

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Ms. Ruth Trager  
Lonza Inc.  
17-17 Route 208  
Fair Lawn, NJ 07410

RECEIVED  
JAN 24 2002

Subject: Bio-Guard P-39  
EPA Registration No. 6836-177  
Amendment dated October 25, 2001  
EPA Receipt Date: October 26, 2001

Dear Ms. Trager:

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

- Revise first aid statements per PR Notice 2001-1
- Change Primary Brand Name to "Lonza Formulation P-39"
- Update Labeling - Directions for Use, Precautionary Statements, and Storage/Disposal Statements

**Conditions**

Revise the label as follows:

1. You must cite specific directions for veterinary clinics. The following language is suggested:

Veterinary Clinics: For cleaning and disinfecting the following hard, non-porous surfaces: equipment not to be used for animal food or water, utensils, instruments, cages, kennels, stables, and catteries. Remove all animals and feeds from premises. animal transportation vehicles, crates, etc. Remove all liter, droppings, and manure from floors, walls, and surfaces of facilities occupied or transversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with potable water. Saturate surfaces with a use solution of 1 1/3 oz of product per 2 gallons of water 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.

**CONCURRENCES**

SYMBOL								
SURNAME								
DATE								

- 2. Since this product may be used in restrooms on glazed porcelain and efficacy data was not submitted to support interior toilet disinfection, you must either state *"Disinfect exterior surfaces of the toilet"* or add the following directions under an appropriate heading: *"Empty water from toilet bowl or urinal. Then disinfect with a use-solution of 1 1/3 oz/ 2 gallons of water. Brush thoroughly over surfaces including under the rim to completely wet surfaces, let stand for 10 minutes, then flush."*
- 3. The statement, "this product should not be used ..... dishes," must be revised to *"Do Not Use This Product on Utensils, Glassware, and Dishes."*
- 4. The use sites, "Industrial areas" and "other non-medical uses" are too broad; they must be expanded by listing specific use sites.
- 5. The barber shop use site tend to trigger specific directions for use for the disinfection of implements and tools. If this product is used in this manner by your customers, the following directions must be added:

Mix 1 1/3 oz. of product per 2 gallons of water 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 reuse. Prepare a fresh solution daily or more often if the solution becomes visible cloudy, dirty, 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.

**General Comments**

Lonza Formulation P-39 is acceptable as this product's new primary brand name.

A stamped label is enclosed for your records. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling. If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



Velma Noble  
 Product Manager (31)  
 Regulatory Management Branch I  
 Antimicrobials Division (7510C)

**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.

**ENVIRONMENTAL HAZARDS**

This product is toxic to fish.  
*(Note to reviewer: If the container size is 5 gallons or greater, the following statements will also be used:)*

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.

**LONZA FORMULATION P-39**

**PINE ODOR  
DISINFECTANT-CLEANER-DEODORANT**

**USE IN INDUSTRIAL, COMMERCIAL and / or  
MEDICAL AREAS ONLY**

\*Kills Pseudomonas, Salmonella and Staphylococcus

\*\*Virucidal

<b>Active Ingredients:</b>	
Pine oil.....	23.81%
Alkyl (C <sub>14</sub> , 58%; C <sub>16</sub> , 28%; C <sub>12</sub> , 14%) dimethyl benzyl ammonium chloride....	11.90%
<b>Other Ingredients:</b> .....	<b>64.29%</b>
<b>Total Ingredients:</b> .....	<b>100.00%</b>

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

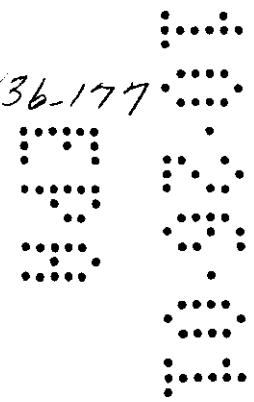
See (side) (back) (left) (right) panel for Precautionary Statements and First Aid.)

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

Manufactured by:  
**LONZA INC., 17-17 Route 208, Fair Lawn, NJ 07410**  
ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

*JAN 24 2002*

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. *6836-177*



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

- Concentrate (Concentrated)
- Disinfectant (Disinfects)
- Deodorant (Deodorizes)
- Cleaner (Cleans)

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.

Use Lonza Formulation P-39 for:

- cleaning and deodorizing.
- one-step cleaning and disinfection.
- disinfection of precleaned, hard nonporous surfaces.
- cleaning and disinfecting hard, nonporous surfaces made of glass, metal, glazed porcelain, linoleum, tile, vinyl, enameled and finished wood. Use on walls, floors and appliances.

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

\*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.

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.

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**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. This product should not be used 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.

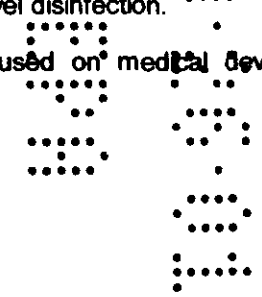
**DISINFECTING**

Hospitals, Veterinary Clinics, Nursing Homes: Use 1 1/4 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 uses: Pre-clean surfaces, then, disinfect with a solution of 1½ 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).

For 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.

(If container size is one gallon or less, use the following Storage and Disposal statements):

**STORAGE AND DISPOSAL**

Store in tightly closed original container in a secure area inaccessible to children. Do not reuse empty container. Discard in trash or recycle.

(If container size is greater than one gallon, use the following Storage and Disposal statements):

**STORAGE AND DISPOSAL**

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

**PESTICIDE STORAGE:**

Store in original container in areas inaccessible to children. Do not reuse empty container.

**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 Recycling:**

Triple Rinse (or equivalent). Then offer for recycling or reconditioning, or purchase 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.

(If not triple rinsed) Triple Rinse (or equivalent). Then offer for recycling or reconditioning, or purchase and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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Fungicide, and Rodenticide Act as  
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