

6836-177

09/23/2002

1/6

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Patricia Moriarty
Sr. Regulatory Associate
Lonza Inc.
17-17 Route 208
Fair Lawn, NJ 07410

SEP 23 2002

Subject: Lonza Formulation P-39
EPA Registration No. 6836-177
Amendment dated: June 19, 2002
EPA Received date: June 25, 2002

Dear: Ms. Patricia Moriarty,

The following amendment submitted in connection with registration under section of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, is acceptable with comments.

Proposed Amendment

- Revisions as per EPA comments letter for P-39 6836-177 dated January 24, 2002.

Label Comments

1. Delete the phrase " of Lonza Formulation P-13 per gallon of water or equivalent dilution" under the **SALON (BARBER) INSTRUMENTS AND TOOLS DISINFECTION /VIRUCIDE* /DIRECTIONS** heading, because it is redundant.
2. Qualify the use sites as follows "microwave ovens (*exterior*); refrigerator (*exterior*)....."
3. Revise the toilet bowl directions for use by adding the statement, "*Bush or swab thoroughly, allow to stand for 10 minutes and flush.*"

CONCURRENCES							
SYMBOL	4. Add the word "potable" to the statement "Thoroughly clean all surfaces with						
SURNAME	A. Peters						
DATE	9/23/02						

soap and detergent and rinse with *potable* water. Under the **VETERINARY PRACTICE/ ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP/ KENNEL DISINFECTION DIRECTIONS** heading.

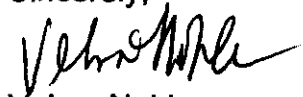
- 5. This product lists vehicles, cars, taxis, trains, mobile homes, etc., specific directions for use for this product must be added to the label. Therefore add the following paragraph:

Vehicles: Clean all vehicles including mats, crates, crabs and wheels with high pressure water and Lonza Formulation P-39. Use 1 1/4 oz of Lonza Formulation P-39 per gallon of water to treat all vehicles. Leave all treated surfaces wet for 10 minutes or more.

General Comments

A stamped label is enclosed for your records. Please submit a copy of your final printed label before distributing or selling the product bearing the revised labeling. If you have any questions regarding this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch1
Antimicrobial Divisions (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

*Kills Pseudomonas, Salmonella and Staphylococcus

**Virucidal

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

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:

SEP 23 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)

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.

Use **Lonza Formulation P-39** on: washable hard nonporous surfaces: floors, walls, cabinets, counters (countertops), stoves (stovetops), sinks, appliances, microwave ovens, 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.

Lonza Formulation P-39 (Note to reviewer: Language in () is optional or interchangeable)
EPA Reg. No. 6836-177
EPA Label Amendment 6/11/02

* 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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
SEP 23 2002

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

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 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 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 1 1/4 oz. of Lonza Formulation P-39 per gallon of water (1 part in 100 parts water).

Lonza Formulation P-39
EPA Reg. No. 6836-177
EPA Label Amendment 6/11/02

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

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 1 1/2 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 1/4 oz./gal. use-solution to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer, allow to stand for 10 minutes and flush.

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 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.

SALON (BARBER) INSTRUMENTS AND TOOLS DISINFECTION / VIRUCIDE* / DIRECTIONS:

Mix 1 1/4 oz. of Lonza Formulation P-39 per gallon of water (or equivalent dilution) of Lonza Formulation P-13 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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 23 2002

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

6836-177

6/6

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

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 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 puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

ACCEPTED
with **COMMENTS**
in EPA Letter Dated:

SEP 23 2002

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