

JAN 2 1997

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

Attention: Eliot I. Harrison, Agent  
Lewis & Harrison

Subject: LONZA FORMULATION S-38  
EPA Registration No. 6836-73  
Your Amendment Dated April 29, 1996  
EPA Received Date May 1, 1996

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to remove redundant product labeling statements and replace the inadvertently removed Herpes Simplex Type 2 use claim, has been reviewed by the Agency and found to be acceptable provided that you make the following labeling changes before you release the product for shipment bearing the amended labeling.

1. At the bottom of the front panel, make a distinct asterisk preceding the HIV-1 reference as follows: "\* Kills HIV-1 on precleaned...".

2. On Page 2 of 6, place a comma after the word "fungicidal" in the second sentence of the first paragraph.

3. On Page 3 of 6, in the upper left-side list of organisms, place the asterisk in front of the HIV-1 reference as follows: "\* HIV-1 (AIDS virus)".

4. Also on Page 3 of 6, revise the left-side sanitizer sentence to read "LONZA FORMULATION S-38 is a sanitizer for hard porous and non-porous, non-food contact surfaces...according to the Sanitizer Test Method,...".

CONCURRENCES							
SYMBOL	7505L						
SURNAME	Daviado						
DATE	10/30/96						

2 of 4

5. Under the "Directions for Use" section on Page 3 of 6, insert the MOU disclaimer statement from Page 6 of 6 before the "Disinfection -" use statement.

6. Move the "Disinfection/\*Virucidal/Mold and Mildew Control Directions:" paragraph from Page 4 of 6 to the "Directions for Use" section on Page 3 of 6, after the MOU disclaimer statement and before the "Disinfection -" use statement.

7. On Page 4 of 6, upper left-side, place a comma after the word "Bars" in the first sentence of the first paragraph. Revise the last sentence of the first paragraph to read "The same AOAC Use-Dilution Test used to confirm suitable performance for hospitals was used."

8. On Page 4 of 6, revise the virucidal heading to read "\* Virucidal Performance", and in the sentence under this heading add an asterisk to the HIV-1 reference as follows: "\* HIV-1 (AIDS virus)".

9. Move the entire section pertaining to HIV-1 use from Page 5 of 6 to Page 4 of 6, after the first sentence under "\* Virucidal Performance".

10. Move the "Non-Acid Toilet Bowl Disinfectant/Cleaner Directions:" statements from Page 6 of 6 to Page 4 of 6 just above the section on "Sanitizing...Surfaces".

11. Under the "Non-Acid Toilet Bowl Disinfectant/Cleaner Directions:" section, the "From Concentrate" and "From Use-Solution" directions should indicate a use dilution of two (2) ounces per gallon only. Remove the references to "0.75-2" and "1-2" ounces. Revise the "From Concentrate" directions to read: "Add 2 ounces to the toilet bowl and mix. Brush thoroughly over exposed surfaces..."

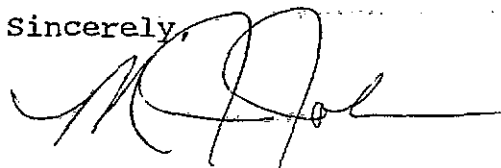
12. In the "Sanitizing Non-Food Contact Surfaces" section on Page 4 of 6, revise the first sentence to read "Add 0.5 ounce per gallon of water to sanitize..."

Please note that some duplication of text still exists in the product labeling, especially on Page 2 of 6, which you might choose to edit further under a separate amendment.

A stamped copy of the LONZA FORMULATION S-38 product labeling is enclosed for your records. Submit one (1) copy of the revised final printed labeling before you release the product for shipment.

If you have any questions concerning this letter, please contact Doreen Aviado of my staff at (703) 305-6554.

Sincerely,



Marion J. Johnson, Jr.  
Product Manager (31)  
Antimicrobial Program Branch  
Registration Division (7505C)

Enclosure

4089  
Precautionary Statements  
Hazards to Humans and Domestic Animals

## DANGER

Keep out of reach of children. 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.

### STORAGE AND DISPOSAL

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

Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Metal container: 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.

(If container is 1 gallon or less, use this container disposal statement.)

Do not reuse empty container (bottle, can, bucket). Wrap container and put in trash.

For bag-in-box containers: Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

JAN 2 1997

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

6836-73

4/29/96

## LONZA FORMULATION S-38

Disinfectant-Cleaner-Sanitizer-Fungicide-Mildewstat-Virucide\*-Deodorizer  
with Organic Soil Tolerance  
for Hospitals, Institutional, Commercial, 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 <sub>14</sub> , 50%; C <sub>12</sub> , 40%; C <sub>16</sub> , 10%) dimethyl benzyl ammonium chloride	1.520%

### Inert Ingredients

96.200%  
100.000%

KEEP OUT OF REACH OF CHILDREN

**DANGER PELIGRO**

SEE LEFT PANEL FOR ADDITIONAL  
PRECAUTIONARY STATEMENTS

Limpiador sin Acido/Desinfectante/Anti-Mohu/Anti-Hongos/Anti-Virulento/Desodorante

EPA Registration No.  
EPA Establishment No.

6836-73  
6836-IL-1

Net Contents

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.

5089  
LONZA FORMULATION S-38 has been formulated to aid in the reduction of cross-contamination in institutions, schools and hospitals. LONZA FORMULATION S-38 is a one-step disinfectant-cleaner that is effective against a broad spectrum of bacteria, is virucidal, fungicidal and inhibits the growth of mold and mildew and their odors when used as directed. LONZA FORMULATION S-38 is an effective one-step sanitizer-cleaner for use on non-food contact surfaces. 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 authorized by the USDA for use in federally inspected meat and poultry plants.

Cross-contamination is of major housekeeping concern not only in hospitals, but in schools, institutions, and industry. LONZA FORMULATION S-38 has been formulated to aid in the reduction of cross-contamination in these areas. 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 an effective one-step sanitizer-cleaner for use on non-food contact surfaces.

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.

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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Fungicide, and Rodenticide Act as  
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6836-73

604-9  
LONZA FORMULATION S-38 is a Hospital Use Disinfectant at 1:64 dilution (2 ounces per gallon, 16 milliliters per liter), Bactericidal according to the AOAC Use-Dilution Test method, Virucidal\* according to the virucidal qualification, Fungicidal according to the AOAC fungicidal test, modified in the presence of 5% organic serum against:

Pseudomonas aeruginosa	Klebsiella pneumoniae
Salmonella choleraesuis	Salmonella schottmuelleri
Staphylococcus aureus	Serratia marcescens
Brevibacterium ammoniagenes	Shigella dysenteriae
Enterobacter aerogenes	Streptococcus faecalis
Escherichia coli	Trichophyton mentagrophytes

HIV-1 (AIDS virus)  
Influenza A/Brazil

Herpes Simplex Type 1  
Herpes Simplex Type 2  
Vaccinia

LONZA FORMULATION S-38 is a sanitizer for hard and non-porous non-food contact surfaces at 1:256 dilution (0.5 ounce per gallon, 1/2 ounce per gallon, 4 milliliters per liter) according to the Sanitizer Test Method, modified in the presence of 300 ppm hard water and 5% organic serum against:

Klebsiella pneumoniae

Staphylococcus aureus

#### Directions for Use

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

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

Apply LONZA FORMULATION S-38 to walls, floors and other hard (inanimate) non-porous surfaces such as tables, chairs, countertops, sinks, toilet bowls, urinals and bedframes with a cloth, mop or mechanical spray device so as to thoroughly wet surfaces. For heavily soiled areas, a preliminary cleaning is required. Prepare a fresh solution daily or when use-solution becomes visibly dirty.

**Disinfection** - To disinfect hard, non-porous surfaces, treated surfaces must remain wet for ten minutes.

#### Preparation of Use-Solution:

Add 1-2 ounces per gallon of water, to disinfectant hard, non-porous surfaces.

For heavy-duty use, add 8 ounces per gallon of water to disinfectant hard, non-porous surfaces.

**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:

Pseudomonas aeruginosa  
Staphylococcus aureus  
Salmonella choleraesuis  
Escherichia coli  
Serratia marcescens  
Klebsiella pneumoniae  
Pseudomonas cepacia

Enterobacter aerogenes  
Salmonella schottmuelleri  
Streptococcus faecalis  
Shigella dysenteriae  
Brevibacterium ammoniagenes

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7049

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 tests used above to confirm suitable performance for hospitals were used.

#### Fungicidal Performance

Lonza Formulation S-38 at 1 oz. per gallon 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.

#### Mold and Mildew Control

At 1 oz./gallon, 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 the general use instructions above). Allow to dry on surface and repeat when mildew growth returns.

#### Virucidal Performance

At 1 oz./gallon 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 Type 1 and 2, HIV-1 (AIDS virus) and Vaccinia on inanimate hard non-porous environmental surfaces.

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

Add 0.5 ounce per gallon of water to sanitizer hard porous and non-porous environmental surfaces. At 1/2 ounce/gallon use-level, 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.

#### Disinfection/Virucidal/Mold and Mildew Control directions:

Apply use-solution to hard (inanimate) non-porous surfaces thoroughly wetting surfaces as recommended and required, 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 visibly dirty.

#### Glass Cleaning/Deodorizing Directions:

Add 0.5 ounce 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.

#### Instruments and Tools:

Use 2 ounces of this product per gallon 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.

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6836-73

6049  
\*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 I (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 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.

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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9049  
Non-Acid Toilet Bowl Disinfectant/Cleaner directions:

**From Concentrate**

Add 0.75-2 ounces to the bowl and mix. Brush over exposed surfaces including under the rim and 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 the 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.

(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.)

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