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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 13, 2001

MEMORANDUM

Subject: Efficacy Review for Lonza Formulation R-82
EPA Reg. No. 6836-78
DP Barcode: D270703
Case No. 023295

From: Ibrahim S. Barsoum, Ph.D., Microbiologist Ibrahim S. Barsoum 3/13/01
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To: Velma Noble PM 31/Jackie Campbell
Regulatory Management Branch I
Antimicrobial Division (7510C)

Applicant: LONZA, Inc..
Fair Lawn, NJ, USA

Formulation From Label:

Active Ingredient(s)	% by wt
Octyl decyl dimethyl ammonium chloride	6.510%
Dioctyl dimethyl ammonium chloride	2.604%
Didecyl dimethyl ammonium chloride	3.906%
Alkyl dimethyl benzyl ammonium chloride	8.680%
Inert Ingredient(s)	78.300%
Total	100.000%

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BACKGROUND:

Registrant has submitted new efficacy data (MRID # 452658-01) in support of HBV virucidal claim using the in-vitro Duck HBV assay. This study was conducted by an independent lab (MicroBiotest) in order to validate the previously submitted in-vivo efficacy data against DHBV performed by Hepadnavirus Testing Inc. on January 28, 2000 on Lonza formulation R-82F.

DATA SUMMARY:

MRID #	452658-01
Project ID #	163-110
Study Completed on:	October 27, 2000
Test Method Used:	Virucidal Effectiveness Test Using Duck Hepatitis B Virus Test.
Author:	Nicole L. Braddock
Performing Lab:	MicroBiotest, Inc. 105B Carpenter Drive, Sterling, VA 20164

BRIEF DESCRIPTION OF TEST:

Test Material Preparation:

0.2 ml of a stock of Duck Hepatitis B virus (DHBV) was spread on sterile glass petri dish carriers and dried for 30 - 60 minutes at room temperature. 2 ml of each of two lots (Lots No. 90048 and 90049) of Lonza Formulation R-82F (1:256 diluted in 400 ppm AOAC hard water) were added on two carriers for 10 minutes at 20 ± 2C. After the contact time, the virus-disinfectant mixture was neutralized with 2ml of 5% FBS, scraped from the surface and loaded onto a sephacryl columns for further neutralization. Serial tenfold dilutions were prepared from the neutralized virus in cell culture medium (CCM).

Infectivity Assay:

Serially diluted samples (tests 10^{-1} - 10^{-6} and controls 10^{-1} - 10^{-8}) were added to Microtiter plate wells containing primary duck hepatocyte (PDH) and incubated overnight at 37 ± 2C in 5% CO_2. The plates were incubated for 7 - 14 days at 37 ± 2C in 5% CO_2 with replacement of CCM on alternate days. Following incubation, media was aspirated, wells were washed with PBS, fixed in alcohol, washed and stained with monoclonal anti-DHBV, incubated for 2 hrs, washed and counter stained with anti-mouse-FITC, incubated for 2 hrs, washed and scored using UV-microscopy. A quaternary ammonium compound (BTC 835) at 175 ppm and 350 ppm was used as a positive control along with the test substances Log_{10} reduction of the virus by the test substances vs control cultures was calculated using the Most Probable Number (MPN) method of statistical analysis.

RECOMMENDATIONS:

Efficacy Supported by the Data

Lonza Formulation R-82F (Lots No. 90048 and 90049) diluted 1:256 in 400 ppm AOAC hard water and added on two glass carriers carrying Duck hepatitis B virus for a 10 minutes contact time at 20 ± 2C proved to be virucidal against DHBV when tested in an in-vitro assay using duck primary hepatocyte cultures. All controls, including neutralizer effectiveness, cytotoxicity, plate and column recovery of the virus, virus stock titer, and cell viability all met the established criteria for a valid test (FR Notice OPP-00673; FRL-6736-5 and DIS/TSS-7). The $\log_{10}$ reduction (LR) of infectious DHBV fluorescent focus forming units (FFFU) determined using the Most Probable Number (MPN) method of analysis was 4.68 with a Standard Error (SE) of 0.12 and is therefore acceptable. A positive control (BTC 835) showed complete killing of the virus at all dilutions tested at 350 ppm and partial killing of the virus at 175 ppm concentration as expected.

LABELING REVIEW:

1- Page 2:

The label claim "Lonza formulation R-82 is recommended for use in federally inspected meat and poultry plants" should be deleted from the label. Although prior authorization from USDA is no longer required, all formulations must be cleared under 21 CFR 178.1010 as sanitizing solutions for food contact surfaces or have a tolerance / exemption from the requirement of a tolerance in 40 CFR Part 180 that covers use as a sanitizing solution for food contact surfaces.

2- Page 3:

Left panel, 5th claim: delete "AOAC" and replace with "EPA" as previously requested by the Agency in a letter dated December 13, 1999.

3- Other recommendations for label modification requested by the Agency in a letter dated December 13, 1999 have been included in the new label.

(C:\copies of reviews\ EPA Reg. No. 6836-78, DP Barcode D270703,Lonza R-82)

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

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention.
IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, or gelatin solution; or if these are not available, drink large quantities of water. Avoid alcohol.
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

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

ENVIRONMENTAL HAZARDS

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

(If container is one gallon or less, use the following storage and disposal statements:)

STORAGE AND DISPOSAL

Do not store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Discard in trash or recycle.

(If container is greater than one gallon, use the following storage and disposal statements:)

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.

LONZA
FORMULATION R-82

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

Effective in hard water up to 400 ppm hardness (calculated as $CaCO_3$) in the presence of 5% serum contamination

Formulated for Effective Poultry Premise Sanitation
Formulated for Effective Swine Premise Sanitation
Formulated for Effective Farm Premise Use

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%
Inert Ingredients:	78.300%
Total	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

SEE LEFT/ SIDE/ RIGHT/ BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 6836-78
EPA Est. No. (as *indicated on container)*
Net Contents: *(insert container size here)*

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:
APR 26 2001

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 6836-78

This product contains no phosphorous

When used as directed, **LONZA FORMULATION R-82** will clean and deodorize surfaces in 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 R-82** has been formulated to aid in the reduction of cross-contamination not only in hospitals, but in schools, institutions and industry. should be deleted

LONZA FORMULATION R-82 is recommended for use in federally inspected meat and poultry plants. This product is recommended for use in Dressing Plants as a disinfectant.

LONZA FORMULATION R-82 delivers unsurpassed non-acid cleaning performance in an economical concentrate. Effective, yet economical, **LONZA FORMULATION R-82** is a heavy duty disinfectant cleaner that disinfects, cleans and deodorizes in one labor saving step.

LONZA FORMULATION R-82 is an economical concentrate that can be diluted for use with a mop and bucket, trigger sprayers, sponge or by soaking.

LONZA FORMULATION R-82 improves labor results by effectively controlling malodors.

LONZA FORMULATION R-82 delivers non-acid disinfectant performance in an economical concentrate.

LONZA FORMULATION R-82 is recommended for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures and toilet bowls.

Use **LONZA FORMULATION R-82** to clean and disinfect finished floors, sinks and tubs.

LONZA FORMULATION R-82 is for use in kitchens, bathrooms and other household areas.

LONZA FORMULATION R-82 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 R-82 will not leave grit or soap scum.

LONZA FORMULATION R-82 is a versatile disinfectant and sanitizer for hard nonporous, nonfood contact surfaces in Veterinarian, Animal Care and Farm Premise applications.

LONZA FORMULATION R-82 is recommended for use 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 R-82 is a versatile cleaner and broad spectrum disinfectant formulated for use on non-critical instruments in Ultrasonic Baths (Ultrasonic cleaning units).

Use **LONZA FORMULATION R-82** to clean and disinfect nonporous salon (barber) tools and instruments: combs, brushes, scissors, blades and manicure instruments.

Use **LONZA FORMULATION R-82** to clean and disinfect finished floors. Can be applied with a damp mop or autoscrubber. Cleans and disinfects without dulling gloss.
To limit gloss reduction use **LONZA FORMULATION R-82** at ½ oz. per gallon.
Do not use on floor finish at 2 oz. per gallon.

LONZA FORMULATION R-82 is for use in hospitals, homes, medical and dental offices, nursing homes, day care centers, nurseries, restaurants, bars, cafeterias, institutional kitchens, convenience stores, food storage areas, public rest rooms, institutions, schools, athletic facilities, camp grounds, food processing plants, dairy farms, hog farms, poultry and turkey farms, kennels, pet animal quarters, zoos, pet shops, animal laboratories, transportation terminals, hotels and motels, business and office buildings, boats, ships, campers, trailers, mobile homes, cars, buses, trains, taxis, airplanes.

LONZA FORMULATION R-82 is for use on the following washable hard, nonporous surfaces: floors, walls, countertops, stovetops, sinks, appliances, refrigerators, cabinets, highchairs, garbage cans, refrigerated storage and display equipment, tables, picnic tables, outdoor furniture, chairs, desks, telephones, bed frames, doorknobs, shower stalls, tubs and tiles, whirlpool bathtubs, toilets, bathtubs, shower stalls, sinks, urinals, toilet bowls, toilet bowl surfaces, related fixtures, kennel runs, cages, coils and drain pans of air conditioning and refrigeration equipment and heat pumps, conductive flooring and other hard nonporous surfaces made of metal, glazed porcelain, glazed ceramic, fiberglass, and plastic, porcelain lining, stainless steel, enameled surfaces, finished woodwork, Formica®, vinyl and plastic upholstery.

LONZA FORMULATION R-82 is recommended 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.

LONZA FORMULATION R-82 is recommended for Swine Premise Sanitation: Waterers and Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns and areas, Nursery blocks, Creep area, Chutes.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

APR 26 2001

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 6836-78

LONZA FORMULATION R-82 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 R-82 is an effective one-step sanitizer-cleaner for use on non-food contact surfaces.

LONZA FORMULATION R-82 kills Pseudomonas aeruginosa (Pseudomonas), Pseudomonas cepacia (Pseudomonas), Staphylococcus aureus (Staph), Methicillin Resistant Staphylococcus aureus (MRSA), Vancomycin Intermediate Resistant Staphylococcus Aureus (VISA), Salmonella choleraesuis (Salmonella), Salmonella schottmuelleri (Salmonella), Salmonella typhi (Salmonella), Streptococcus pyogenes (Strep), Streptococcus faecalis (Enterococcus faecalis), Acinetobacter baumannii (Acinetobacter), Brevibacterium ammoniagenes (Brevibacterium), Enterobacter aerogenes, Escherichia coli (E. coli), Klebsiella pneumoniae (Klebsiella), Serratia marcescens, Shigella dysenteriae Shigella), Adenovirus Type 5 (Adenovirus), Hepatitis B Virus (HBV), HIV-1 (the AIDS Virus), Herpes Simples Virus Types 1 & 2 (Herpes), Influenza Type A / Brazil (Influenza), Vaccinia (Pox Virus), Trichophyton mentagrophytes (the Athlete's Foot Fungus).

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

LONZA FORMULATION R-82 meets ~~AOAC~~ EPA Use-Dilution Test Standards for hospital disinfectants.

LONZA FORMULATION R-82 meets EPA Sanitizer Test standards for non-food contact sanitizers.

LONZA FORMULATION R-82 is effective against Avian Influenza virus, Avian Infectious Bronchitis Virus, Pseudorabies Virus, Canine Distemper Virus, Newcastle's Disease Virus.

LONZA FORMULATION R-82 is a Hospital Use Disinfectant at 1:256 dilution (½ 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:

Pseudomonas aeruginosa	Brevibacterium ammoniagenes
Pseudomonas cepacia	Enterobacter aerogenes
Staphylococcus aureus	Escherichia coli
Salmonella choleraesuis	Klebsiella pneumoniae
Salmonella schottmuelleri	Serratia marcescens
Salmonella typhi	Shigella dysenteriae
Streptococcus pyogenes	Vibrio cholerae
Acinetobacter baumannii	

Enterococcus faecalis- Vancomycin Resistant – VRE
Staphylococcus aureus - Methicillin-Resistant – MRSA
Staphylococcus aureus - Multi-Drug Resistant
Staphylococcus aureus-Vancomycin Intermediate Resistant – VISA

*Hepatitis B Virus (HBV)
*Herpes Simplex Virus Types 1 & 2
*HIV-1 (AIDS Virus)
*Influenza Type A / Brazil
*Vaccinia (Pox Virus)
*Adenovirus Type 5 at 1:64 dilution (2 oz. per gallon)

LONZA FORMULATION R-82 is a sanitizer for hard nonporous non-food contact surfaces at 1:1024 dilution (200 ppm active, ½ oz. per 4 gallons) according to the method for Sanitizers - Non-Food Contact Surfaces, modified in the presence of 500 ppm hard water plus 5% organic serum in 60 seconds against:

Klebsiella pneumoniae	Staphylococcus aureus

LONZA FORMULATION R-82 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.

ACCEPTED
with COMMENTS
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. 6836-78

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DIRECTIONS FOR USE

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

Preparation of Use-Solution:
Add (mix) ½ oz. per gallon of water (1:256) to disinfect hard, nonporous surfaces.
For heavy duty use, add (mix) 2 oz. per gallon of water (1:64) to disinfect hard, nonporous surfaces.

Disinfection / Virucidal* / Fungicidal / Mold and Mildew Control Directions:
Apply use-solution to hard, nonporous surfaces, thoroughly wetting surfaces with a cloth, mop, sponge or sprayer. Treated surfaces must remain wet for 10 minutes. Wipe dry with a cloth, sponge or mop. Prepare a fresh solution daily or more often if use-solution becomes diluted or soiled. Rinse all surfaces that come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse. This product should not be used to clean utensils, glassware and dishes.
For heavily soiled areas, a preliminary cleaning is recommended.
For sprayer applications, use a coarse spray device. Spray 6-8 inches from surface, rub with brush, sponge or cloth. Do not breathe spray.

(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 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.

Non-Acid Toilet Bowl Disinfectant / Cleaner Directions:
Remove gross filth prior to disinfection.
From Concentrate:
Add ½ oz. to the bowl and mix. Brush over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.
From Use-Solution:
Empty toilet bowl or urinal and apply ½ oz. per gallon use-solution to exposed surfaces and under the rim with a cloth, mop, sponge or mechanical spray. 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 and flush.

FOR USE ON FINISHED FLOORS: To limit gloss reduction use **LONZA FORMULATION R-82** at ½ oz. per gallon. Apply with a damp mop or autoscrubber.

FOR CLEANING AND DEODORIZING: Add use-solution to hard nonporous surfaces, thoroughly wetting surfaces with a cloth, mop, sponge or sprayer. Allow surfaces to air dry.

SALON (BARBER) INSTRUMENTS AND TOOLS DISINFECTION / VIRUCIDE / FUNGICIDE DIRECTIONS:
Mix 1 oz. (30 ml) of **LONZA FORMULATION R-82** per gallon of water (1/4 oz. [7.5 ml] of **LONZA FORMULATION R-82** per quart of water) to disinfect hard nonporous instruments and tools. Completely immerse combs, brushes, rollers, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Fresh solution should be prepared daily or more often if solution becomes diluted or soiled.
Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

FUNGICIDAL DIRECTIONS:
For use in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities follow disinfection directions.
LONZA FORMULATION R-82, at ½ oz. per gallon (1:256) in 250 ppm hard water and 5% serum, is an effective one-step fungicide against Trichophyton mentagrophytes
LONZA FORMULATION R-82, at ½ oz. per gallon of water (1:256), in 400 ppm hard water, is an effective fungicide against Trichophyton mentagrophytes (the athlete's foot fungus) when used on precleaned surfaces.

MOLD AND MILDEW: At ½ oz. per gallon, **LONZA FORMULATION R-82** will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, nonporous surfaces. Follow disinfection instructions. Allow to dry on surface. Repeat when mildew growth returns.

***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 or HBV must be thoroughly cleaned from surfaces and objects before application of **LONZA FORMULATION R-82.**
Contact time: Leave surface wet for 1 minute (60 seconds) for HIV-1 and 10 minutes for HBV with ½ 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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

APR 26 2001

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 6836-78

SANITIZING NON-FOOD CONTACT SURFACE DIRECTIONS:
Add (mix) ½ oz. per 4 gallons of water to sanitize hard nonporous surfaces. Treated surfaces must remain wet for 60 seconds. Do not use in food preparation, food handling and food storage areas. This product is not to be used on glassware, dishware, cookware and utensils.

ULTRASONIC BATH DISINFECTANT DIRECTIONS:
Use **LONZA FORMULATION R-82** to disinfect hard nonporous objects compatible with Ultrasonic cleaning units.
Pour fresh solution at 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.

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 feeding or watering animals, 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 ½ oz. of **LONZA FORMULATION R-82** per gallon of water *(or equivalent dilution)* for a period of 10 minutes. Wipe or allow to air dry. 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-82 per gallon of water *(or equivalent dilution)* for a period of 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. Ventilate buildings, cars, boats and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

POULTRY AND SWINE PREMISE DISINFECTION DIRECTIONS:
Remove all animals and feeds from premises, vehicles and enclosures such as coops and crates. Remove all litter, droppings and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Use ½ oz. of **LONZA FORMULATION R-82** per gallon of water. Saturate surfaces with the recommended disinfecting solution for 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

Hatcheries: Use ½ oz. of **LONZA FORMULATION R-82** per gallon of water to treat hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard nonporous surfaces. Leave all treated surfaces wet for 10 minutes or more. Wipe dry with a clean cloth or sponge or allow to air dry.

Vehicles: Clean all vehicles including mats, crates, cabs and wheels with high pressure water and **LONZA FORMULATION R-82**. Use ½ oz. of **LONZA FORMULATION R-82** per gallon of water to treat all vehicles. Leave all treated surfaces wet for 10 minutes or more. Wipe dry with a clean cloth or sponge or allow to air dry.

Shoe Bath Sanitizer Directions: To prevent tracking harmful organisms into animal areas, shoe baths containing one inch of freshly made solution should be placed at all entrances to buildings and hatcheries. Scrape waterproof work boots and place in a ½ oz. per gallon of water solution for 60 seconds prior to entering area. Change the solution in the bath daily or when 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 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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

APR 26 2001

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 16836-78

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