

Lonza, Inc.
17-17 Route 208
Fair Lawn, New Jersey 07410

APR 17 1995

Attention: Eliot Harrison

Subject: Lonza Formulation S-38
EPA Registration Number 6836-73
Your Submission Dated October 17, 1994
EPA Received Date October 19, 1994

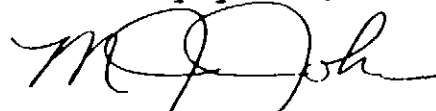
The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to add additional use sites, is acceptable provided you make the following label revisions:

- A. On the left panel of page 2, the listing of USDA is acceptable. The Agency files show that authorization is for the use of the product in federally inspected meat and poultry plants in a letter by the USDA dated April 22, 1988. The acceptable authorization is based on the fact that the product specific formulation has been authorized by the USDA.
- B. On the right panel of page 2, delete the terms "concentrate" and "maximizes".
- C. On the upper left panel of page 3, delete the wording "current".
- D. The left and right panel of page 3, delete the wording "current".

A stamped copy of the product labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-305-6966.

Sincerely yours,



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

**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 puncture and 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.

LONZA FORMULA

Disinfectant-Cleaner-Sanitizer-Fungicide-Mild
with Organic Soil Tolerant
for Hospitals, Institutional and

Active Ingredients

Octyl decyl dimethyl ammonium chloride
Dioctyl dimethyl ammonium chloride
Didecyl dimethyl ammonium chloride ...
Alkyl (C14, 50%; C12, 40%; C16, 10%)
dimethyl benzyl ammonium chloride

Inert Ingredients.....

KEEP OUT OF REACH OF

DANGER

SEE SIDE PANEL FOR A
PRECAUTIONARY STATEMENT

EPA Registration No.
EPA Establishment No.
Net Contents

Manufactured by
LONZA INC., 17-17 Route 208, Fa

ACCEPTED
w/ COMMENTS
in EPA JETTED
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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 is a ~~concentrate~~ that can be used with a mop and bucket, trigger sprayers, sponge, or by soaking.

LONZA FORMULATION S-38 ~~concentrate~~ labor results by effectively controlling odors.

LONZA FORMULATION S-38 Cleans, shines, deodorizes and disinfects all non-porous household surfaces. Inhibits the growth mold and mildew, leaving bathrooms & 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 Area	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, 16 milliliters per liter), Bactericidal according to the ~~AOAC~~ 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)	Herpes Simplex Type 1
Influenza A/Brazil	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
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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.

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.

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

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.

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*** 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 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).

"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 (2 ounces per gallon, 16 milliliters per liter) **use-solution**. Use a 10 minute contact time for disinfection against all other virus, bacteria, and fungi claimed.

DISPOSAL OF INFECTIOUS MATERIALS: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

(*MATA EL VIH EN SUPERFICIES/OBJECTOS EXPUESTOS AL MEDIO AMBIENTE PREVIAMENTE CONTAMINADOS CON SANGRE/LIQUIDOS CORPORALES, CUANDO SE LOS HA LIMPIADO PREVIAMENTE, en lugares destinados al cuidado de la salud u otros lugares donde se prevea la posibilidad de contaminación de superficies/objetos inanimados con sangre o líquidos corporales y en los que dichas superficies/objetos pueden estar relacionados con el potencial de transmisión del virus de la inmunodeficiencia humana tipo (VIH-1) (asociado con el SIDA).

"INSTRUCCIONES ESPECIALES PARA LA LIMPIEZA Y DESCONTAMINACION CONTRA EL VIH-1 SOBRE SUPERFICIES/OBJECTOS CONTAMINADOS CON SANGRE/LIQUIDOS CORPORALES."

PROTECCION PERSONAL: La limpieza deberá hacerse siempre usando guantes de látex protectores, batas, máscaras y protección de la vista.

PROCEDIMIENTO DE LIMPIEZA: La sangre y otros líquidos corporales que contienen el VIH deben limpiarse completamente de las superficies y los objetos antes de aplicar **LONZA FORMULATION S-38**.

TIEMPO DE CONTACTO: Dejar la superficie mojada durante 10 minutos con (2 onzas por galón, 16 milliliters por liter) de **solución utilizable**. Dejar 10 minutos de tiempo contacto para la desinfección contra todos los otros virus, bacterias y hongos declarados.

ELIMINACION DE MATERIALES INFECCIOSOS: La sangre, los líquidos corporales, materiales de limpieza y ropa deben someterse al autoclave y eliminarse de acuerdo con la reglamentaciones locales sobre eliminación de desechos infecciosos.)

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Non-Acid Toilet Bowl Disinfectant/Cleaner directions:

From concentrate:

Add (2 ounces, 60 milliliters) to the toilet bowl and mix. Brush thoroughly 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 (2 ounces per gallon, 16 milliliters per liter) 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 Heavy-duty use:

Empty toilet bowl or urinal and apply (8 ounces per gallon, 64 milliliters per liter) use-solution to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer, allow to stand for 10 minutes and flush.

(Instrucciones para el desinfectante/limpiador no ácido de inodoro:

Con el concentrado:

Agregar (2 onzas, 60 milliliters) a la taza del inodoro y mezclar. Cepillar completamente sobre las superficies expuestas y debajo del reborde, dejando setar por 10 minutos y correr el agua.

Con la solución utilizable:

Vaciar la taza del inodoro o orinal y aplicar una solución utilizable de (2 onzas por galón, 16 milliliters por liter) a las superficies expuestas, inclusive debajo del reborde, con un trapo, estropajo, esponja o rociador, dejar estar por 10 minutos y correr el agua.

Para uso pesado:

Vaciar la taza del inodoro o orinal y aplicar una solución utilizable de (8 onzas por galón, 64 milliliters por galón) a las superficies expuestas, inclusive debajo del reborde, con un trapo, estropajo, esponja o rociador, dejar estar por 10 minutos y correr el agua.)

Glass Cleaning/Deodorizing Directions:

Add (0.5 ounce per gallon, 1/2 ounce per gallon, 4 milliliters per liter; 1 ounce per gallon, 8 milliliters per liter; 2 ounces per gallon, 16 milliliters per liter) 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 breathe spray mist.

(Instrucciones para el limpiador/deodorizar superficies vidrio:

Agregar (0.5 onza por galón, 1/2 onza por galón, 4 milliliters por liter; 1 onza por galón, 8 milliliters por liter; 2 onzas por galón, 16 milliliters por liter) de agua, para limpiar y desodorizar ventanas, espejos y superficies vidrio.

Utilizar un aparato de rociado grueso. Rocíar 6 a 8 pulgadas desde la superficie, frotar con un cepillo, esponja o trapo. No respirar el vapor del rociador.)

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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(1) Alternate Use directions

PELIGRO:

Si no sabe el inglés, solicite instrucciones a su supervisor antes de este producto.

Directions for Use

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

(Instrucciones de uso)

El empleo de este producto de manera contraria a lo indicado en su etiqueta constituye una violación de la Ley Federal.)

(This product is not to be used 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.)

(Este producto no debe usarse en ninguna superficie o instrumento que: (1) haya de introducirse directamente en el organismo humano, ya sea en la circulación sanguínea o en contacto con ésta o con zonas orgánicas normalmente estériles, o (2) haya de entrar en contacto con mucosas intactas aunque habitualmente no atraviese la barrera hematoencefálica o no penetre de alguna otra manera en zonas normalmente estériles del organismo.)

Preparation of use-solution:

Add (2 ounces per gallon, 16 milliliters per liter) of water (1:64), to disinfect hard, non-porous surfaces.

For heavy duty use, add (8 ounces per gallon, 64 milliliters per liter) of water (1:16), to disinfect hard, non-porous surfaces.

(Preparación de solución utilizable:

Agregar (2 onzas por galón, 16 milliliters por liter) de agua (1:64), para desinfectar superficies duras no porosas.

Para uso pesado, agregar (8 onzas por galón, 64 milliliters por galón) de agua (1:16), para desinfectar superficies duras no porosas.)

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.

(Instrucciones de desinfección/control de virucidad/moho y enmohecimiento:

Aplicar la solución utilizable a superficies duras (inanimadas) no porosas mojando completamente las superficies según lo recomendado y requerido, con un trapo, estropajo, esponja o rociador.)

For heavily soiled areas, a preliminary cleaning is required.

(Para áreas muy manchadas, se requiere una limpieza preliminar.)

For sprayer applications, use a coarse spray device. Spray 6-8 inches from surface, rub with brush, sponge or cloth. Do not breathe spray mist.

(Para aplicaciones de rociador, utilizar un aparato de rociado grueso. Rociar 6 a 8 pulgadas desde la superficie, frotar con un cepillo, esponja o trapo. No respirar el vapor del rociador.)

Treated surfaces must remain wet for 10 minutes. Prepare a fresh solution daily or when use solution becomes visibly dirty.

(Las superficies tratadas deben mantenerse mojadas durante 10 minutos. Preparar una solución fresca a diario o cuando la solución utilizable esté visiblemente sucia.)

Sanitizing Non-Food Contact Surface directions:

Add (0.5 ounce per gallon, 1/2 ounce per gallon, 4 milliliters per liter) of water, to sanitize hard porous and non-porous environmental surfaces. Treated surfaces must remain wet for 60 seconds.

(Instrucciones de esterilización de superficies que no están en contacto con alimentos:

Agregar (0,5 onza por galón, 1/2 onza por galón, 4 milliliters por liter) de agua, para esterilizar superficies duras porosas y no porosas en contacto con el medio ambiente. Las superficies tratadas deben mantenerse mojas durante 60 segundos.)

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Non-Acid Toilet Bowl Disinfectant/Cleaner Application:

1. **From concentrate:**
Add 0.75 oz. to the toilet bowl (0.75 gallon) and mix. Brush over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.
2. **From use-solution:**
Empty toilet bowl or urinal and apply a 1 oz. /gal. use-solution to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer. Allow to stand for 10 minutes and flush.

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. per gallon, LONZA FORMULATION S-38 to control the growth of mold and mildew and their odors on hard, non-porous surfaces. Thoroughly wet all treated surfaces completely. Allow to dry on surface and repeat when mildew growth returns.

Virucidal Performance

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

Sanitizing Non-Food Contact Surfaces (such as floors, walls, tables, etc.)
At 1/2 oz./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.

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*** 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 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).

"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 MATERIALS: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

PELIGRO:

Si no puede leer en ingles, pregunte a su supervisor sobre las instrucciones de uso apropiadas antes de trabajar con este producto.

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