

OCT - 3 2003

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

Subject: Lonza Formulation S-37F
EPA Registration No. 6836-137
Amendment Date: July 2, 2003
EPA Receipt Date: July 7, 2003

Dear Mr. Sloan,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

- Update First Aid Statements per PR Notice 2001-1

Conditions

Revise the label as follows:

1. Page 1: Revise the "Precautionary Statements" by adding the phrase, "protective clothing" to the 4th statement and the statement, "Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling." Also, delete the statement, "Avoid contamination of food."

Page 2: Directions for Use Revisions

2. Qualify the surface, tile, as hard nonporous by stating "glazed" tile. (Located left panel 2nd paragraph)
3. Revise the "Disinfection" directions by adding the statement, "Allow surfaces to air dry." It must appear after the contact time.
4. Under "Fungicidal Performance, add the statement, "Follow disinfection directions."
5. Page 5: Revise the "Sanitizing Food Contact Surfaces" Directions by deleting the statement, "For heavily soiled ... S-37F," and replace it with "Prior to application, remove gross food particles and soil by a pre-flush or pre-scraped and when necessary, pre-soaked to remove gross food particles and soil. Then thoroughly, wash or flush

SYMBOL							
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

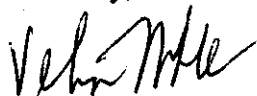
equipment and utensils with a good detergent or compatible cleaner followed by a potable water rinse." Also, add the statements " Allow sanitized surfaces to drain or air dry. Do not rinse." They must appear after the contact time.

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL							
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PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles or face shield) and protective gloves (rubber or chemical resistant) when handling. Harmful if swallowed. Avoid contamination of food.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

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

(If the container size is 5 gallons or greater, the following Environmental Hazards statements will be used.)

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.

**LONZA
FORMULATION S-37F**

DISINFECTANT, CLEANER, SANITIZER,
FUNGICIDE

MILDEWSTAT, VIRUCIDE, DEODORIZER

WITH ORGANIC SOIL TOLERANCE

FOR HOSPITALS, INSTITUTIONAL AND
INDUSTRIAL USE

Active Ingredients

Octyl decyl dimethyl ammonium chloride	2.10%
Dioctyl dimethyl ammonium chloride	0.84%
Didecyl dimethyl ammonium chloride	1.26%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	2.80%
Other Ingredients	93.00%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

See (left) (right) (side) (back) panel for Precautionary
Statements and First Aid

EPA Reg. No. 6836-137

EPA Est. No. *(Insert EPA Establishment No. Here)*

Net Contents: *(insert container size here)*

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 3 - 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 6836-137

LONZA FORMULATION S-37F
EPA REG. NO. 6836-137
EPA DRAFT LABEL 6-24-03

Cross-contamination is of major housekeeping concern not only in hospitals, but in schools, institutions and industry. LONZA FORMULATION S-37F has been formulated to aid in reduction of cross-contamination in these areas.

LONZA FORMULATION S-37F 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-37F 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-37F 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.

DIRECTIONS FOR USE

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

LONZA FORMULATION S-37F is a proven one-step cleaner - disinfectant - sanitizer - fungicide - mildewstat - virucide in the presence of moderate amounts of organic soil.

Apply LONZA FORMULATION S-37F to walls, floors and other hard nonporous surfaces such as tables, chairs, countertops, sinks, tile, glazed porcelain 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 more often if the use solution becomes visibly dirty.

Rinse all surfaces that come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes as a disinfectant.

DISINFECTION - To disinfect hard, nonporous surfaces, add 1 oz. per gallon of water. Treated surfaces must remain wet for 10 minutes. The activity of LONZA FORMULATION S-37F 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 positive organisms as represented by:

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

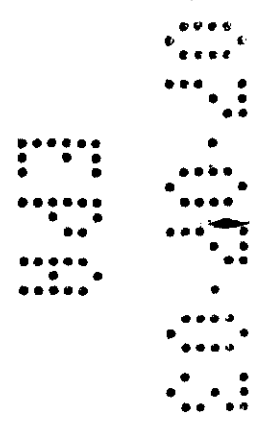
VIRUCIDAL PERFORMANCE: At 1 oz. per gallon use-level LONZA FORMULATION S-37F was evaluated in the presence of 5% serum found to be effective against the following viruses found on hard, nonporous, surfaces:

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

FUNGICIDAL PERFORMANCE:

LONZA FORMULATION S-37F 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 1 oz. per gallon.

MOLD AND MILDEW CONTROL: At 1 oz per gallon, LONZA FORMULATION S-37F 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.



(Note for reviewer: For labels that list medical premises and metal and/or stainless steel surfaces, one of the following statements must be used:)

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.

(or)

This product is not for use on medical device surfaces.

SANITIZING FOOD CONTACT SURFACES: At 1 oz. per 3 1/2 gallons water use LONZA FORMULATION S-37F 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 S-37F. Rinse with clean water, then apply recommended dilution of LONZA FORMULATION S-37F 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-37F can be used in accordance with the U.S. Public Health Service food service sanitation recommendation.

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 3 1/2 gallon solution of LONZA FORMULATION S-37F (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 3 1/2 gallon solution of LONZA FORMULATION S-37F (150 ppm active) by rinsing, spraying or swabbing until thoroughly wetted.
5. Allow sanitized surface to drain and air dry. Do not rinse.

(If container size is 1 gallon or less, the following storage and disposal statements will be used:)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not reuse empty container. Discard in trash or recycle.

(If container size is greater than gallon, the following storage and disposal statements will be used:)

STORAGE AND DISPOSAL

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

Pesticide Storage

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

(Plastic containers): 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 way of smoke.

(Metal Containers): 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.

