhibits the growth of mold and mildew leaving bathrooms and kitchens clean and smelling fresh.
- kills household germs; effective against Pseudomonas aeruginosa (pseudomonas), Staphylococcus aureus (staph), Streptococcus faecalis (strep), Influenza A/Brazil and Trichophyton mentagrophytes (Athlete's foot fungus).
- is a multi-surface cleaner, deodorizer, and disinfectant. Use on windows, mirrors and other glass surfaces.

- is a (concentrated) (one-step) (Hospital Use)
 disinfectant cleaner that is effective against a broad
 spectrum of bacteria, is virucidal* (including HlV-1, the
 AIDS Virus), fungicidal, and inhibits the growth of mold
 and mildew, and their odors, when used as directed.
- is an effective one-step sanitizer-cleaner for use on non-food contact surfaces.
- meets AOAC efficacy standards for hospita disinfectants.
- meets EPA Sanitizer Test standards for non-food contact sanitizers.
- is a proven "one-step" disinfectant cleaner sanitizer - fungicide - mildewstat - virucide* in the presence of moderate amounts of organic soil (5% serum contamination).
- meets AOAC Germicidal & Detergent standards for previously cleaned food-contact surfaces.
- has been cleared by the FDA in 21 CFR §178.1010 for use on food processing equipment, utensils and other food-contact articles.



APD 4 - 2003

Under the Federal Insectionie.
Fungicide, and Rodenticide Act an amended, for the pesticide, registered under EPA Reg. No. 6836-138

Cross-contamination is of major housekeeping concern. LONZA FORMULATION S-38F has been formulated to aid in the reduction of cross-contamination not only in hospitals, but in schools, institutions and industry.

Use Lonza Formulation S-38F

- as a sanitizer on all surfaces not requiring a rinse in official establishments operating under the Federal meat, poultry, shell egg grading and egg products inspection
- in federally inspected Meat & Poultry Plants as a food contact sanitizer and / or disinfectant. This product was authorized by USDA as category D2 under the prior authorization program and its formula has not been changed — a sanitizer for all surfaces not always requiring a rinse.
- on the multi-touch surfaces responsible for crosscontamination and infection.
- as a disinfectant on hard, nonporous surfaces.
- in kitchens, bathrooms and other household areas.
- to clean and disinfect finished floors, sinks and tubs.
- with a mop and bucket, trigger sprayer, sponge or by soaking.
- for non-scratch cleaning of sinks, showers and tubs, shower doors and curtains, glazed ceramic tiles, fiberglass, fixtures and toilet bowls.
- to clean and disinfect nonporous salon / barber tools and instruments: combs, brushes, scissors, blades and manicure instruments.
- for sanitizing and disinfecting of ultrasound transducers, probes, mammography compressor plates and other hard nonporous surfaces.
- to clean and disinfect finished floors. Can be applied with damp mop or autoscrubber. Cleans and disinfects without dulling gloss.
- on coils and drain pans of air conditioning and refrigeration equipment and heat pumps. Follow the directions for sanitization of non-food contact surfaces.
- for Poultry Premise Sanitation (Hatcheries):

Egg Receiving Area
Chick Processing Area
Chick Holding Room

Tray Dumping Area Egg Holding Area Chick Loading Area Hatchery Room

Setter Room
Poultry Buildings
Buggies
Egg Flats

Racks Trays Ceilings Floors

Sidewalls Drinkers

Poultry House related

equipment

other hard, nonporous surfaces in the Hatchery

environment.

· for Swine Premise Sanitation:

Farrowing Barns and areas

Creep area Loading Equipment Hauling Equipment Dressing Plants Waterers and Feeders

Chutes

Nursery blocks

for Farm Premise Sanitation:

floors walls
feed racks mangers
troughs forks,
automatic feeders shovels,
fountains and waterers scrapers

and other nonporous surfaces in barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals.

- as a commercial sanitizer on dishes, glassware, and utensils.
- as a sanitizer in bottling and beverage dispensing equipment.
- as a sanitizer in sanitary filling of bottles and cans.
- in sanitizing bottles or cans in the final rinse application, and for external spraying of filler and closing machines.
- as a sanitizer in beer fermentation and holding tanks.
- as a Food-Grade Shell Egg sanitizer, with best results achieved in water temperatures ranging from 78°-110°F. LONZA FORMULATION S-38F may be applied through automatic washing systems, immersion tanks, foaming apparatus and low-pressure sprayers.

Lonza Formulation S-38F is a phosphate free, germicidal detergent effective in the presence of a moderate amount of organic soil on hard nonporous surfaces found at mushroom farms. Lonza Formulation S-38F has been designed for use between mushroom crops. Areas of intended use include breezeways and track alleys before spawning, inside and outside walls of mushroom houses, lofts, floors, storage sheds and casing rings. Use of Lonza Formulation S-38F should be limited to areas where compost and mushrooms are not present.

ACCEPTED with COMMENTS in EPA Letter Dated:

дрк 4 - 2003

Under the Federal Insecticide, Fungicide, and Rodenficide Act as amended, for the pesticide, registered under EPA Reg. No. 6836-138

EPA draft label 11-19-02

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

(AREAS OF USE:)

Use Lonza Formulation S-38F in:

Bathrooms

Homes (households)

Kitchens

Clinics Dental offices Hospitals Medical Offices

Medical related facilities

Nursing homes Sick Rooms

Day care centers

Nurseries

Bars Cafeterias

Convenience stores Egg Processing plants

Federally inspected meat and poultry plants

Food processing plants
Food preparation areas
Food storage areas
Institutional kitchens

Restaurants

USDA inspected food processing

facilities

Athletic facilities Barber shops

Business and office buildings

Colleges

Correctional facilities

Dressing rooms ACCEPTED
Exercise facilities th COMMENTS
Factories in EPA Letter Dated:

Hotels

Institutional facilities APR 4 - 2003

Institutions
Locker rooms
Locker rooms
Angleide, and Rodenticide Act as
Motels
amended, for the persicide,

Prisons registered under EPA Reg. No. Public facilities 6836-128

Public rest rooms

Salons Schools

Shower and bath areas

Camp grounds

Play ground equipment

Animal laboratories

Dairy farms
Hog farms
Kennels
Poultry farms
Pet animal quarters

Pet shops Turkey farms

Zoos

Airports Airplanes Boats Buses Campers Cars

Mobile homes

Ships Taxis Trailers Trains

Transportation terminals Vehicles (Emergency)

(TYPES OF SURFACES:)

Use Lonza Formulation S-38F on washable hard, nonporous surfaces

OT:

Appliances Basins

Bathroom fixtures

Bathtubs Cabinets Cages Chairs

Coils and drain pans of air conditioning and refrigeration equipment and heat pumps

Conductive flooring
Counters (countertops)
Countertop laminates

Desks

Doorknobs (and handles)

Floors

Floors - high speed burnished

Garbage cans Highchairs Kennel runs Microwave ovens

Mirrors

Outdoor furniture Refrigerators

Pefrigerated storage and display

equipment Showers Shower stalls

Sinks (bathroom, kitchen)

Stoves (stovetops)

Tables (picnic tables)

Telephones Toilets

Toilet bowls

Toilet bowl surfaces

Tubs

Tites, glazed Ultrasonic baths

Urinals Walls

Whirlpool bathtubs

Windows

Beer fermentation and holding tanks

Blenders

Bottling or premix dispensing

equipment

Chopping blocks, plastic and other

nonporous Cooking utensils

Coolers Cutlery

Cutting Boards, plastic and other

nonporous

Dishes

Eating Utensils

Food processors Glassware

ice Chests

Kitchen equipment

Refrigerator bins used for meat, fruit,

vegetables and eggs

Silverware Slurpy Machines Tupperware®

Other hard nonporous surfaces made of:

Fiberglass Formica®

Glass

Glazed ceramic

Glazed enameled surfaces

Glazed porcelain

Metal

Plastic (such as polystyrene or

polypropylene) Sealed stone Stainless steel

Upholstery, vinyl and plastic

Woodwork, finished

LONZA FORMULATION S-38F EPA Reg. No. 6836-138

EPA draft label 11-19-02

(Note to reviewer: Language in () is optional or interchangeable)

Resubmission of Label in Response to Agency Letter Dated 10-24-02

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24 02

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

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

Klebsiella pneumoniae

Staphylococcus aureus

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

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

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

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

LONZA FORMULATION S-38F fulfills the criteria of Appendix F of the Grade "A" Pasteurized Milk Ordinances 1999 Recommendations of the U.S. Public Health Services in waters up to 300 ppm of hardness calculated as CaCO₃ when evaluated by the AOAC Germicidal and Detergent Sanitizer Method.

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

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

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

Acinetobacter baumannii (Acinetobacter) Corynebacterium ammoniagenes (Brevibacterium ammoniagenes)

Enterobacter aerogenes Enterococcus faecalis - Vancomycin resistant (VRE)

Escherichia coli (E. coli)

ESBL Escherichia coli - (Extended spectrum beta-

lactamase producing E. coli)

Klebsiella pneumoniae (Klebsiella)

Pseudomonas cepacia (Pseudomonas)

Salmonella schottmuelleri (Salmonella)

Serratia marcescens

Shigella dysenteriae (Shigella)

Staphylococcus aureus Methicillin-Resistant (MRSA)

Staphylococcus aureus - Vancomycin Intermediate Resistant - (VISA) Streptococcus faecalis (Strep)

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

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

Staphylococcus aureus (Staph)
Salmonella choleraesuis (Salmonella)

Corynebacterium ammoniagenes (Brevibacterium ammoniagenes)

Enterobacter aerogenes

Escherichia coli (E. coli)

Klebsiella pneumoniae (Klebsiella)

Salmonella schottmuelleri (Salmonella)

Serratia marcescens

Shigella dysenteriae (Shigella)

Streptococcus faecalis (Strep)

ACCEPTED with CON MENTS in EPA In the Dated:

APR 4 - 2003

Under the Federal Insecticide.
Fungicide, and Hadenticide Actes
amended, for the pesticide,
registered under EPA Rea. No.

Lonza Formulation S-38F EPA Reg. No. 6836-138 EPA draft label 11-19-02 (Note to reviewer: Language in () is optional or interchangeable)

6836-135

For *Virucidal Effectiveness:

At 1 oz. per gallon of water, LONZA FORMULATION S-38F was evaluated in the presence of 5% serum and found to be effective against the following viruses:

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

Dilution:

Disinfection (1:64)	. 2	OZ.	per	gallon	of war	ter
Disinfection (1:128)	. 1	oz.	per	gallon	of wa	ter
Sanitizer (1:256)	1/2	OZ.	per	gallon	of wa	ter
	٠.,		(1	50 ppr	n activ	/e)

DIRECTIONS FOR USE

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

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

Preparation of Use-Solution;

DISINFECTION / 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.

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

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

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

For fungicidal activity

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

For mold and mildew control:

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

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

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

(or

This product is not for use on medical device surfaces.

TO CLEAN AND DEODORIZE: Mix 1 –2 oz. of Lonza Formulation S-38F per gallon of water to clean and deodorize surfaces. Apply using a cloth, mop, sponge or sprayer. Wipe or allow to air dry.

GLASS CLEANING / DEODORIZING DIRECTIONS:

Add ½ - 2 oz. of LONZA FORMULATION S-38F per gallon of water to clean and deodorize windows, mirrors and glass surfaces. Use a coarse spray device. Spray 6 - 8 inches from surface. Rub with a sponge or cloth. Do not breathe spray.

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

If surfaces are visibly dirty, preclean first.

From Concentrate:

Add 1-2 oz. to the bowl water and mix. Thoroughly brush or swab over exposed surfaces including under the rim with a cloth, mop or sponge. Allow to stand for 10 minutes and flush.

From Use Solution:

Empty toilet bowl or urinal and apply a 1-2 oz. per gallon use-solution to exposed surfaces and under the rim with a cloth, mop, sponge or sprayer. Brush or swab thoroughly, allow to stand for 10 minutes and flush.

For Heavy Duty Use:

Empty toilet bowl or urinal and apply an 8 oz. per gallon use-solution to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer. Brush or swab thoroughly, allow to stand for 10 minutes and flush.

FOR USE ON FINISHED FLOORS: To limit gloss reduction use LONZA FORMULATION 33E at 1 – 2 oz. per gallon. Apply with a damped of process grabber. Allow surface to remain wet for 10 minutes. Wife or allow to air dry. Do not use on floor finish approx. per gallon.

Lonza Formulation S-38F EPA Reg. No. 6836-138 EPA draft label 11-19-02 (Note to reviewer: Language in () is optional or interchangeable)

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Resubmission of Label in Response to Agency Letter Dated 10-24-02

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

Use (Mix) 1 - 2 oz. of LONZA FORMULATION S-38F per gallon of water ($\frac{1}{4}$ - $\frac{1}{2}$ oz. per quart of water) (or equivalent dilution) to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, rollers, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Prepare fresh solution daily or more often if solution becomes diluted or soiled.

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

ULTRASONIC BATH DISINFECTANT DIRECTIONS:

Use LONZA FORMULATION S-38F to disinfect hard nonporous non-critical objects compatible with Ultrasonic cleaning units. Pour fresh use-solution of 1 - 2 oz. of Lonza Formulation S-38F per gallon of water directly into bath chamber. Pre-clean heavily soiled objects. Place objects into unit and operate for a minimum of 10 minutes, according to the manufacturer's directions. Remove objects and wash with sterile water (sterile water for injection) or allow to air dry. Prepare fresh solution for each use.

DISINFECTION OF WHIRLPOOL UNITS: After using the whirlpool unit, drain, and refill with fresh water to just cover the intake valve. Add 1-2 oz. of Lonza Formulation S-38F for each gallon of fresh water added. Start the pump to circulate the solution. Wash down the unit sides, seat of the chair lift and any related equipment with a clean swab, brush or sponge. Treated surfaces must remain wet for 10 minutes. After the unit has been thoroughly cleaned, drain the solution from the unit and rinse cleaned surfaces with fresh water. Repeat for heavily soiled units.

For Bag - In - Box Containers:

How to use this package:

This package is designed to be used with dilution control systems only. Open package and connect to dispense according to directions on box top.

Trigger Sprayers:
-Fill bottle from dispenser.
Apply to surfaces as specified in directions above.

Mop Buckets:
Fill bucket from dispenser.
Set up "Wet Floor" signs.
Mop floor surface as specified in directions above

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

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

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

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

CONTACT TIME: Leave surface wet for 10 minutes DISPOSAL OF INFECTIOUS MATERIAL: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

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

For cleaning and disinfecting hard nonporous surfaces: equipment used for animal food or water, atensils, 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 sufferes with soap or detergent and rinse with water. Saturate sumbles with a use-solution of 1 - 2 oz. of LONZA FORMULATION S-38F per gallon of water (or equivalent dilution) for a period of 10 minutes. Wipe or allow to air dry. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for removing litter and manure. Rinse all surfaces that come in contact with lood, 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.

> ACCEPTED with COMMENTS in EPA Letter Dated:

> > APR 4 - 2003

Under the Federal Insecticide, Pingicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 6836-138

Lonza Formulation S-38F EPA Reg. No. 6836-138 EPA draft label 11-19-02 (Note to reviewer: Language in () is optional or interchangeable)

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Resubmission of Label in Response to Agency Letter Dated 10-24-02

FARM PREMISE USE:

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

POULTRY AND SWINE PREMISE DISINFECTION DIRECTIONS:

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

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

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

Shoe Bath Sanitizer Directions: To prevent 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 ½ oz. per gallon of water solution for 60 seconds prior to entering area. Change the solution in the bath daily or more often if solution appears diluted or soiled.

Dressing Plant Disinfectant Directions: Disinfect equipment, utensils, walls and floors in poultry and animal dressing plants. Disinfect offal rooms, exterior walls and loading platforms of dressing plants. Cover or remove all food and packaging materials. Remove all heavy soils prior to application. Saturate all surfaces with a 1 – 2 oz. per gallon of water use solution of Lonza Formulation S-38F. Scrub to loosen all soils. Surfaces must remain wet for 10 minutes, then thoroughly rinsed with potable water before operations are resumed.

MUSHROOM FARM PREMISE USE:

Site Preparation: The first step in any on-going sanitation program 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 S-38F per gallon of water (or equivalent dilution). Apply use solution with a cloth, mop, sponge, sprayer or by immersion to thoroughly wet the surfaces. Treated surfaces 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 2 oz. of Lonza Formulation S-38F per gallon of water. Heavily soiled areas may require repeated cleaning before treatment.

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

ACCEPTED with COMMENTS in EPA Letter Dated:

APR 4 - 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 6836 - 138 SANIITIZING NON FOOD CONTACT SURFACES: (such as floors, walls, and tables.). Add ½ oz. of LONZA FORMULATION S-38F per gallon of water. LONZA FORMULATION S-38F is an effective sanitizer against Staphylococcus aureus and Klebsiella pneumoniae in the presence of 5% serum on porous and non-porous environmental surfaces. Treated surfaces must remain wet for 60 seconds. Wipe dry with a sponge, mop, or cloth or allow to air dry.

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

TO SANITIZE BARBER / SALON INSTRUMENTS AND TOOLS: Immerse hard, nonporous barber / salon instruments and tools (such as combs, brushes, razors, scissors, blades and manicure instruments) in a use-solution of ½ oz. of Lonza Formulation S-38F per gallon of water (or equivalent dilution) for at least 60 seconds (one minute). Rinse thoroughly and dry before use. Prepare a fresh solution daily or more often if solution becomes visibly diluted, cloudy or soiled.

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

TO SANITIZE FOOD CONTACT SURFACES:

(or)

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

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

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

Apply a use-solution of ½ oz. of Lonza Formulation S-38F per gallon of water (or equivalent dilution) (150 ppm active) to precleaned hard surfaces thoroughly wetting surfaces with a cloth, mop, sponge, coarse sprayer or by immersion. Surfaces must remain wet for at least 60 seconds (one minute) followed by adequate draining and air drying. Do not rinse. Prepare a fresh solution for each use. For mechanical application, use-solution may not be reused for sanitizing applications but may be reused for other purposes such as cleaning.

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

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

TO SANITIZE BEVERAGE DISPENSING EQUIPMENT:

- Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing.
- Fill equipment with a solution of ½ oz. Lonza
 Formulation S-38F per gallon of water (or equivalent
 dilution) (150 ppm active).
- Allow solution to remain in equipment for at least 60 seconds.
- 4. Drain thoroughly before reuse and allow to air dry.

TO SANITIZE SANITARY FILLING EQUIPMENT:

Wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing. Prepare a use-solution of ½ oz. of Lonza Formulation S-38F per gallon of water (or equivalent dilution) (150 ppm active) for final washer and rinser applications. Allow surfaces to remain wet for at least 60 seconds. Drain thoroughly before reuse and allow to air dry.

ACCEPTED

with COMMENTS in EPA Letter Dated:

APR 4 - 2003

Under the Federal Insecticide,

(Note to reviewer: Language in () is optional or interchangeable) ingicide, and Rodenticide Act as

amended, for the perticide, registered under EPA Reg. No. 1836-138

TO SANITIZE BEER FERMENTATION AND STORAGE TO SANITIZE BEVERAGE DISPENSING EQUIPMENT: TANKS:

Wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing. Prepare a use-solution of ½ oz. of Lonza Formulation S-38F per gallon of water (or equivalent dilution) (150 ppm active) for mechanical or automated systems. Allow surfaces to remain wet for at least 60 seconds. Drain thoroughly and allow to air dry before reuse.

TO SANITIZE EGG SHELLS INTENDED FOR FOOD:

To sanitize previously cleaned food-grade eggs in shell egg and egg product processing plants, spray with a usesolution of ½ oz. of Lonza Formulation S-38F per gallon of warm water (or equivalent dilution) (150 ppm active). The solution must be equal to or warmer than the eggs. but not to exceed 130°F. Wet eggs thoroughly and allow to drain. Eggs sanitized with this product shall be subjected to a thorough potable water rinse only if they are to be broken immediately for use in the manufacture of egg products. Eggs must be reasonably dry before casing or breaking. The solution must not be re-used for sanitizing eggs.

Note: Only clean, whole eggs can be used for sanitizing. Dirty, cracked or punctured eggs cannot be sanitized.

Lonza Formulation S-38F can be used in accordance with the U.S. Public Health Service food service sanitization recommendations.

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

CLEANING AND SANITIZING: Equipment and utensils shall be thoroughly pre-flushed or pre-scraped and when necessary, pre-soaked to remove gross food particles and soil.

- 1. Thoroughly wash equipment and utensils in hot detergent solution.
- 2. Rinse utensils and equipment thoroughly with clean water.
- 3. Sanitize equipment and utensils by immersion in a use solution of ½ oz. of Lonza Formulation S-38F per gallon of water (150 ppm active quat) (or equivalent dilution) for at least 60 seconds at a temperature of 75°F.
- 4. For equipment and utensils too large to sanitize by immersion, apply a use-solution of ½ oz. of Lonza Formulation S-38⊬ per gailon of water (150 ppm active quat) (or equivalent dilution) by rinsing, spraying or swabbing until thoroughly wet.
- 5. Allow popitized surface to drain and air dry. Do not rinse.

- 1. Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing.
- 2. Fill equipment with a solution of ½ oz. Lonza Formulation S-38F per gallon of water (or equivalent dilution) (150 ppm active quat).
- Allow solution to remain in equipment for at least 60 seconds.
- 4. Drain thoroughly and allow to air dry before reuse.

(Note to reviewer: If container is one gallon or less, the following Storage and Disposal statements will be used:)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Discard in trash or recycle.

(Note to reviewer: If container is greater than one gallon, the following Storage and Disposal statements will be used:)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or

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.

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