

6836-76

10/17/2003

1/5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 17 2003

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

Subject: Lonza Formulation S-23
EPA Registration No. 6836-76
Amendment Date: July 17, 2003
EPA Receipt Date: July 21, 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 Statement" by adding the statement, "Wash thoroughly with soap and water after handling."
2. Bold the "First Aid" subheadings, "If swallowed/If on skin or clothing/ If in eyes," as well as the "Note to Physician" heading.
3. Under the Disinfection/Virucidal Directions, add the statement, "Wipe dry with cloth, sponge, or mop or allow surfaces to air dry." It should appear after the contact time. Also, clarify the surfaces, tile and porcelain, as hard nonporous by stating "glazed" tile and "glazed" porcelain, and delete "toilet bowls" from the list because this label carries specific use directions on page 3.
4. Under Fungicidal Performance, add the statement, "follow disinfection directions."
5. Revise the "Non food Contact Surface Sanitizing" directions to read :

At 1 oz per 2 gallons of water Lonza Formulation S-23 is an effective sanitizing agent against S. aureus and K. pneumoniae in the presence of 5% serum on porous and

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

2/5

nonporous non food contact environmental surfaces. 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.

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								
SURNAME								
DATE								

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, face shield or safety glasses), protective clothing and protective (rubber or chemical resistant) gloves. Harmful if swallowed. Remove contaminated clothing and wash 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.

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-23

Disinfectant-Cleaner-Sanitizer-Fungicide
Mildewstat-Virucide*-Deodorizer

For Schools, Non-Medical Institutional and Industrial Use

Effective in hard water up to 400 ppm hardness (calculated as CaCO₃) in the presence of 5% serum contamination.

Active Ingredients:

Octyl decyl dimethyl ammonium chloride.....	1.20%
Diocetyl dimethyl ammonium chloride.....	0.48%
Didecyl dimethyl ammonium chloride.....	0.72%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride.....	1.60%
Other Ingredients:.....	<u>96.00%</u>
Total:.....	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Registration No. 6836-76
EPA Establishment No. 6836-IL-1
Net Contents

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 17 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 6836-76

Cross contamination is of major housekeeping concern in schools, non-medical institutions and industry. **LONZA FORMULATION S-23** has been formulated to aid in the reduction of cross contamination in these areas.

LONZA FORMULATION S-23 is a one-step disinfectant - cleaner that is effective against a broad spectrum of bacteria, is virucidal, fungicidal, and will prevent the growth of mold and mildew and their odors when used as directed.

LONZA FORMULATION S-23 is an effective one-step sanitizer - cleaner for use on non-food, contact surfaces.

When used as directed, **LONZA FORMULATION S-23** 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.

LONZA FORMULATION S-23 is a proven "one-step" disinfectant - cleaner - sanitizer - fungicide - mildewstat - virucide which is effective in water up to 400 ppm hardness in the presence of 5% serum contamination.

The activity of **LONZA FORMULATION S-23** 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:

Staphylococcus aureus
Salmonella choleraesuis

Brevibacterium ammoniagenes
Enterobacter aerogenes
Escherichia coli
Klebsiella pneumoniae
Salmonella typhi
Serratia marcescens
Shigella dysenteriae
Streptococcus faecalis
Streptococcus pyogenes

VIRUCIDAL PERFORMANCE*. At 2 oz. per gallon use-level, **LONZA FORMULATION S-23** was evaluated in the presence of 5% serum and 400 ppm hard water and found to be effective against the following viruses: Influenza A/Brazil, Herpes Simplex Types I and II and Vaccinia on inanimate, hard, non-porous, environmental surfaces.

DIRECTIONS FOR USE

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

DISINFECTION / VIRUCIDAL DIRECTIONS: To disinfect use 2 oz. per gallon of water. Apply **LONZA FORMULATION S-23** to walls, floors and other hard, inanimate, non-porous surfaces such as tables, chairs, countertops, sinks, tile, porcelain, toilet bowls, urinals and bedframes with a cloth, mop or coarse (mechanical) spray device so as to thoroughly wet surfaces. Treated surfaces must remain wet for 10 minutes.

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

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.

Prepare a fresh solution daily or more often if the solution becomes visibly dirty or diluted.

For heavily soiled areas, a preliminary cleaning is required.

FUNGICIDAL PERFORMANCE:

LONZA FORMULATION S-23 is an effective fungicide against Trichophyton mentagrophytes (the athlete's foot fungus) when used on surfaces such as locker rooms, dressing rooms, shower and bath areas, exercise facilities, etc., at 2 oz./gallon.

MOLD AND MILDEW CONTROL. At 2 oz./gallon, **LONZA FORMULATION S-23** 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.

**NON-ACID TOILET BOWL AND URINAL
DISINFECTANT / CLEANER APPLICATION:**

Remove gross filth prior to disinfection.

From concentrate:

Add 1.5 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 2 oz./gal. 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.

SANITIZING NON-FOOD CONTACT SURFACES

(such as floors, walls, tables) At 1 oz. per 2 gallons use-level, **LONZA FORMULATION S-23** is an effective sanitizer against *Staphylococcus aureus* and *Klebsiella pneumoniae*, on hard, porous and non-porous, environmental surfaces. Treated surface must remain wet for 60 seconds. Wipe dry with a clean cloth, mop or sponge or allow to air dry.

(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

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 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.

5/5