

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP - 4 1997

Lonza, Inc.
17-17 Rte. 208
Fair Lawn, NJ 07410

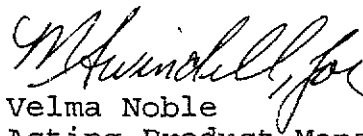
ATTN: Eliot Harrison, Agent for Lonza

SUBJECT: Lonza Formulation S-38
EPA Registration No. 6836-73
Amendment Dated June 3, 1997

Dear Mr. Harrison:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records. If you have any further questions, please contact Ms. Barbara Pringle at (703) 308-6236.

Sincerely,



Velma Noble
Acting Product Manager 31
Regulatory Management Branch I
Antimicrobial Division (7510W)

CONCURRENCES

SYMBOL	7510W						
SURNAME	Pringle						
DATE	9-3-97						

Precautionary Statements**Hazards to Humans and Domestic Animals**

DANGER. Corrosive. Causes eye and skin damage. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed. Avoid contamination of food.

STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse.

If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution; or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

(If the container size is 5 gallons or greater, use the following Environmental Hazards Statements)

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 EPA Letter Dated:

SEP - 4 1997

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

6836-73

LONZA FORMULATION S-38

Disinfectant-Cleaner-Sanitizer-Fungicide-Mildewstat-Virucide*-Deodorizer
with Organic Soil Tolerance
for Hospitals, Institutional, Commercial, Home, Farm and Industrial Use
Acid-Free Cleaner
Acid-Free Disinfectant

Active Ingredients

Octyl decyl dimethyl ammonium chloride	1.140%
Dioctyl dimethyl ammonium chloride	0.456%
Didecyl dimethyl ammonium chloride	0.684%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₈ , 10%) dimethyl benzyl ammonium chloride	1.520%

Inert Ingredients

98.200%
100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

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

EPA Reg. No. 6836-73

EPA Est. No. 6836-IL-1

Net Contents (insert container size here)

Manufactured by:

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

Kills HIV-1 on precleaned environmental surfaces/objects previously soiled with blood/body fluids.

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

LONZA FORMULATION S-38 is authorized by the USDA for use in inedible product processing areas, nonprocessing areas, and/or exterior areas in official establishments operating under the Federal meat, poultry, shell egg grading, and egg products inspection programs.

LONZA FORMULATION S-38 is a one-step disinfectant cleaner that is effective against a broad spectrum of bacteria, is virucidal (including HIV-1), fungicidal, and inhibits the growth of mold and mildew and their odors when used as directed.

LONZA FORMULATION S-38 is a proven "one-step" cleaner-disinfectant-sanitizer-fungicide-mildewstat-virucide in the presence of moderate amounts of organic soil.

When used as directed, LONZA FORMULATION S-38 will 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 mal odors.

LONZA FORMULATION S-38 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, exercise facilities.

LONZA FORMULATION S-38 is recommended for use in hospitals, medical and dental offices, nursing homes, public rest rooms, institutions, schools, colleges, athletic facilities, food processing plants, food storage areas, kitchens, restaurants and bars, airports, transportation terminals, hotels and motels.

This product contains no phosphorous.

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an amendment to the pesticide,
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6836-73

LONZA FORMULATION S-38 is an alkaline pH disinfectant cleaner that disinfects, cleans and deodorizes in one labor-saving step.

LONZA FORMULATION S-38 can be used with a mop and bucket, trigger sprayers, sponge, or by soaking.

LONZA FORMULATION S-38 effectively controls odors.

LONZA FORMULATION S-38 cleans, shines, deodorizes and disinfects all non-porous household surfaces. Inhibits the growth of mold and mildew, leaving bathrooms and kitchens clean and smelling fresh.

LONZA FORMULATION S-38 is recommended for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures, and toilet bowls.

LONZA FORMULATION S-38 is for use in kitchens, bathrooms and other household areas.

LONZA FORMULATION S-38 kills household germs in minutes; effective against harmful pseudomonas, staph and strep, influenza A/Brazil and athlete's foot fungus.

LONZA FORMULATION S-38 is a multi-surface cleaner, deodorizer, and disinfectant. Use on windows, mirrors, and other glass surfaces.

Use LONZA FORMULATION S-38 on the multi-touch surfaces responsible for cross-contamination and infection.

Use LONZA FORMULATION S-38 on finished floors, high speed burnished floors, conductive flooring, tables, chairs, bathroom bowls, basins, countertops, bed rails, door knobs and handles, glass surfaces including windows and mirrors.

LONZA FORMULATION S-38 is recommended for Poultry Premise Sanitation (Hatcheries):

Egg Receiving Area	Tray Dumping Areas	Chick Processing Area
Egg Holding Area	Chick Holding Room	Chick Loading Area
Setter Room	Hatchery Room	Poultry Buildings

LONZA FORMULATION S-38 is recommended for Swine Premise Sanitation:

Farrowing Barns and Areas	Dressing Plants	Blocks
Waterers and Feeders	Loading Equipment	Creep Area
Hauling Equipment	Nursery	Chutes

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LONZA FORMULATION S-38 is a Hospital Use Disinfectant at 1:64 dilution (2 ounces per gallon) modified in the presence of 5% organic serum against

Pseudomonas aeruginosa
Salmonella choleraesuis
Staphylococcus aureus
Brevibacterium ammoniagenes
Enterobacter aerogenes
Escherichia coli
Enterococcus faecalis (vancomycin-resistant)
Staphylococcus aureus (methicillin-resistant)

Klebsiella pneumoniae
Salmonella schottmuelleri
Serratia marcescens
Shigella dysenteriae
Streptococcus faecalis
Pseudomonas cepacia

'HIV-1 (AIDS virus)
 Herpes Simplex Type 2
 Influenza A/Brazil

Herpes Simplex Type 1
 Vaccinia

Trichophyton mentagrophytes

LONZA FORMULATION S-38 is a sanitizer for hard porous and non-porous non-food contact surfaces at 1:256 dilution (0.5 ounce per gallon) according to the Sanitizer Test Method, modified in the presence of 300 ppm hard water and 5% organic serum against:

Klebsiella pneumoniae

Staphylococcus aureus

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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.

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.

Add 1-2 oz. of **LONZA FORMULATION S-38** per gallon of water. For heavy-duty use, add 8 oz. of **LONZA FORMULATION S-38** per gallon of water.

Apply use-solution to hard, non-porous surfaces, such as walls, floors, tables, chairs, countertops, sinks, toilet bowls, urinals, and bedframes, thoroughly wetting all surfaces with a cloth, mop, sponge or sprayer. For heavily soiled areas, a preliminary cleaning is required. For spray applications, use a coarse spray device. Spray 6-8 inches from surface, rub with brush, sponge or cloth. Do not breath spray mist. Treated surfaces must remain wet for 10 minutes. Prepare a fresh solution daily or when use solution becomes visible dirty.

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Disinfection Directions

For Hospitals, Medical and Dental Offices and Nursing Homes: Add 2 oz. per gallon of water. The activity of LONZA FORMULATION S-38 has been evaluated in the presence of 5% serum by the AOAC Use-Dilution Test and found to be effective against a broad spectrum of gram negative and gram positive organisms, as presented by:

<i>Pseudomonas aeruginosa</i>	<i>Enterobacter aerogenes</i>
<i>Staphylococcus aureus</i>	<i>Salmonella schottmuelleri</i>
<i>Salmonella choleraesuis</i>	<i>Streptococcus faecalis</i>
<i>Escherichia coli</i>	<i>Shigella dysenteriae</i>
<i>Serratia marcescens</i>	<i>Brevibacterium ammoniagenes</i>
<i>Klebsiella pneumoniae</i>	
<i>Pseudomonas cepacia</i>	
<i>Enterococcus faecalis</i> (vancomycin-resistant)	
<i>Staphylococcus aureus</i> (methicillin-resistant)	

For Schools, Public Rest Rooms, Athletic Facilities, Food Processing Plants, Food Storage Areas, Kitchens, Restaurants, Bars, Transportation Terminals, Hotels, Motels and Other Non-Medical Institutional and Industrial Uses: At 1 oz. per gallon of water, LONZA FORMULATION S-38 delivers cleaning and germicidal effectiveness. It is effective against *Staphylococcus aureus*, *Salmonella choleraesuis* and *Escherichia coli*. The same AOAC Use-Dilution Test to confirm performance for hospitals was used.

Fungicidal Performance

LONZA FORMULATION S-38 at 1 oz. per gallon of water 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, exercise facilities.

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Mold and Mildew Control

At 1 oz. per gallon of water, LONZA FORMULATION S-38 will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, non-porous surfaces (as indicated in general instructions above). Allow to dry on surface and repeat when mildew growth returns.

Virucidal Performance

At 1 oz. per gallon of water use level, LONZA FORMULATION S-38 was evaluated in the presence of 5% serum and found to be effective against the following viruses: Influenza A/Brazil, Herpes Simplex Types 1 and 2, HIV-1 (AIDS virus) and Vaccinia on inanimate hard non-porous environmental surfaces.

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

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

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

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

CONTACT TIME: Leave surface wet for 10 minutes with 1 oz. per gallon use-solution.

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.

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Poultry and Swine Premise Disinfectant

Remove all animals and feeds from premises, trucks, coops and crates. Remove all litter, droppings and manure from floors, walls and surfaces of facilities 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-38** per gallon of water. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes. Ventilate buildings, 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, 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-38** per gallon of water, to treat hatcheries, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces exposed to disinfectant solution for 10 minutes or more.

Vehicles:

Clean all vehicles including mats, crates, cabs and wheels with high pressure water and **Lonza Formulation S-38**. Use 1 oz. of **Lonza Formulation S-38** per gallon of water to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution for 10 minutes or more.

Shoe Bath Sanitizer Directions:

To prevent tracking of harmful organisms into animal areas, shoe baths containing one inch of freshly made disinfectant solution should be placed at all entrances to buildings and hatcheries. Scrape shoes and place in a 1 oz. of **Lonza Formulation S-38** per gallon of water solution for 60 seconds prior to entering area. Change the disinfectant solution in the bath daily or when solution appears dirty.

Dressing Plant Disinfectant Directions:

Disinfect equipment, utensils, walls and floors in poultry and animal dressing plants with a solution of 1 oz. of **Lonza Formulation S-38** per gallon of water. Equipment and utensils must remain wet for 10 minutes, then thoroughly rinsed with potable water before operations are resumed. Disinfect offal rooms, exterior walls and loading platforms of dressing plants.

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Non-Acid Toilet Bowl Disinfectant/Cleaner Directions:

From Concentrate

Add 1 -2 oz. to the bowl water and mix. Brush over exposed surfaces including under the rim. Allow to stand for 10 minutes and flush.

From Use-Solution

Empty toilet bowl or urinal and apply 1-2 ounces per gallon use-solution to exposed surfaces including 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 8 ounces 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.

Salon (Barber) Instruments and Tools Disinfectant Directions:

Use 1-2 oz. of LONZA FORMULATION S-38 per gallon of water (or 1/4-1/2 oz. of LONZA FORMULATION S-38 per quart of water). Completely immerse pre-cleaned combs, brushes, scissors, clipper blades, razors, manicure implements and other non-porous instruments so that surfaces remain wet for 10 minutes. Rinse thoroughly and dry before use. Change solution daily or when visibly dirty.

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.

Sanitizing Non-Food Contact Surfaces (such as floors, walls, tables, etc.)

At 0.5 ounce per gallon of water, LONZA FORMULATION S-38 is an effective sanitizer against Staphylococcus aureus and Klebsiella pneumoniae in the presence of 5% serum on porous and non-porous environmental surfaces. Treated surfaces must remain wet for 60 seconds.

Glass Cleaning/Deodorizing Directions:

Add 0.5-2 ounces of LONZA FORMULATION S-38 per gallon of water to clean and deodorize windows, mirrors, and glass surfaces. Use a coarse spray device. Spray 6-8 inches from surface, rub with sponge or cloth. Do not breath spray mist.

For Bag-in-Box Containers:

How to Use this package:

This package is designed to be used with the Green Earth Dilution Control System only. Open package and connect to dispense according to directions on box top.

Trigger Sprayers:

1. Fill bottle from dispenser.
2. Apply to surfaces as specified in directions above.

Mop Buckets:

1. Fill bucket from dispenser.
2. Setup "Wet Floor" signs.
3. Mop floor surface as specified in directions above.

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

STORAGE AND DISPOSAL

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

(If the container size 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.
- Do not store on side.
- Avoid creasing or impacting side walls.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or 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.

(For Bag-In Box Containers:) Completely empty bag into application equipment.

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