11/25/2009

UNITED STATES ENVIRONMENTAL PROTEC AN AGENCY



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

NOV 2 5 2009

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

SUBJECT:

Lonza Formulation S-39

EPA Registration No.: 6836-74

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.

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Product Manager (31)

Regulatory Management Branch I

CONCURRENCE TO DIAIS DIVISION (7510P)

SYMBOL
Enclosure: Stamped Label
SURNAME

DATE

Printed on Recycled Paper

OFFICIAL FILE COPY

PRECAUTIONARY STATEMENTS HAZARD TO HUMANS AND DOMESTIC ANIMALS

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.

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.

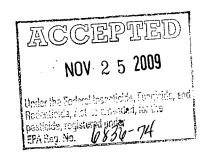
IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

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-39

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

For Schools, Industry, and Non-Medical Institutions

[Bouquet], [Cinnamon], [Citrus], [Clean], [Fern], [Floral], [Fougere], [Fresh], [Fresh & Clean], [Fresh 'N Clean], [Lavender], [Lemon], [Mint], [Palm], [Peppermint], [Pine], [Rose], [Sassafras], [Woody] [Scent] [Scented] [Odor] [Fragrance]

Active Ingredients:

Octyl decyl dimethyl ammonium chloride0.54	.0%
Dioctyl dimethyl ammonium chloride0.21	6%
Didecyl dimethyl ammonium chloride0.32	4%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%)	
dimethyl benzyl ammonium chloride0.72	0%
Other Ingredients98.20	0%
Total:100.00	

KEEP OUT OF REACH OF CHILDREN

DANGER **PELIGRO**

See [left] [right] [side] [back] panel for Precautionary Statements and First Aid

EPA Reg. No.6836-74 EPA Est. No. (Insert EPA Establishment number here) Net Contents (insert container size here) [Country of origin (insert country)] [Manufactured in (insert country)] [Barcode]

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

(Note to reviewer: Language in [] is optional or interchangeable)

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-mildewstat-virucide 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 [Staph] Salmonella enterica [Salmonella]

Brevibacterium ammoniagenes
Escherichia coli [E. coli]
Klebsiella pneumoniae
Salmonella schottmuelleri [Salmonella]
Şalmonella typhi [Salmonella]
Serratia marcescens
Shigella dysenteriae
Streptococcus pyogenes [Strep]
[a cause of Scarlet fever]
[a cause of Rheumatic fever]

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 Virus Type 1 Influenza A/Brazil Virus Vaccinia Virus

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. Wipe dry with cloth, sponge, or mop or allow surfaces to air dry.

For heavily soiled 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] [a cause of ringworm] [a cause of ringworm of the foot] 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 filth 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.

SANITIZING-NON-FOOD CONTACT SURFACES

(such as floors, walls, tables).

At 5 oz per 4.5 gallons of water 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 nonfood 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.

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

- Respiratory illnesses attributable to Pandemic 2009 H1N1are 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.

(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.