

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

6836-141

10/23

JUN - 7 1995

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

Attention: Eliot I. Harrison
Agent for Lonza

Subject: Lonza Formulation 70-12F
EPA Registration No. 6836-141
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 changes listed below before you release the product for shipment bearing the amended label.

1. Remove the statement "Lonza Formulation 70-12F is an effective one-step sanitizer-cleaner for use on food contact...surfaces." One-step claims are not applicable to food contact surface sanitizers.
2. The "virucidal" claim must be keyed with an asterisk to the paragraph listing the specific 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 70-12F is formulated for this problem area. It both cleans and disinfects effectively and is virucidal when used as directed. Its hard surface disinfecting action will reduce the hazard of cross-contamination from environmental surfaces. LONZA FORMULATION 70-12F 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 70-12F will deodorize surfaces in toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas and will inhibit the growth of mold and mildew and their odors when used as directed.

**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 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). The 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 one gallon or less, use this container disposal statement.) Do not reuse empty container (bottle, can, bucket). Wrap container and put in trash.

**LONZA
FORMULATION 70-12F**

HIGHLY CONCENTRATED GERMICIDE
BASED ON A UNIQUE BLEND OF QUATERNARIES
WITH ORGANIC SOIL LOAD TOLERANCE

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

Active Ingredients

Octyl decyl dimethyl ammonium chloride	3.750%
Dioctyl dimethyl ammonium chloride	1.500%
Didecyl dimethyl ammonium chloride	2.250%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	5.000%

Inert Ingredients

87.500%
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

<u>EPA Registration No.</u>	6836-141
<u>EPA Establishment No.</u>	6836-IL-1
<u>Net Contents</u>	

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN - 7 1977

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

6836 141

BEST COPY AVAILABLE

DIRECTIONS FOR

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

LONZA FORMULATION 70-12F is a proven one-step cleaner-disinfectant-sanitizer-fungicide-mildewstat-virucide in the presence of moderate amounts of organic soil.

Apply LONZA FORMULATION 70-12F 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 1/2 oz. per gallon of water. Treated surfaces must remain wet for 10 minutes. At this use-level, LONZA FORMULATION 70-12F is also virucidal and fungicidal.

1/2 oz. per gallon use level. The broad spectrum activity of LONZA FORMULATION 70-12F against the following by the AOAC Use-Dilution test:

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

VIRUCIDAL PERFORMANCE. At 1/2 oz. per gallon use-level, LONZA FORMULATION 70-12F was evaluated in the presence of 5% serum and found to be effective against the following viruses:

Influenza A/Hong Kong	Herpes Simplex Type 1 and Type 2
Vaccinia	

found on inanimate hard, non-porous environmental surfaces.

AOAC FUNGICIDAL TEST: LONZA FORMULATION 70-12F 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, etc.

MILDEWSTATIC PERFORMANCE: At 1/2 oz. per gallon, LONZA FORMULATION 70-12F 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 1/3 oz. per 2 gallons water, use LONZA FORMULATION 70-12F 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 equipment or utensils, pre-wash with LONZA FORMULATION 70-12F. Rinse with clean water, then apply recommended dilution of LONZA FORMULATION 70-12F 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 70-12F 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 final 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 1/3 oz. per 2 gallon solution of LONZA FORMULATION 70-12F (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 1/3 oz. per 2 gallon solution of LONZA FORMULATION 70-12F (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.

02/07/92

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 7 1992

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

6836-141

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