

6836-136

10/29/2001

1/12

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 29 2001

Eliot Harrison
 Agent for Lonza
 Lewis & Harrison, LLC
 122 C Street, NW Ste. 740
 Washington, DC 20001

Subject: Lonza Formulation S-18F
 EPA Registration No. 6836-136
 Amendment Dated May 1, 2001
 EPA Received Date: May 2, 2001

Dear Mr. Harrison:

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below:

- Major label revisions: adding additional marketing statements, use sites, surfaces, and directions for use, and organisms
- Update the first aid statements according to PR Notice 2001-1

(**General Comments**

Label Comments:

1. On page 2, 4th claim, the second sentence, should be revised to state "Use Lonza Formulation R-82F in federally Inspected Meat and Poultry Facilities as a food contact sanitizer and/or disinfectant. The statement, "USDA category D-2 - a sanitizer for all surfaces not always requiring a rinse," is confusing.
2. On page 2, 10th claim on right panel, "Lonza Formulation S-18F as a hatching-egg sanitizer, with best results achieved in water temperatures ranging from 78°-110°F," must be deleted. This claim is regulated by the FDA in which you will need to submit a letter from FDA approving this use. You will also need to develop specific use directions.
3. On page 5, 1st claim on left panel will need to be revised to cite the specific 21 CFR citation, 21 CFR 178.1010 (b)(33)(c)(28).

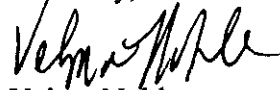
CONCURRENCES

SYMBOL							
SURNAME							
DATE							

4. On page 7, the statement, "*wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing.*" must be added to the Sanitize Sanitary Filling Equipment as the first sentence.
5. On page 7, the instructions, "*Remove gross filth and soil by preflush or pre-scrape when necessary presoak. Then, wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing.*" needs to be included as the first two sentences under the Sanitize Beer Fermentation and Storage Tanks directions.

A stamped label is enclosed for your records. Please submit one (1) copy of the final printed label to the Agency before you release this product for shipment. If 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)

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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 rubber gloves. Harmful if swallowed and/or if absorbed through the skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing before reuse.

FIRST AID

Call a poison control center or doctor for treatment advice.

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: 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.

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

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

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

ACCEPTED
with COMMENTS
in Final Letter Dated:

OCT 29 2001

Under the Federal Insecticide,
Fungicide and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 6836-136

LONZA FORMULATION S-18F

One-Step Disinfectant

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

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

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

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

For use in federally inspected meat and poultry plants

An effective sanitizer for use on food contact surfaces

- Staphylocidal • Pseudomonacidal
- Salmonellacidal • Fungicidal • Virucidal*

Active Ingredients:

Octyl decyl dimethyl ammonium chloride.....	3.255%
Dioctyl dimethyl ammonium chloride	1.302%
Didecyl dimethyl ammonium chloride.....	1.953%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride.....	4.340%
Inert Ingredients:	89.150%
Total:	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER
(PELIGRO)

SEE LEFT/ SIDE/ RIGHT/ BACK PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS and FIRST AID

EPA Reg. No. 6836-136

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

Net Contents (insert container size here)

Manufactured by:

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

This product contains no phosphorous.

When used as directed, **LONZA FORMULATION S-18F** will 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.

Cross-contamination is of major housekeeping concern. **LONZA FORMULATION S-18F** 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-18F** in federally inspected meat and poultry plants; USDA category D2 - a sanitizer for all surfaces not always requiring a rinse.

LONZA FORMULATION S-18F delivers non-acid cleaning performance in an economical concentrate. Effective, yet economical, **LONZA FORMULATION S-18F** is a heavy-duty disinfectant cleaner that disinfects, cleans and deodorizes in one labor saving step.

LONZA FORMULATION S-18F is an economical concentrate that can be diluted for use with a mop and bucket, trigger sprayers, sponge or by soaking.

LONZA FORMULATION S-18F improves labor results by effectively controlling malodors.

LONZA FORMULATION S-18F delivers non-acid disinfectant performance in an economical concentrate.

Use **LONZA FORMULATION S-18F** for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures and toilet bowls.

Use **LONZA FORMULATION S-18F** to clean and disinfect finished floors, sinks and tubs.

Use **LONZA FORMULATION S-18F** in kitchens, bathrooms and other household areas.

LONZA FORMULATION S-18F 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.

LONZA FORMULATION S-18F will not leave grit or soap scum.

LONZA FORMULATION S-18F is a versatile disinfectant for Veterinarian, Animal Care and Farm Premise applications.

LONZA FORMULATION S-18F is a complete, chemically balanced disinfectant and sanitizer that provides clear use solutions even in the presence of hard water.

LONZA FORMULATION S-18F deodorizes by killing microorganisms that cause offensive odors.

Use **LONZA FORMULATION S-18F** as a disinfectant on hard, nonporous surfaces.

Use **LONZA FORMULATION S-18F** as a commercial sanitizer on dishes, glassware, and utensils.

Use **LONZA FORMULATION S-18F** as a sanitizer in bottling and beverage dispensing equipment.

Use **LONZA FORMULATION S-18F** as a sanitizer in sanitary filling of bottles and cans.

Use **LONZA FORMULATION S-18F** in sanitizing bottles or cans in the final rinse application, and for external spraying of filler and closing machines.

Use **LONZA FORMULATION S-18F** as a sanitizer in beer fermentation and holding tanks.

Use **LONZA FORMULATION S-18F** for sanitizing and disinfecting of ultrasound transducers, probes, mammography compressor plates and other hard nonporous surfaces.

Use **LONZA FORMULATION S-18F** as a Hatching-Egg sanitizer, with best results achieved in water temperatures ranging from 78°-110°F. **LONZA FORMULATION S-18F** may be applied through automatic washing systems, immersion tanks, foaming apparatus and low-pressure sprayers.

Use **LONZA FORMULATION S-18F** on coils and drain pans of air conditioning and refrigeration equipment and heat pumps. Follow the directions for sanitization of non-food contact surfaces.

LONZA FORMULATION S-18F is a versatile cleaner and broad-spectrum disinfectant formulated for use only on non-critical instruments in Ultrasonic Baths (Ultrasonic cleaning units).

Use **LONZA FORMULATION S-18F** to clean and disinfect nonporous salon / barber tools and instruments: combs, brushes, scissors, blades and manicure instruments.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 29 2001

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 6836-136

Use **LONZA FORMULATION S-18F** to clean and disinfect finished floors. Can be applied with damp mop or autoscrubber. Cleans and disinfects without dulling gloss. To limit gloss reduction, use **LONZA FORMULATION S-18F** at 1 oz. per gallon.
Do not use on floor finish at 4 oz. per gallon.

Use **LONZA FORMULATION S-18F** in homes, hospitals, medical and dental offices, nursing homes, day care centers, nurseries, restaurants, bars, cafeterias, institutional kitchens, food preparation and storage areas, convenience stores, food storage areas, public rest rooms, institutions, schools and colleges, athletic facilities, locker rooms, dressing rooms, shower and bath areas, exercise facilities, camp grounds, play grounds, public facilities, food processing plants, USDA inspected food processing facilities, dairy farms, hog farms, poultry and turkey farms, egg processing plants, kennels, pet animal quarters, zoos, pet shops, animal laboratories, transportation terminals, hotels and motels, factories, business and office buildings, barber shops, salons, boats, ships, campers, trailers, mobile homes, cars, buses, trains, taxis, airplanes and ultrasonic baths.

Use **LONZA FORMULATION S-18F** on washable hard, nonporous surfaces: floors, walls, countertops, stovetops, sinks, appliances, refrigerators, dishes, glassware, silverware, cutlery and other eating and cooking utensils; plastic and other nonporous cutting boards and chopping blocks; coolers, ice chests; refrigerator meat, fruit, vegetable and egg bins; Tupperware®, Kitchen equipment, food processors, blenders, slurry machines, beer fermentation and holding tanks, bottling or premix dispensing equipment, cabinets, highchairs, garbage cans, refrigerated storage and display equipment, tables, picnic tables, outdoor furniture, chairs, desks, telephones, doorknobs, shower stalls, tubs and glazed tiles, **whirlpool bathtubs**, toilets, bathtubs, sinks, urinals, toilet bowls, toilet bowl surfaces, other bathroom fixtures, kennel runs, cages, coils and drain pans of air conditioning and refrigeration equipment and heat pumps, conductive flooring and hard nonporous surfaces made of metal, stainless steel, glazed porcelain, glazed ceramic, sealed stone, fiberglass, plastic (such as polystyrene, polypropylene), **porcelain tiling**, enameled surfaces, finished woodwork, Formica®, vinyl and plastic upholstery.

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

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in EPA Letter Dated:

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. **6836-136**

Lonza Formulation S-18F
EPA Reg. No. 6836-136
EPA amendment 5/1/01

Use **LONZA FORMULATION S-18F** for Poultry Premise Sanitation (Hatcheries) of hard nonporous surfaces in: 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, Sidewalks and Floors, Drinkers and other Poultry House related equipment, and all other hard nonporous surfaces in the Hatchery environment.

Use **LONZA FORMULATION S-18F** for Swine Premise Sanitation of hard nonporous surfaces: Waterers and Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns and areas, Nursery blocks, Creep area, Chutes.

Use **LONZA FORMULATION S-18F** 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-18F 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-18F** 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-18F** should be limited to areas where compost and mushrooms are not present.

LONZA FORMULATION S-18F is effective against Citrus Canker Disease (*Xanthomonas axonopodis* pv. citri) at 2000-ppm active quat.

LONZA FORMULATION S-18F is effective against:
Avian Infectious Bronchitis Virus
Avian Influenza Virus
Canine Distemper Virus
Newcastle's Disease Virus
Pseudorabies Virus

LONZA FORMULATION S-18F 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), fungicidal, and inhibits the growth of mold and mildew and their odors when used as directed.

LONZA FORMULATION S-18F meets AOAC Use-Dilution Test Standards for hospital disinfectants.

LONZA FORMULATION S-18F is a one-step (Hospital use) disinfectant at 1:128 dilution (1 oz. per gallon), 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 (Acinetobacter)
Brevibacterium ammoniagenes (Brevibacterium)
Campylobacter jejuni (Campylobacter)
Enterobacter aerogenes
Enterococcus faecalis (Enterococcus)
Enterococcus faecalis - Vancomycin resistant (VRE)
Escherichia coli (E. coli)
Klebsiella pneumoniae (Klebsiella)
Pseudomonas cepacia (Pseudomonas)
Salmonella schottmuelleri (Salmonella)
Salmonella typhi (Salmonella)
Serratia marcescens
Shigella dysenteriae (Shigella)
Staphylococcus aureus Methicillin-Resistant (MRSA)
Staphylococcus aureus Multi-Drug Resistant
Staphylococcus aureus - Vancomycin Intermediate Resistant - (VISA)
Streptococcus pyogenes (Strep)
Vibrio cholerae

(Viruses:)

*Hepatitis B Virus (HBV)
*Herpes Simplex Virus Types 1 & 2 (Herpes)
*HIV-1 (the AIDS Virus)
*Influenza Type A / Brazil (Influenza)
*Respiratory Syncytial Virus (RSV)
*Vaccinia (Pox Virus)
*Adenovirus Type 5 (Adenovirus) at 1:32 dilution (4 oz. per gallon)

(Animal Viruses:)

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

(Fungi:)

Trichophyton mentagrophytes (the Athlete's Foot Fungus).
Aspergillus niger

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Lonza Formulation S-18F
EPA Reg. No. 6836-136
EPA amendment 5/1/01

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LONZA FORMULATION S-18F meets EPA's Sanitizer Test standards for non-food contact sanitizers at 200 ppm active, 1 oz. per 4 gallons, modified in the presence of 500 ppm hard water plus 5% organic serum. LONZA FORMULATION S-18F eliminates 99.9% of Staphylococcus aureus and Klebsiella pneumoniae in 60 seconds.

Lonza Formulation S-18F meets AOAC Germicidal & Detergent standards for previously cleaned food-contact surfaces.

LONZA FORMULATION S-18F is an effective sanitizer for use on food contact surfaces at 1 oz. per 4 - 5 1/2 gallons of water (200 - 150 ppm active quat) in waters up to 600 ppm hardness in 60 seconds against:

Escherichia coli
Staphylococcus aureus

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-18F 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 600 ppm of hardness calculated as CaCO₃ when evaluated by the AOAC Germicidal and Detergent Sanitizer Method against Escherichia coli and Staphylococcus aureus.

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Lonza Formulation S-18F has been cleared by the FDA in 21 CFR §178.1010 for use on food processing equipment, utensils and other food-contact articles.

Use Lonza Formulation S-18F as a sanitizer for all surfaces not always requiring a rinse in official establishments operating under the Federal meat, poultry, shell egg grading and egg products inspection programs.

Lonza Formulation S-18F is an effective fungicide against Trichophyton mentagrophytes (the athlete's foot fungus) when used on surfaces in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities.

LONZA FORMULATION S-18F is a mildewstat at 1:128 dilution (1 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.

Dilution:

Disinfection 1 oz. per gallon of water
Sanitizer 1 oz. per 4 gallons of water
..... (200 ppm active)
Sanitizer 1 oz. per 5 ½ gallons of water
..... (150 ppm active)

DIRECTIONS FOR USE

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

Preparation of Disinfectant Use-Solution:

Add (mix) 1 oz. per gallon of water (1:128).
For heavy duty use, add (mix) 8 oz. per gallon of water (1:16).

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.

DISINFECTION / VIRUCIDAL* DIRECTIONS:

Apply use-solution to hard, nonporous surfaces with a cloth, mop, sponge, sprayer or by immersion, thoroughly wetting surfaces.

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

Treated surfaces must remain wet for 10 minutes. Wipe dry with a cloth, sponge or mop or allow to air dry.

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

After use to disinfect food contact surfaces, rinse with potable water.

For heavily soiled areas, a preliminary cleaning is recommended.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 29 2001

Lonza Formulation S-18F Under the Federal Insecticide,
EPA Reg. No. 6836-136 Fungicide, and Rodenticide Act as
EPA amendment 5/1/01 amended, for the pesticide,
registered under EPA Reg. No. 6836-136

(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.

FUNGICIDAL DIRECTIONS:

For use in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities follow disinfection directions.

LONZA FORMULATION S-18F at 1 oz. per gallon in 250 ppm hard water and 5% serum is an effective one-step fungicide against Trichophyton mentagrophytes.

LONZA FORMULATION S-18F at 1 oz. per gallon in 400 ppm hard water is an effective fungicide against Trichophyton mentagrophytes (the athlete's foot fungus) when used on pre-cleaned surfaces.

MOLD AND MILDEW CONTROL: At 1 oz. per gallon, LONZA FORMULATION S-18F will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, nonporous surfaces. Follow disinfection instructions. Allow to air dry on surface. Repeat when mildew growth returns.

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

Remove gross filth prior to disinfection.

From Concentrate:

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

For Heavy Duty Use:

Empty toilet bowl or urinal and apply a 4 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.

TO CLEAN AND DEODORIZE: Mix 1 oz. per gallon of water to clean and deodorize surfaces. Apply using a cloth, mop, sponge or sprayer. Wipe or allow to air dry.

FOR USE ON FINISHED FLOORS: To limit gloss reduction use LONZA FORMULATION S-18F at 1 oz. per gallon. Apply with a damp mop or autoscrubber.

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

Mix 1 oz. of LONZA FORMULATION S-18F per gallon of water to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, rollers, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Fresh solution should be prepared daily or more often if solution becomes diluted or soiled.

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

ULTRASONIC BATH DISINFECTANT DIRECTIONS:

Use LONZA FORMULATION S-18F to disinfect hard nonporous non-critical objects compatible with Ultrasonic cleaning units. Pour fresh solution of 1 oz. of Lonza Formulation S-18F 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.

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with COMMENTS
in EPA Letter Dated:

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Under the Federal Insecticide,
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registered under EPA Reg. No. 6836-136

***KILLS HIV AND HBV 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)

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

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

CLEANING PROCEDURE: Blood and other body fluids containing HIV-1 or HBV must be thoroughly cleaned from surfaces and objects before application of LONZA FORMULATION S-18F.

CONTACT TIME: Leave surface wet for 1 minute (60 seconds) for HIV-1 and 10 minutes for HBV with a 1 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 oz. of Lonza formulation S-18F 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.

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 1 oz. of Lonza Formulation S-18F per 4 - 5 1/2 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.

TO SANITIZE FOOD CONTACT SURFACES: Use 1 oz. of Lonza Formulation S-18F per 4 - 5 ½ gallons of water (200 - 150 ppm active quat) for sanitizing and cleaning of equipment and utensils in food processing, dairy industry, bars, restaurants, institutional kitchens, meat and poultry processing plants and farms. Do not rinse with water. Allow to air dry.

For heavily soiled equipment or utensils, pre-wash with Lonza Formulation S-18F. Rinse with clean water. Then apply recommended dilution of Lonza Formulation S-18F with a cloth, coarse mechanical spray device (spray surface until thoroughly wetted) or immersion. Treated surfaces must remain wet for one minute. Prepare a fresh solution for every use. DO NOT reuse mechanically applied use solution for sanitizing.

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

Use Lonza Formulation S-18F 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 1 oz. of Lonza Formulation S-18F per gallon of 4 - 5 ½ gallons of water (or equivalent dilution) (200 - 150 ppm active) to pre-cleaned hard surfaces thoroughly wetting surfaces with a cloth, mop, sponge, sprayer or by immersion. Surfaces must remain wet for at least 60 seconds (one minute) followed by adequate draining and air drying. Prepare a fresh solution daily or more often if solution becomes visibly diluted, clouded or soiled. For mechanical application, use-solution may not be reused for sanitizing applications.

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

Immerse precleaned glassware, dishes, silverware, cooking utensils and other similar size food processing equipment in a use-solution of 1 oz. of Lonza Formulation S-18F per 4 - 5 ½ gallons of water (or equivalent dilution) (200 - 150 ppm active) for at least 60 seconds. Drain thoroughly and allow to air dry before reuse.

TO SANITIZE BEVERAGE DISPENSING EQUIPMENT:

1. Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing.
2. Fill equipment with a solution of 1 oz. Lonza Formulation S-18F per 4 - 5 ½ gallons of water (or equivalent dilution) (200 - 150 ppm active).
3. 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:

Prepare a use-solution of 1 oz. of Lonza Formulation S-18F per 4 - 5 ½ gallons of water (or equivalent dilution) (200 - 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.

TO SANITIZE BEER FERMENTATION AND STORAGE TANKS:

Prepare a use-solution of 1 oz. of Lonza Formulation S-18F per 4 - 5 ½ gallons of water (or equivalent dilution) (200 - 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 use-solution of 1 oz. of Lonza Formulation S-18F per 4 - 5 ½ gallons of warm water (or equivalent dilution) (200 - 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.

ACCEPTED
with COMMENTS
In EPA Letter Dated:

OCT 29 2001

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. **6836-136**

Lonza Formulation S-18F 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 must 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 1 oz. of Lonza Formulation S-18F per 4 - 5½ gallons of water (200 - 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 1 oz. of Lonza Formulation S-18F per 4 - 5½ gallons of water (200 - 150 ppm active quat) (or equivalent dilution) by rinsing, spraying or swabbing until thoroughly wet.
5. Allow sanitized surface to drain and air dry. Do not rinse.

**WISCONSIN STATE BOARD OF HEALTH
DIRECTIONS FOR EATING ESTABLISHMENTS**

1. Scrape and pre-wash utensils and glasses whenever possible.
2. Wash with a good detergent or compatible cleaner.
3. Rinse with clean water.
4. Sanitize in a use-solution of 1 oz. Lonza Formulation S-18F per 4 - 5½ gallons of water (200 - 150 ppm active) (or equivalent dilution). Immerse all utensils for at least two minutes or for contact time specified by governing sanitary code.
5. Place sanitized utensils on a rack or drain board to air-dry

TO SANITIZE BEVERAGE DISPENSING EQUIPMENT:

1. Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing.
2. Fill equipment with a solution of 1 oz. Lonza Formulation S-18F per 4 - 5½ gallons of water (or equivalent dilution) (200 - 150 ppm active quat).
3. Allow solution to remain in equipment for at least 60 seconds.
4. Drain thoroughly and allow to air dry before reuse.

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Lonza Formulation S-18F
EPA Reg No 6836-136
EPA amendment 5/1/01

**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 oz. of LONZA FORMULATION S-18F 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 1 oz. of LONZA FORMULATION S-18F 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. Then allow to air dry.

VEHICLES: Clean all vehicles including mats, crates, cabs and wheels with high pressure water and LONZA FORMULATION S-18F. Use 1 oz. of LONZA FORMULATION S-18F per gallon of water to treat all vehicles. Leave all treated surfaces wet for 10 minutes or more.

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 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.

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 oz. of Lonza Formulation S-18F 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.

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

For cleaning and disinfecting the following hard nonporous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. 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. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 1 oz. of LONZA FORMULATION S-18F per gallon of water (or equivalent dilution) for a period of 10 minutes. 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 oz. of LONZA FORMULATION S-18F 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.

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-18F 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 S-18F 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 though treatment of equipment. Effective against *Xanthomonas axonopodis* pv. citri (Citrus Canker Disease) at 2000 ppm active quat. Treat all equipment thoroughly with a dilution ratio of 1:109 (1.2 oz. of Lonza Formulation S-18F per gallon of water or 6 oz. of Lonza Formulation S-18F per 5 gallons of water, or equivalent dilution) (2000 ppm active quat). Treatments can be applied to outer clothing, shoes, trucks, attached trailers, field harvesting equipment including cargo area, wheels, tires, undercarriage, hood, roof, fenders, and any other part of the transportation equipment that can be taken into infested areas. To prevent the spread of Citrus Canker Disease by this artificial means of transportation, treatments are made by trigger spraying, dipping or brushing. After use, all surfaces that come in contact with food or crop must be rinsed with potable water. Clothing should be either rinsed or laundered before reuse. Footwear should be rinsed before reuse.

for a period
of 10 minutes
allows air
dry

Thoroughly clean all surfaces w/ soap or
detergent and rinse w/ potable water.

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(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 containers 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.

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