

6836-177

02-13-2012

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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



United States
Environmental Protection
Agency

Office of Pesticide Programs

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

FEB 13 2012

Subject: Lonza Formulation P-39
Registration No.: 6836-177
Amendment Dated: November 11, 2011
Date Received: November 15, 2011
Submission #: 906919

Dear Ms. Holcombe,

The following amendment, submitted in connection with registration under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable:

Proposed Amendment

All pages:

- Revise Note to reviewer that language in square brackets is optional of interchangeable. The note appears in the footer.

Page 1)

- Add optional marketing Statement
- Add optional Spanish signal word.
- Add optional placeholders for non-FIFRA Dot Symbols, country of origin, country of manufacture and barcode.
- Update Lonza Address

Page 2)

- Remove, "This product is toxic to fish", from the Environmental Hazards section. This statement is not required for indoor use products.

Page 3)

- Add note to reviewer regarding optional graphics for areas of use and types of surfaces.

Page 5)

- Add note to reviewer and the following optional Spanish language statement and English translation: Si usted no entinede la etiqueta, busque a alguien para que se la explique a usted en detalle. [If you do not understand the label, find someone to explain it to you in detail]

Page 7)

- Revise exiting storage and disposal language.
- Add storage and disposal language for nonrefillable sealed containers.

CONCURRENCES

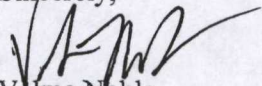
| SYMBOL | | | | | | | |
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| SURNAME | | | | | | | |
| DATE | | | | | | | |

General Comments:

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Velma Noble PM Team 31 at (703) 308-6233 or Jamil Mixon at (703) 308-8032.

Sincerely,



Velma Noble,
Product Manager, Team 31
Regulatory Management Branch
Antimicrobials Division (7510P)

Enclosure: Stamped Label

CONCURRENCES

| | | | | | | | | |
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LONZA FORMULATION P-39

PINE ODOR
DISINFECTANT-CLEANER-DEODORANT

*Kills Pseudomonas, Salmonella and Staphylococcus

**Virucidal

**Kills Influenza

Active Ingredients:

| | |
|--|---------|
| Pine oil | 23.81% |
| Alkyl (C ₁₄ , 58%; C ₁₆ , 28%; C ₁₂ , 14%) dimethyl benzyl ammonium chloride..... | 11.90% |
| Other Ingredients: | 64.29% |
| Total Ingredients: | 100.00% |

KEEP OUT OF REACH OF CHILDREN

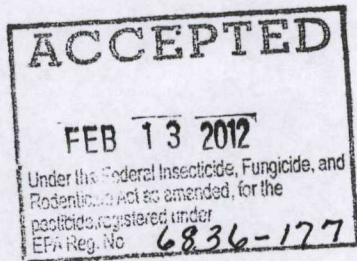
DANGER [PELIGRO]

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

EPA Reg. No. 6836-177
EPA Est. No. (as indicated on container)
Net Contents: (as indicated on container)

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

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



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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. Harmful if swallowed. Avoid contamination of food. Wear protective eyewear (goggles, face shield or safety glasses) protective clothing and rubber 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. Measures against circulatory depression and convulsion may be needed.

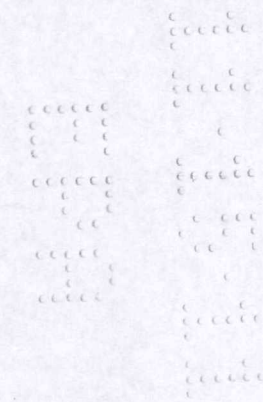
{Note to reviewer: If the container size is 5 gallons or greater, the following statements will be used:}

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.

PHYSICAL OR CHEMICAL HAZARD

Do not use or store near heat or open flame.



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{Note to reviewer: The following is considered optional marketing language:}

- Concentrate [Concentrated]
- Disinfectant [Disinfects]
- Deodorant [Deodorizes]
- Cleaner [Cleans]

{Note to reviewer: Each entry below also represents a graphic depicting the corresponding area of use. The graphics will only represent individual objects or outsides or insides of buildings as described below. No people, animal, or food will be depicted in graphics.}

Use **Lonza Formulation P-39** in homes,[households], hospitals, medical and dental offices, nursing homes, healthcare facilities, day care centers, nurseries, restaurants, bars, cafeterias, [institutional] kitchens, food processing plants, food storage areas, convenience stores, institutional facilities, public rest rooms, institutions, schools, colleges, athletic facilities, locker rooms, dressing rooms, shower and bath areas, exercise facilities, bathrooms, public facilities, veterinary offices, animal care and animal laboratory facilities, zoos , pet shops, kennels transportation terminals, hotels and motels, factories, business and office buildings, boats, ships, campers, trailers, mobile homes, cars, buses, trains, taxis and airplanes.

{Note to reviewer: Each entry below also represents a graphic depicting the corresponding type of surface. No people, animal, or food will be depicted in graphics. Only exteriors of microwaves and refrigerators will be depicted. Toy graphics will be submitted to Agency for review.}

Use **Lonza Formulation P-39** on: washable hard nonporous surfaces: floors, walls, cabinets, counters [countertops], stoves [stovetops], sinks, appliances, exterior microwave ovens and refrigerators, high chairs, tables, picnic tables, outdoor furniture, chairs, desks, telephones, door knobs, garbage cans, bathtubs, shower stalls, shower walls, glass shower doors tubs and glazed tiles, urinals, toilets, toilet bowls, toilet bowl surfaces, chrome fixtures, other bathroom fixtures, and hard nonporous surfaces made of metal, stainless steel, chrome, glazed porcelain, glazed ceramic, linoleum, sealed stone, fiberglass and plastic [such as polystyrene, polypropylene] enameled surfaces, finished woodwork, vinyl and plastic upholstery,

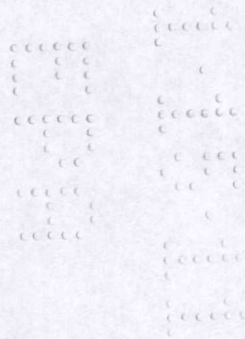
Lonza Formulation P-39:

- is effective against [a wide variety of] gram-positive and gram-negative bacteria.
- is an excellent deodorant.
- [and] is [especially] effective in controlling odors that are bacterial in origin.
- mixes with water to form clear, stable use solutions.
- Has a pleasant pine odor.
- may be used through automatic floor scrubbing equipment.
- is for use in industrial, commercial and / or medical areas.

Use **Lonza Formulation P-39** for:

- cleaning and deodorizing.
- one-step cleaning and disinfection.
- disinfection of precleaned, hard nonporous surfaces.

Use solutions are non-corrosive and non-staining to plastic, vinyl, synthetics, enamel, tile and most common metals.



{Note to reviewer: the following is considered optional marketing language:}

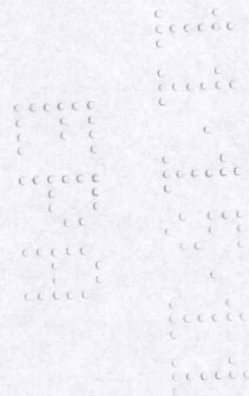
* Effective at 1 oz. per gallon of water against *Pseudomonas aeruginosa* [PRD-10], *Salmonella choleraesuis* [ATCC 10708], and *Staphylococcus aureus* [ATCC 6538], when tested by the A.O.A.C. Use Dilution Test Method, for precleaned, hard, nonporous surfaces.

** An effective virucide at 1 oz. per gallon of water against Influenza Virus Type A/Brazil.

- 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.

Lonza Formulation P-39 has not been tested for effectiveness against *Mycobacterium tuberculosis* and must not be relied upon when tuberculocidal activity is intended.

Lonza Formulation P-39 reduces the surface tension of water, improving its wettability. Microbes are capable of mass reproduction in sub-visible pores, scratches and cracks of surfaces. The exceptional wettability of **Lonza Formulation P-39** improves the penetration of the use solution into areas that otherwise might not be reached.



{If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.}

[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.

APPLICATION INFORMATION

Select the proper use-dilution of **Lonza Formulation P-39** from the directions below.

Apply the use solution with a clean mop, sponge, cloth, squeegee or mechanical scrubber. For disinfection, thoroughly wet the surfaces to be treated. Surfaces must remain moist for at least 10 minutes to assure proper germicidal action. Wipe dry with a clean cloth or sponge or allow to air dry.

Rinse all surfaces that come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse. Do not use this product to clean utensils, glassware and dishes.

Prepare fresh use solutions daily. Do not reuse solutions. Discard solutions when they become visibly soiled.

CLEANING

To Clean and Deodorize or to Preclean Prior to Disinfection. Depending on the soil level of the area to be cleaned, use 1 to 2 oz. of **Lonza Formulation P-39** per gallon of water.

DISINFECTING

Hospitals, Healthcare Facilities [Clinics], Nursing Homes: Use 1¼ oz. of **Lonza Formulation P-39** per gallon of water [1 part to 100 parts water] for one-step cleaning and disinfection of areas with light to medium soil loads. For heavily soiled areas, preclean as described above, and then disinfect with 1 oz. of **Lonza Formulation P-39** per gallon of water [1 part to 127 parts water].

{Note to 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. 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 to be used on medical device surfaces.

Schools, Industrial areas, Homes, Barber Shops, Restrooms, Restaurants, Food and Meat Processing Plants [non-food, processing areas], Public Rooms, Other Non-Medical use sites: Pre-clean surfaces, then, disinfect with a solution of 1 1/3 oz. of **Lonza Formulation P-39** in 2 gallons of water [1 part to 190 parts water]. Alternatively, clean and disinfect in one operation, using 1¼ oz. of **Lonza Formulation P-39** per gallon of water [1 part in 100 parts water].

DEODORIZING garbage cans, garbage trucks, Industrial waste receptacles and garbage handling equipment, it is especially important to pre-clean for the product to perform properly. Then, apply a wetting concentration of 1½ to 3 oz., of **Lonza Formulation P-39** per 2 gallons of water.

FOR MILDEW CONTROL: Follow directions for hospital disinfection. Repeat treatment every seven days, or more often if new growth appears.

TOILET BOWL / URINAL DISINFECTANT AND CLEANER DIRECTIONS:

Empty toilet bowl or urinal and apply a 1 ¼ oz./gal. use-solution to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer, Brush or swab thoroughly, allow to stand for 10 minutes and flush.

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SALON [BARBER] INSTRUMENTS AND TOOLS DISINFECTION / VIRUCIDE* / DIRECTIONS:

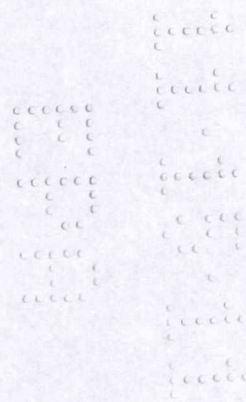
Mix 1 ¼ oz. of **Lonza Formulation P-39** per gallon of water [or equivalent dilution] to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, rollers, razors, scissors, blades, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Prepare a fresh solution daily or more often if the solution becomes visibly diluted, cloudy or soiled.

Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

**VETERINARY PRACTICE / ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP / KENNELS
DISINFECTION DIRECTIONS:**

For cleaning and disinfecting the following hard nonporous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with potable water. Saturate surfaces with a use-solution of 1 1/4 oz. of **Lonza Formulation P-39** per gallon of water [1 part to 100 parts water] [or equivalent dilution] for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

VEHICLES: Clean all vehicles including mats, crates, cabs and wheels with high pressure water and this product. Use 1 1/4 ounces of this product per gallon of water to treat vehicles. Leave all surfaces wet for 10 minutes or more.



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{Note to reviewer: For Nonrefillable Containers, Label has Household and Residential Uses -- 5 gallons or less}

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for recycling if available.

{or}

Store in original container in areas inaccessible to children. Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for reconditioning if appropriate.

{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.

{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.

{Note to reviewer: For Nonrefillable Sealed Containers: Packaging options can be in sealed containers or bottles designed for use dilution systems to reduce worker exposure to the concentrate. None of these can be triple rinsed because they are closed sealed containers. The following text will be used on these sealed container types:}

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. Wrap empty container and put in trash.