

PM 31

6836-138

8/19/97

Page 193

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 19 1997

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

ATTN: Eliot Harrison, Agent

SUBJECT: LONZA FORMULATION S-138F
EPA Registration No. 6836-138
Amendment Dated August 19, 1997

Dear Mr. Harrison:

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, deleting the food contact surface use and adding the "allow to air dry" statement under the "Disinfection" claim are acceptable.

A stamped copy is enclosed for your records. Submit two (2) copies of the final printed labeling before you release the product for shipping.

If you have any further questions, please contact Ms. Barbara Pringle at (703) 308-6236.

Sincerely,



Velma Noble
Acting Product Manager 31
Registration Management Branch I
Antimicrobials Division (7510W)

Enclosure

CONCURRENCES							
SYMBOL	7510W						
SURNAME	Pringle						
DATE	8-19-97						

LONZA FORMULATION S-38F has been formulated to aid in the reduction of cross-contamination in homes, institutions, schools, hospitals and industry.

LONZA FORMULATION S-38F 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-38F is an effective one-step sanitizer cleaner for use on non-food contact surfaces.

When used as directed, LONZA FORMULATION S-38F 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 malodors.

**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. Remove and wash contaminated clothing before reuse.

(If container is 5 gallons or more, 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 instructions:)

STORAGE AND DISPOSAL

Do not store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Wrap and put in trash.

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

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

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.

**LONZA
FORMULATION S-38F**

DISINFECTANT, CLEANER, SANITIZER, FUNGICIDE
MILDEWSTAT, VIRUCIDE, DEODORIZER
WITH ORGANIC SOIL LOAD TOLERANCE
FOR HOME, HOSPITALS, INSTITUTIONAL AND
INDUSTRIAL USE

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 ₁₆ , 10%) dimethyl benzyl ammonium chloride	1.520%

Inert Ingredients

96.200%
100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. 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. Do not induce vomiting. Call a physician immediately.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

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

EPA Registration No. 6836-138

EPA Establishment No. 6836-IL-1

Net Contents

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

AUG 19 1997

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide registered under 25(a) EPA No. 6836-138



DIRECTIONS FOR USE

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

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

Apply LONZA FORMULATION S-38F to walls, floors and other hard non-porous surfaces such as tables, chairs, countertops, sinks, tile, porcelain and bed frames 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.

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

DISINFECTION: To disinfect hard, nonporous surfaces, add 1 oz. per gallon of water. Treated surfaces must remain wet for 10 minutes. Allow to air dry.

FOR HOSPITALS AND NURSING HOMES: Add 2 oz. per gallon of water. The activity of LONZA FORMULATION S-38F 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 represented by:

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

FOR SCHOOLS, NON-MEDICAL INSTITUTIONAL AND INDUSTRIAL USES: At 1 oz. per gallon, LONZA FORMULATION S-38F delivers cleaning and germicidal effectiveness. It is effective against Staphylococcus aureus, Salmonella choleraesuis and Escherichia coli. The same AOAC tests used to confirm suitable performance for hospitals were used.

VRUCIDAL PERFORMANCE: At 1 oz. per gallon, LONZA FORMULATION S-38F was evaluated in the presence of 5% serum and found to be effective against the following viruses on hard, nonporous surfaces.

- | | |
|---------------------|------------------------------|
| *Influenza A/Brazil | Herpes Simplex Types 1 and 2 |
| Vaccinia | HIV-1 (AIDS Virus) |

***KILLS HIV-1 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-38F.

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.

FUNGICIDAL PERFORMANCE: At 1 oz. per gallon, LONZA FORMULATION S-38F is an effective fungicide against Trichophyton metagrophytes (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-38F will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, nonporous surfaces. Thoroughly wet all treated surfaces. Allow to dry on surface and repeat when mildew growth returns.

LAUNDRY SANITIZER. This product sanitizes by controlling or reducing the growth of odor-causing bacteria when used on washable laundry items such as bed spreads, sheets, pillow cases, diapers, towels, and other wet linens. Use 1 oz. per 25 lbs. of dry weight fabric. Dilute the appropriate amount of LONZA FORMULATION S-38F in one to two gallons of water then add to the washwheel in the final rinse. Laundered fabric may also be treated by soaking.

SANITIZING FOOD CONTACT SURFACES: At 1/2 oz. per gallon, use LONZA FORMULATION S-38F for sanitizing and cleaning of equipment and utensils in food processing, dairy industry, bars, restaurants, institutional kitchens, meat and poultry processing plants and farms. Do not rinse with water. For heavily soiled surfaces, pre-clean with LONZA FORMULATION S-38F. Rinse with clean water, then apply recommended dilution of LONZA FORMULATION S-38F with a cloth, mechanical spray device (spray surface until thoroughly wetted) or immersion. Treated surfaces must remain wet for one minute. Prepare a fresh solution for every use. DO NOT reuse mechanically applied use solution for sanitizing. LONZA FORMULATION S-38F can be used in accordance with the U.S. Public Health Service food service sanitation recommendation.

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.

**U.S. PUBLIC HEALTH SERVICE
FOOD SERVICE SANITIZATION RECOMMENDATIONS**

CLEANING AND SANITIZING: Equipment and utensils shall be thoroughly preflushed or prescraped and when necessary, pre-soaked to remove gross food particles and soil.

1. Thoroughly wash equipment and utensils in a hot detergent solution.
2. Rinse utensils and equipment thoroughly with clean water.
3. Sanitize equipment and utensils by immersion in a 1/2 oz. per gallon solution of LONZA FORMULATION S-38F (150 ppm active) for at least 60 seconds at a temperature of 75°F.
4. For equipment and utensils too large to sanitize by immersion, apply a 1/2 oz. per gallon solution of LONZA FORMULATION S-38F (150 ppm active) by rinsing, spraying or swabbing until thoroughly wetted.

Allow sanitized surface to drain and air dry. Do not rinse. Wash thoroughly with soap and water after handling.

ACCEPTED
with COMMENTS
to EPA Letter Dated
JUL 12 1997

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide registration under EPA Reg. No. 6836-138