6836-74

10/17/2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 1 7 2003

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

Subject: Lonza Formulation S-39 EPA Registration No. 6836-74 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" to read "DANGER. Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear goggles or faceshield, protective clothing, and chemical resistant gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse."
- 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.
- 4. Revise the "Non food Contact Surface Sanitizing" directions to read :

At 5 oz per 4.5 gallons of water Lonza Formulation S-39 is an effective sanitizing agent against S. aureus and K. pneumoniae in the presence of 5% serum on porous and nonporus 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.

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General Comments

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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)

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PRECAUTIONARY STATEMENTS HAZARD TO HUMANS AND DOMESTIC ANIMALS

DANGER: 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.

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-39

Disinfectant – Cleaner - Sanitizer-Fungicide – Mildewstat - Virucide* - Deodorizer With Organic Soil Tolerance

For Schools, Industry, and Non-Medical Institutions

Active Ingredients:

Octyl decyl dimethyl ammonium chloride	0.540%
Dioctyl dimethyl ammonium chloride	
Didecyl dimethyl ammonium chloride	0.324%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%)	
dimethyl benzyl ammonium chloride	0.720%
Other Ingredients	8.200%
Total:	

KEEP OUT OF REACH OF CHILDREN

DANGER

PELIGRO

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration No.6836-74 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 1 7 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Actas amouded, for the pesticide, registered under EPA Reg. No. 6836-74

LONZA FORMULATION S-39 EPA NO. 6836-74 EPA DRAFT LABEL 7-15-03

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LONZA FORMULATION S-39 is an industrial cleaner which disinfects as it cleans. It is especially designed for schools, non-medical institutions and industry. A single application removes dirt and grime, disinfects, is virucidal, fungicidal, and inhibits the growth of mold and mildew and their odors.

When used as directed, the hard surface disinfecting action of LONZA FORMULATION S-39 will reduce the hazard of cross-contamination.

LONZA FORMULATION S-39 is an effective one-step sanitizer for non-food contact surfaces.

When used as directed, LONZA FORMULATION S-39 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-39 is a proven "one-step" cleaner-disinfectant-sanitizer-fungicide-mildewstatvirucide in the presence of moderate amounts of organic soil.

The activity of LONZA FORMULATION S-39 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 gram positive organisms as presented by:

Staphylococcus aureus Salmonella choleraesuis

Brevibacterium ammoniagenes Escherichia coli Klebsiella pneumoniae Salmonella schottmuelleri Salmonella typhi Serratia marcescens Shigella dysenteriae Streptococcus pyogenes

VIRUCIDAL PERFORMANCE

At 2 oz. per gallon use-level, LONZA FORMULATION S-39 was evaluated in the presence of 5% serum and found to be effective against the following viruses:

Herpes Simplex Type 1 Influenza A/Brazil, 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 DIRECTIONS:

Use 2 oz. of LONZA FORMULATION S-39 per gallon of water. Apply to walls, floors and other hard nonporous surfaces such as tables, chairs, countertops, and sinks with a cloth, mop or coarse mechanical spray device so as to thoroughly wet surfaces. Treated surfaces must remain wet for ten minutes.

For heavily solled areas, a preliminary cleaning is required.

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

FUNGICIDAL PERFORMANCE

LONZA FORMULATION S-39 is effective against Trichophyton mentagrophytes (the athlete's foot fungus) when used on surfaces in areas such as locker rooms, shower and bath areas, exercise areas, dressing rooms, at 2 oz./gallon. Follow Disinfection directions.

MOLD AND MILDEW CONTROL

At 2 oz./gallon, LONZA FORMULATION S-39 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 or more often if mildew growth returns.

NON-ACID TOILET BOWL AND URINAL DISINFECTANT / CLEANER APPLICATION

Remove gross fifth prior to disinfection.

From concentrate:

Add 1.5 oz. to the bowl (0.75 gallon) and mix. Brush thoroughly over exposed surfaces including 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. usesolution to exposed surfaces including under the rim with a cloth, mop, sponge or coarse mechanical spray. Brush or swab thoroughly, allow to stand for 10 minutes and flush.

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SANITIZING-NON-FOOD CONTACT SURFACES (such as floor, walls, tables).

At 5 oz. per 4.5 gallon use-level and a 30 second contact time, LONZA FORMULATION S-39 is an effective sanitizing agent against Staphylococcus aureus and Klebsiella pneumoniae in the presence of 5% serum on porous and nonporous non-food contact environmental surfaces. 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 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.

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