

6836-76

11/25/2009

1/5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

NOV 25 2009

Ms. Joanna Holcombe
Lonza, Inc.
90 Boroline Road
Allendale, NJ 07401

SUBJECT: Lonza Formulation S-23
EPA Registration No.: 6836-76
Amendment Date: November 19, 2009
EPA Receipt Date: November 19, 2009

Dear Ms. Holcombe,

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

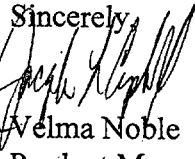
Proposed Amendment

- Update Storage and Disposal per PRN 2007-4
- Add Pandemic H1N1 Claims

General Comments

A stamped copy of the accepted label 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 Velma Noble at (703) 308-6233.

Sincerely,

Velma Noble

Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

CONCURRENCES							
SYMBOL	Enclosure:.....	Stamped Label					
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. Wash thoroughly with soap and water after handling. 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

This pesticide is toxic to fish and aquatic invertebrates. 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%
Dioctyl 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:	96.00%
Total:	100.00%

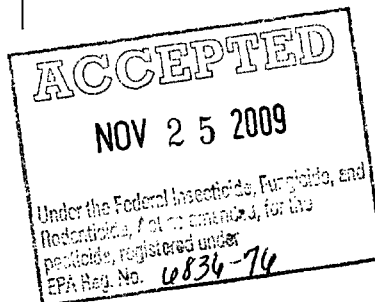
KEEP OUT OF REACH OF CHILDREN

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
[Country of origin (insert country)]
[Manufactured in (insert country)]
[Barcode]

Manufactured by:
LONZA INC.
90 Boroline Road
Allendale, NJ 07401



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 enterica

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 Virus Type A/Brazil, Herpes Simplex Virus Types I and II and Vaccinia Virus 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, glazed tile, glazed porcelain, 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. Wipe dry with cloth, sponge or mop or allow surfaces to air dry.

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. Follow disinfection directions.

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 of water **LONZA FORMULATION S-23** is an effective sanitizer against *Staphylococcus aureus* and *Klebsiella pneumoniae* in the presence of 5% serum, porous and non-porous non food contact environmental surfaces. Apply use solution with a mop, cloth or coarse mechanical sprayer so as to thoroughly wet surfaces. Treated surface must remain wet for 30 seconds. Wipe dry with a cloth, mop or sponge or allow surfaces to air dry.

(Note to reviewer: the following is considered optional marketing language:)

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. This product (Product Name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.
- This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus.

6/15

5/5

(Note to reviewer: For Nonrefillable Containers for commercial, industrial, and institutional uses – all sizes – No Reuse Rinsate Statement for Public Health Use products)

STORAGE AND DISPOSAL

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

Pesticide Storage: Open dumping is prohibited. Store in original container in areas inaccessible to children.

PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or 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:

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.

(Plastic and Metal Containers:) Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

(For metal containers only: DO NOT cut or weld metal containers.)

(Bag in Box Containers:) Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.