

6836-139

10/1/2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 1 2004

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

Subject: Lonza Formulation R-82F
EPA Registration No. 6836-139
Amendment Date: March 17, 2004
EPA Receipt Date: March 18, 2004

Dear Mr. Sloan,

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

- Addition of Bacterial Stability Claim

Conditions

Revise the label as follows:

1. Page 3: Specify that the picnic tables and Outdoor (patio) furniture are hard nonporous surfaces by stating *Non-wooden picnic tables and "Outdoor (patio) furniture except cushions and wood frames.*
2. Page 3: The new surfaces related to non-critical medical device/equipment surfaces should be deleted from the "Areas of Use" section and listed under the "Types of Surfaces" section.
3. Page 4: Since Ringworm is caused by several different fungi, revise the claim to read as "*Trichopyton mentagrophytes* (A cause of ringworm) or (A cause of ringworm of the foot).
4. Page 7: Revise the "Fogging Device Hatchery Room Sanitizer" and "Fogging Device Incubator and Hatcher Sanitizer" directions are incomplete. It would seem they needed to merged for completeness. It must read as follows:

Remove all animals and feed from premises, vehicles, and enclosures. Remove all litter and manure from floors, walls, and surfaces of the room to be treated. Empty all troughs,

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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

[For Hatchery Room: Mix two parts of product to five parts water (1 gallons to 2.5 gallons of water) Insert nozzle of fogger through suitable opening to room. With the setting in maximum output, for one minute for each 4000 cubic feet of space in the room]

[For Incubator and Hatcher: mix 12 oz per 116 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 1 oz per gallon on an hourly or every other hourly basis. If this solution is used, fog for 30-90 seconds once per hour or once every 2 hours.

When fogging is completed, ventilate buildings, and other closed spaces. Do not allow people to contact or breathe this fog. Do not house livestock or employ equipment until treatment has been absorbed or dried. Do not enter until fog has settled approx. 30-60 minutes after fogging is completed. Thoroughly scrub all treated feed racks, mangers, troughs, and rinse with potable water before reuse.

Note: Text is acceptable as presented.

5. Page 9: Revise the "Shoe Foam Directions" heading to read "Shoe Foam Sanitizer Directions." Also, revise the phrase, "to prevent tracking of harmful bacteria into animal areas" to state "*to prevent cross contamination into animal areas...*" under the "Shoe Bath and Shoe Foam" Sanitizer Directions.
6. Typographical Errors
 - Page 6: Under the "Bacterial Stability of Use-Dilution" directions, delete "Phenocide 256" and state "*Lonza Formulation R-82F*."
 - Page 10: Under Citrus Canker Disease Control," revise phrase "though treatment" to read "*through* treatment."
 - Page 11: Under the "U.S Public Health Service" heading, change "sanitzation" to read "*sanitization*."

Data Summary

Data Requirement	Means of Support	Status
DC-103F Aged Use Solution <i>P. aeruginosa</i>	Submitted study, MRID 460507-07	Acceptable, 1:256 use solution in diluted soft water effective for up to 1 yr stored sealed container

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 the State Water Board or Regional Office of the U.S. Environmental Protection Agency.

**ACCEPTED
with COMMENTS
in EPA Letter Dated:
OCT 1 2004**

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

6836-139

LONZA FORMULATION R-82F

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 • 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 ₁₆ , 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. 6836-139
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-82F:

- 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 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.
- 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.

Cross-contamination is of major housekeeping concern. **LONZA FORMULATION R-82F** 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-82F

- 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.
- as a disinfectant on hard, nonporous surfaces.
- in kitchens, bathrooms and other household areas.
- to clean and disinfect finished floors, sinks and tubs.
- with a mop and bucket, trigger sprayer, sponge or by soaking.
- for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures and toilet bowls.
- to clean and disinfect nonporous salon / barber tools and instruments: combs, brushes, scissors, blades and manicure instruments.
- for sanitizing and disinfecting of ultrasound transducers, probes, mammography compressor plates and other hard nonporous surfaces.
- to clean and disinfect finished floors. Can be applied with damp mop or autoscrubber. Cleans and disinfects without dulling gloss.
- on coils and drain pans of air conditioning and refrigeration equipment and heat pumps. Follow the directions for sanitization of non-food contact surfaces.
- for Poultry Premise Sanitation [Hatcheries]: Egg Receiving Area, Egg Holding Area; Setter Room, Tray Dumping Area, Trays, Buggies, Racks, Egg Flats, Chick Holding Room, Hatchery Room, Chick Processing Area, Chick Loading Area, Poultry Buildings, Ceilings, Sidewalls and Floors, Drinkers and other Poultry House related equipment, and all other hard, nonporous surfaces in the Hatchery environment.
- for Swine Premise Sanitation: Waterers and Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns and areas, Nursery blocks, Creep area, Chutes.
- for Farm Premise Sanitation of hard nonporous surfaces: floors, walls, feed racks, mangers, troughs, automatic feeders, fountains and waterers, forks, shovels, scrapers and other nonporous surfaces in barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals.

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

(AREAS OF USE:)

Use Lonza Formulation R-82F in:

Bathrooms
Homes [households]
Kitchens

Dental offices
Hospitals
Medical Offices
Nursing homes
Non-critical medical device surfaces
[Medical] [Hospital] Beds
Bed frames
Bed rails
Crutches
Non-critical [hospital] [medical]
equipment surfaces
[Medical] Examining tables
[Medical] [Hospital] Lamps
[Medical] [Hospital] Scales
Stands
Stethoscopes
Walkers
Wheel chairs

Day care centers
Nurseries

Bars
Cafeterias
Convenience stores
Egg Processing 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
Exercise facilities
Factories
Hotels
Institutional facilities
Institutions
Locker rooms
Motels
Prisons
Public facilities
Public rest rooms
Schools
Shower and bath areas
Salons [Beauty]

Camp grounds
Play ground equipment

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

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

(TYPES OF SURFACES:)

Use Lonza Formulation R-82F on
washable hard, nonporous surfaces
of:

Appliances
Bathroom fixtures
Bathtubs
Cabinets
Cages
Chairs
Coils and drain pans of air
conditioning and refrigeration
equipment and heat pumps
Conductive flooring
Counters [countertops]
Countertop laminates
Desks
Doorknobs
Floors
Foot Spas
Garbage cans
Highchairs
Kennel runs
Microwave ovens
Outdoor furniture,
Refrigerators
Refrigerated storage and display
equipment
Showers

[Fiberglass] Shower stalls
[Fiberglass] Sinks (bathroom, kitchen)
Stoves [stovetops]
Tables [picnic tables]
Telephones
Toilets
Toilet bowls
Toilet bowl surfaces
Tubs [Fiberglass]
Tiles, glazed
Ultrasonic baths
Urinals
Walls
Whirlpool bathtubs

Beer fermentation and holding tanks
Beverage dispensing equipment
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
Food dispensing equipment
Glassware
Ice Chests
Ice cream dispensing equipment [Soft
Serve]
Kitchen equipment
Refrigerator bins used for meat, fruit,
vegetables and eggs
Silverware
Slurpy Machines
Tupperware®

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.)

Use Lonza Formulation R-82F

- 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 R-82F** may be applied through automatic washing systems, immersion tanks, foaming apparatus and low-pressure sprayers.

Lonza Formulation R-82F 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-82F** 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-82F** should be limited to areas where compost and mushrooms are not present.

LONZA FORMULATION R-82F 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-82F eliminates 99.9% of *Staphylococcus aureus* and *Klebsiella pneumoniae* in 60 seconds.

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

LONZA FORMULATION R-82F is effective against:

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

LONZA FORMULATION R-82F 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.

(Note to reviewer: only one of the two use-dilution ranges will be used on a container label)

LONZA FORMULATION R-82F is an effective sanitizer for use on food contact surfaces at [½ oz. per 4 – 5 ½ gallons of water (200 – 150 ppm active quat)] (or) [½ oz. per 2 – 5 ½ gallons of water (400 – 150 ppm active quat)] in waters up to 500 ppm hardness in 60 seconds against:

Campylobacter jejuni
Escherichia coli
Staphylococcus aureus

LONZA FORMULATION R-82F is an effective sanitizer for use on food contact surfaces at [½ oz. per 4 gallons of water (200 active quat)] (or) [½ oz. per 2 – 4 gallons of water (400 – 200 ppm active quat)] in waters up to 500 ppm hardness in 60 seconds against:

Campylobacter jejuni
Escherichia coli
ESBL *Escherichia coli* – (Extended spectrum beta-lactamase producing *E. coli*)
Shigella sonnei
Staphylococcus aureus
Vibrio cholerae
Yersinia enterocolitica

LONZA FORMULATION R-82F is an effective sanitizer for use on food contact surfaces at [1 oz. per 5 ½ gallons of water (300 active quat)] (or) [1 oz. per 4 – 5 ½ gallons of water (400 – 300 ppm active quat)] in waters up to 500 ppm hardness in 60 seconds against:

Campylobacter jejuni
Escherichia coli
ESBL *Escherichia coli* – (Extended spectrum beta-lactamase producing *E. coli*)
Salmonella choleraesuis
Shigella sonnei
Staphylococcus aureus
Vibrio cholerae
Yersinia enterocolitica

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.

Articles that can be immersed in solution must remain in solution for 60 seconds.

Articles or surfaces too large for immersing should be thoroughly wetted or flooded by rinsing, spraying or swabbing.

Allow all sanitized surfaces to drain thoroughly [and air dry].

LONZA FORMULATION R-82F 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 500 ppm of hardness calculated as CaCO_3 when evaluated by the AOAC Germicidal and Detergent Sanitizer Method.

LONZA FORMULATION R-82F is a [one-step] [Hospital Use] disinfectant at 1:256 dilution [$\frac{1}{2}$ 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:]

Trichophyton mentagrophytes [the Athlete's Foot Fungus]
[cause of Ringworm]
Aspergillus niger

Dilution:

Disinfection (1:256).....	1/2 oz. per gallon of water
Sanitizer (1:512)	1 oz. per 4 gallons of water
.....	[400 ppm active]
Sanitizer (1:723)	1 oz. per 5 1/2 gallons of water
.....	[300 ppm active]
Sanitizer (1:1024)	1/2 oz. per 4 gallons of water
.....	[200 ppm active]
Sanitizer (1:1446)	1/2 oz. per 5 1/2 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.

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

Preparation of Disinfectant Use-Solution:

[Add] [Mix] 1/2 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.

For fungicidal activity, Lonza Formulation R-82F 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-82F is a one-step fungicide at 1/2 oz. per gallon in 250 ppm hard water and 5% serum.

At 1/2 oz. per gallon in 400 ppm hard water, Lonza Formulation R-82F must be used on precleaned surfaces.

For mold and mildew Repeat treatment every seven days, or more often if new growth appears.

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

(Note to reviewer: **ONE OF** the following two statements will be used.)

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

(or)

BACTERICIDAL STABILITY OF USE-DILUTION: Tests confirm that Phenocide 256, when diluted in soft water [via use of automatic dispensing devices], remains effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella choleraesuis* for [up to 7 days] [[up to one week] [for up to one month] [up to 2 months] [up to 3 months] [to 4 months] [to 5 months] [up to 6 months] [up to 7 months] [up to 8 months] [up to 9 months] [up to 10 months] [up to 11 months] [up to 12 months] [up to one year] when stored in a sealed container such as a spray bottle. If product becomes visibly dirty or contaminated, the use-dilution must be discarded and fresh product prepared. Always use clean, properly labeled containers when diluting this product. Bactericidal stability of the use-dilution does not apply to open containers such as buckets or pails.

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

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

(or)

This product is not for use on medical device surfaces.

TO CLEAN AND DEODORIZE: Mix 1/2 oz. of Lonza Formulation R-82F 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 1/2 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 1/2 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, allow to stand for 10 minutes, brush or swab thoroughly and flush.

FOR USE ON FINISHED FLOORS: To limit gloss reduction use **LONZA FORMULATION R-82F** at ½ 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-82F** per gallon of water [1/4 oz. [7.5 ml] of **LONZA FORMULATION R-82F** 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-82F** to disinfect hard nonporous, non-critical objects compatible with Ultrasonic cleaning units. Pour fresh use-solution of ½ 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 (BATH(S) (UNITS)) [FOOT SPAS]:

After using the [whirlpool [bath] [unit]] [foot spa], drain and refill with fresh water to [just cover the intake valve] [cover the highest jet] [2 inches above the highest jet]. Add ½ oz. of **Lonza Formulation R-82F** for each gallon of fresh water added. Start the pump to circulate the solution. Wash down [the [deck] [seat of chair lift] [any related equipment]] [and] any uncovered surfaces on the [bath] [unit] [foot spa] with a clean swab, brush or sponge with the solution. Treated surfaces must remain wet for 10 minutes. After the [bath] [unit] [foot spa] has been thoroughly disinfected, drain and rinse surfaces with fresh water. Wipe dry with a clean sponge or cloth or allow to air dry. Repeat for heavily soiled units.

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

After using the [whirlpool (bath) (unit)] [foot spa], drain and refill with fresh water to (just cover the intake valve) (cover the highest jet) (2 inches above the highest jet). Add ½ ounce of **Lonza Formulation R-82F** for each 2 - 4 gallons of fresh water added. Start the pump to circulate the solution. Wash down the [(deck) (seat of chair lift) (any related equipment) and] any uncovered surfaces on the (bath) (unit) (foot spa) with a clean swab, brush or sponge with the solution. Treated surfaces must remain wet for at least 60 seconds. Drain bath and wipe dry with a clean sponge or cloth or allow to air dry.

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

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

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

Cleaning procedure: Blood and other body fluids containing HIV or HBV or HCV must be thoroughly cleaned from surfaces and objects before application of **LONZA FORMULATION R-82F**.

Contact time: Leave surface wet for 1 minute [60 seconds] for HIV-1 and 10 minutes for HBV and HCV. 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] ½ oz. of **Lonza Formulation R-82F** 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-82F 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-82F per gallon of water [or equivalent dilution] for a period of 10 minutes. Wipe or allow to air dry. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. Rinse all surfaces that come in contact with food, including equipment used for feeding or watering, with potable water before reuse. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

FARM PREMISE USE:

Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with a use-solution of ½ oz. of LONZA FORMULATION R-82F 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-82F 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-82F 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.

FOGGING DEVICE HATCHERY ROOM SANITIZER DIRECTIONS:

Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of the room to be treated. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Close room off so fog is confined to room to be treated. Mix two parts of LONZA FORMULATION R-82F to five parts water [1 gallon of LONZA FORMULATION R-82F to 2.5 gallons water] [or equivalent dilution]. Insert the nozzle of the fogger through a suitable opening into the room. With the setting in maximum output, for one minute for each 4000 cubic feet of space in the room. Do not allow people to contact or breathe this fog and do not enter until the fog has settled (30 - 60 minutes after fogging is completed).

**FOGGING DEVICE INCUBATOR AND HATCHER
SANITIZER DIRECTIONS:**

Mix 12 ounces **LONZA FORMULATION R-82F** to 116 ounces water [or equivalent dilution]. Fog 3 - 8 ounces of this into setters and hatchers immediately after transfer. Repeat daily in setters and every 12 hours in hatchers. Discontinue hatchers treatments at least 24 hours prior to pulling the hatch. It is acceptable to fog setters and hatchers with a 1 ounce per gallon [or equivalent dilution] solution of **LONZA FORMULATION R-82F** on an hourly or every other hour basis. If this is done, fog for 30 - 90 seconds once per hour or once every two hours. When fogging is completed, ventilate buildings, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse. **Do not allow people to contact or breathe this fog and do not enter until the fog has settled (30 - 60 minutes after fogging is completed).**

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

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

VEHICLES: Treat all vehicles including mats, crates, cabs and wheels with water and **LONZA FORMULATION R-82F**. Use ½ oz. of **LONZA FORMULATION R-82F** 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 ½ 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 DIRECTIONS:

To prevent tracking harmful organisms into animal areas, and the packaging and storage areas of food plants. Apply a foam layer approximately ½ to 2 inches thick made from a solution of ½ oz. of **LONZA FORMULATION R-82F** per 2 - 5 ½ gallons of water [400 - 150 ppm active quat] [or equivalent dilution], at all entrances to buildings, hatcheries, production and packaging rooms by using a foam generating machine or aerator to apply the foam layer. Follow the foaming directions as specified by the manufacturer of the foam generator or aerator. Scrape waterproof work [boots] [shoes]. Stand or walk through foamed area for 60 seconds prior to entering area. Wash and replace Foam Area at least daily or more often if the Foam Area appears diluted or soiled.

DRESSING PLANT DISINFECTANT DIRECTIONS:

Disinfect equipment, utensils, walls and floors in poultry and animal dressing plants. Disinfect offal rooms, exterior walls and loading platforms of dressing plants. Cover or remove all food and packaging materials. Remove all heavy soils prior to application. Saturate all surfaces with a ½ 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.

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 ½ oz. of **Lonza Formulation R-82F** 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 1 oz. of **Lonza Formulation R-82F** per gallon of water. Heavily soiled areas may require repeated cleaning before treatment.

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

CITRUS CANKER DISEASE CONTROL:

For prevention of Citrus Canker Disease through treatment of 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 part of the transportation 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-82F per gallon of water] [or] [6 oz. of Lonza Formulation R-82F 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. On a final printed label, **ONLY ONE** dilution rate will be used in the sections below that contain a choice of dilution rates in the sanitization directions.]

either:

½ oz. Lonza Formulation R-82F per 4 – 5 ½ gallons of water (200 – 150 ppm active quat) [or equivalent dilution]

(or)

½ oz. Lonza Formulation R-82F per 2 – 5½ gallons of water (400 – 150 ppm active quat) [or equivalent dilution]

or

½ oz. Lonza Formulation R-82F per 4 gallons of water (200 active quat) [or equivalent dilution]

(or)

½ oz. Lonza Formulation R-82F per 2 – 4 gallons of water (400 – 200 ppm active quat) [or equivalent dilution]

or

1 oz. Lonza Formulation R-82F per 5 ½ gallons of water (300 active quat) [or equivalent dilution]

(or)

1 oz. Lonza Formulation R-82F per 4 – 5½ gallons of water (400 – 300 ppm active quat) [or equivalent dilution]

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 R-82F 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 [insert dilution from dilution box] to pre-cleaned 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 coarse spray.

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

TO SANITIZE [BEVERAGE] [SOFT SERVE ICE CREAM] [OTHER FOOD] DISPENSING EQUIPMENT:

1. Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing.
2. Fill equipment with a solution of [insert dilution from dilution box].
3. Allow solution to remain in equipment for at least 60 seconds.
4. Drain thoroughly [and allow to air dry] before reuse.

TO SANITIZE SANITARY FILLING EQUIPMENT:

Wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing. Prepare a use-solution of [insert dilution from dilution box] 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:

Wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing. Prepare a use-solution of [insert dilution from dilution box] 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 [insert dilution from dilution box]. 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 R-82F 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 [insert dilution from dilution box] 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 [insert dilution from dilution box] 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 [insert dilution from dilution box]. 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

NOTE: A clean potable water rinse following sanitization is not permitted under Section HFS 196.13 of the Wisconsin Administrative Code.

(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.