

6836-33

11/14/2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 14 2003

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

Subject: Lonza Formulation 70-12
EPA Registration No. 6836-33
Amendment Date: August 18, 2003
EPA Receipt Date: August 19, 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. Revise the "Precautionary Statements" by including the phrase "protective clothing" to the 4th statement; adding the statement, *Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco;* and deleting the statement, "avoid contamination of food."
2. Bold the subheadings (If in eyes, If on skin/clothing, and If swallowed) under First Aid as well as "Note to Physician."
3. Page 2: Revise 4th sentence of 1st claim in left column by stating hard *nonporous* surface.
4. Revise the "Disinfection" directions by adding the statement, *Allow surfaces to air dry or wipe excess liquid with cloth, sponge, or mop.*
5. Revise the "Non food Contact Surface Sanitizing" directions to read:

At 1/3 oz per 2 gallons of water Lonza Formulation 70-12 is an effective sanitizing agent against S. aureus and K. pneumoniae in the presence of 5% serum on porous and nonporous non food contact environmental surfaces.

CONCURRENCES

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Apply use solution with a mop, cloth, or coarse mechanical sprayer so as to thoroughly wet surfaces. Treated surfaces must remain wet for 30 seconds. Wipe dry with cloth, sponge, or mop or allow surfaces to air dry.

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.

If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



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

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HIGHLIGHTED
COPY

PRECAUTIONARY STATEMENTS

HAZARDS 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, safety glasses or face shield) and protective gloves (rubber or chemical resistant) when handling. Harmful if swallowed. Avoid contamination of food. Remove and wash contaminated clothing before reuse.

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.

(Note to reviewer: If 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 70-12

Highly Concentrated Germicide

Based on a Unique Blend of Quaternaries

with Organic Soil Load Tolerance

Disinfectant – Cleaner – Sanitizer – Fungicide

Mildewstat - Virucide* - Deodorizer for Hospitals

Institutional and Industrial Use

Active Ingredients

Octyl decyl dimethyl ammonium chloride	3.750%
Diocetyl 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%
Other Ingredients	87.500%
Total:.....	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER (PELIGRO)

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

EPA Reg. No.6836-33

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

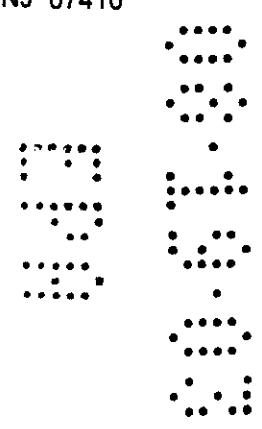
Net Contents: *(insert container size here)*

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 14 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 6836-33



Cross-contamination is of major housekeeping concern not only in hospitals, but in schools, institutions and industry. **LONZA FORMULATION 70-12** 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.

When used as directed, **LONZA FORMULATION 70-12** 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.

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

Use **LONZA FORMULATION 70-12** on walls, floors and other hard nonporous surfaces such as tables, chairs, countertops, sinks and bedframes.

The broad spectrum activity of **LONZA FORMULATION 70-12** has been evaluated at 1/2 oz. per gallon in the presence of 5% serum and found to be effective against the following by the AOAC Use-Dilution test:

- Pseudomonas aeruginosa (Pseudomonas)
- Staphylococcus aureus (Staph)
- Salmonella choleraesuis (Salmonella)

- Brevibacterium ammoniagenes
- Enterobacter aerogenes
- Escherichia coli (E. coli)
- Klebsiella pneumoniae
- Pseudomonas cepacia
- Salmonella schottmuelleri
- Shigella dysenteriae
- Streptococcus faecalis

LONZA FORMULATION 70-12 is effective against Trichophyton mentagrophytes (the athlete's foot fungus) when used on surfaces in areas such as locker rooms, showers and bath areas, exercise areas, dressing rooms, etc.

***VIRUCIDAL PERFORMANCE.**

At 1/2 oz. per gallon use-level, **LONZA FORMULATION 70-12** was evaluated in the presence of 5% serum and found to be effective against the following viruses: Herpes Simplex Types 1 and 2, HIV-1 (AIDS virus) and Influenza A₂ (Hong Kong) Vaccinia

PELIGRO

SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.

DIRECTIONS FOR USE

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

DISINFECTION / VIRUCIDAL / FUNGICIDAL DIRECTIONS:

To disinfect hard, non-porous surfaces, use 1/2 oz. of **LONZA FORMULATION 70-12** per gallon of water. Apply with a cloth, mop or mechanical spray device so as to thoroughly wet surfaces. Treated surfaces must remain wet for 10 minutes.

For heavily soiled areas, a preliminary cleaning is required.

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

Prepare a fresh solution daily or when use solution becomes visibly dirty.

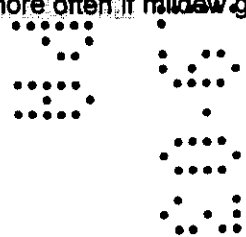
(Note for reviewer: For labels that list medical premises and metal and/or stainless steel surfaces, one of the following statements must be used.)

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. *(Optional sentence: This product may be used to preclean 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.

MILDEWSTATIC PERFORMANCE: At 1/2 oz. per gallon, **LONZA FORMULATION 70-12** will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, nonporous surfaces. Follow Disinfection Directions. Allow to dry on surface. Repeat (weekly) (every 7 days) or more often if mildew growth returns.



Non-Acid Toilet Bowl and Urinal Disinfectant / Cleaner Application.

Remove heavy soil prior to disinfection.

From concentrate:

Add 1/2 oz. to the bowl (0.75 gallons) and mix. Brush thoroughly over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.

From use dilution:

Empty toilet bowl or urinal and apply a 1/2 oz. per gallon use-solution to exposed surfaces and under the rim with a cloth, mop, sponge or coarse (mechanical) spray. Brush or swab thoroughly, allow to stand for 10 minutes and flush.

***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 gloves, gowns, masks and eye protection.

CONTACT TIME: Leave surface wet for 10 minutes with a 1/2 oz. per gallon use-solution."

CLEANING PROCEDURE: Blood and other body fluids containing HIV must be thoroughly cleaned from surfaces and objects before application of **LONZA FORMULATION 70-12**.

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.

SANITIZING NON-FOOD CONTACT SURFACES:

(such as floors, walls, tables)

At 1/3 oz. per 2 gallon use-level, 30 second contact time, **LONZA FORMULATION 70-12** is an effective sanitizing agent in waters of up to 600 ppm hardness against *Staphylococcus aureus* and *Klebsiella pneumoniae* in the presence of 5% serum on porous and nonporous environmental surfaces.

(Note to reviewer: If the container size is one 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 store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Discard in trash or recycle.

(Note to reviewer: If container is greater than one gallon, the following storage and disposal statements will be used:)

STORAGE AND DISPOSAL

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

Pesticide Storage

Store in original container in areas inaccessible to children. 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 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.

(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.

