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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 21 1995

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

Attention: Eliot I. Harrison
Agent for Lonza

Subject: Lonza Formulation S-21F
EPA Registration No. 6836-140
MOU Compliance Amendment dated January 25, 1995

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, will be acceptable provided that you make the labeling change listed below before you release the product for shipment bearing the amended label.

1. Virucidal claims must be keyed with an asterisk to the specific paragraph which lists the viruses tested.

A stamped copy of your labeling is enclosed for your records. Submit five (5) copies of the final printed label prior to release of the product for shipment.

If you have any questions concerning this letter, please contact Wanda Mitchell at (703) 305-6141.

Sincerely,



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

CONCURRENCES

SYMBOL	SURNAME	DATE						

Cross-contamination is of major housekeeping concern not only in hospitals, but in schools, institutions and industry. LONZA FORMULATION S-21F has been formulated to aid in the reduction of cross-contamination in these areas. LONZA FORMULATION S-21F 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 21F is an effective one-step sanitizer-cleaner for use on food contact, as well as non-food contact surfaces. When used as directed, LONZA FORMULATION S-21F 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.

PRECAUTIONARY STATEMENTS
HAZARD 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.

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.

STORAGE AND DISPOSAL

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

21 1995

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

6836-140

LOK FORMULATION S-21F

DISINFECTANT, CLEANER, SANITIZER, FUNGICIDE
MILDEWSTAT, VIRUCIDE, DEODORIZER
WITH ORGANIC SOIL TOLERANCE
FOR 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

Active Ingredients

Octyl decyl dimethyl ammonium chloride	1.650%
Dioctyl dimethyl ammonium chloride	0.660%
Didecyl dimethyl ammonium chloride	0.990%
Alkyl (C_{14} , 50%; C_{12} , 40%; C_{16} , 10%) dimethyl benzyl ammonium chloride	2.200%

Inert Ingredients

94.500%
100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER

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.

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration No.
EPA Establishment No.
Net Contents

6836-140
6836-IL-1

MANUFACTURED BY:
LONZA INC., 17-17 Route 208, Fair Lawn, N.J. 07410

DIRECTIONS FOR

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

LONZA FORMULATION S-21F is a proven "one-step" disinfectant-cleaner-disinfectant-fungicide-mildewstat-virucide which is effective in water up to 400 ppm hardness in the presence of 5% serum contamination.

Apply **LONZA FORMULATION S-21F** to walls, floors and other hard (inanimate) non-porous surfaces such as tables, chairs, countertops, sinks, tile, porcelain 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, add 2 oz. per gallon of water. Treated surfaces must remain wet for 10 minutes. At 1 1/4 oz. per gallon of water, **LONZA FORMULATION S-21F** will disinfect hard non-porous surfaces in schools, industry and non medical institutions.

At 2 oz. per gallon use level, the activity of **LONZA FORMULATION S-21F** has been evaluated in the presence of 5% serum and 400 ppm hard water 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:

<i>Pseudomonas aeruginosa</i>	
<i>Staphylococcus aureus</i>	<i>Streptococcus faecalis</i>
<i>Salmonella choleraesuis</i>	<i>Shigella dysenteriae</i>
<i>Escherichia coli</i>	<i>Brevibacterium ammoniagenes</i>
<i>Streptococcus pyogenes</i>	<i>Salmonella typhi</i>
<i>Klebsiella pneumoniae</i>	<i>Serratia marcescens</i>
<i>Enterobacter aerogenes</i>	<i>Pseudomonas cepacia</i>

FOR SCHOOLS, INDUSTRY AND NON-MEDICAL INSTITUTIONS USE: At 1 1/4 oz. per gallon water, **LONZA FORMULATION S-21F** delivers excellent cleaning and germicidal effectiveness. It is effective against *Staphylococcus aureus*, *Salmonella choleraesuis*, *Escherichia coli* and *Serratia marcescens*. The same AOAC tests used to confirm performance for hospitals were used.

VIRUCIDAL PERFORMANCE: At 1 1/4 oz. per gallon use-level **LONZA FORMULATION S-21F** was evaluated and found to be effective in the presence of 5% serum and 400 ppm hard water against the following viruses:

Influenza A/Brazil	Herpes Simplex Type 1
Vaccinia	and Type 2

found on inanimate, hard, non-porous, environmental surfaces.

FUNGICIDAL CONTROL: **LONZA FORMULATION S-21F** 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 at 2 oz. per gallon.

MOLD AND MILDEW CONTROL: At 1 1/4 oz. per gallon, **LONZA FORMULATION S-21F** 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.

SANITIZING FOOD CONTACT SURFACES: At 1 oz. per 2 3/4 gallons water use **LONZA FORMULATION S-21F** for sanitizing and cleaning of equipment and utensils in food processing, dairy industry, bars, restaurants, institutional kitchens, meat and poultry processing plant and farms. Do not rinse with water. For heavily soiled equipment or utensils, pre-wash with **LONZA FORMULATION S-21F**. Rinse with clean water, then apply recommended dilution of **LONZA FORMULATION S-21F** 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-21F** 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 pre-flushed or pre-scraped 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 oz. per 2 3/4 gallon solution of **LONZA FORMULATION S-21F** (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 oz. per 2 3/4 gallon solution of **LONZA FORMULATION S-21F** (150 ppm active) by rinsing, spraying or swabbing until thoroughly wetted.
5. Allow sanitized surface to drain and air dry. Do not rinse.

Wash thoroughly with soap and water after handling.

02/03/93