

6836-87

51412011

1 of 5

Ms. Ruth Trager
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

MAY -4 2011

SUBJECT: Lonza DC-102
EPA Registration Number: 6836-87
Application Dated: February 3, 2011
Receipt Date: February 4, 2011

Dear Ms. Trager:

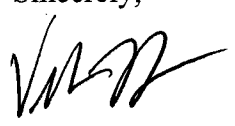
The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is acceptable.

- Remove the claim for Pseudomonas aeruginosa and all hospital use sites from the label.

General Comments

A stamped copy of the accepted label is enclosed. Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0199 or Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble
Product Manager (31)

CONCURRENTLY
Regulatory Management Branch I
Antimicrobials Division (7510P)

SYMBOL							
SURNAME							
DATE							

2015

LONZA DC-102

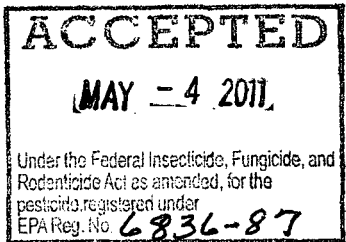
QUATERNARY PINE-OIL

Disinfectant-Cleaner-Sanitizer-Fungicide
Mildewstat-Deodorizer With Organic Tolerance
For Medical and Non-Medical Use Areas*
Plus Disinfectant Hard Water
(400 ppm Calculated as CaCO₃) Tolerance

For Non-Medical Use Areas**

For Hospital - Institutional - Industrial and School Use

Active Ingredients	
Octyl decyl dimethyl ammonium chloride	0.570%
Dioctyl dimethyl ammonium chloride	0.228%
Didecyl dimethyl ammonium chloride	0.342%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	0.760%
Pine-Oil	2.500%
Other Ingredients	95.600%
Total	100.000%



KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

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

EPA Reg. No. 6836-87
 EPA Est. No. *(Insert EPA Est. No. 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

**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. Wear protective eyewear (goggles or face shield), protective clothing and protective gloves (rubber or chemical resistant) when handling. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash 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.

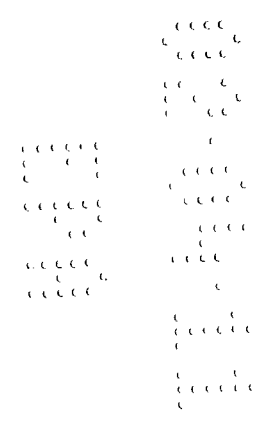
(Note to reviewer: For container sizes of 5 gallons or greater, the following Environmental Hazards statements will be used:)

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.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.



Cross contamination is of major housekeeping concern in schools, ~~medical institutions~~ and industry. **LONZA FORMULATION DC-102** has been formulated to aid in the reduction of cross contamination in these areas.

LONZA DC-102 is a one-step disinfectant cleaner that is effective against a broad spectrum of bacteria, is fungicidal, and will prevent the growth of mold and mildew and their odors when used as directed.

~~LONZA DC-102 is an effective one-step sanitizer-cleaner for use on non-food contact surfaces.~~

When used as directed, **LONZA DC-102** 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 malodors.

LONZA DC-102 is a proven "one-step", cleaner-disinfectant-sanitizer-fungicide-mildewstat in the presence of organic soil.

PELIGRO

SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES DE USO APOIADAS 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.

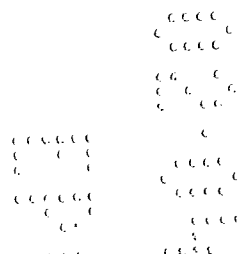
Apply **LONZA DC-102** to walls, floors and other hard, nonporous surfaces such as tables, chairs, countertops, and sinks with a cloth, mop or coarse mechanical spray. Surface must be sprayed until thoroughly wetted. Surfaces must remain wet for ten minutes. Allow surfaces to air dry or wipe excess liquid with cloth, mop, or sponge. For heavily soiled areas, a preliminary cleaning is required. Prepare a fresh solution daily or when use solution becomes visibly dirty.

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

DISINFECTION

NON-MEDICAL USE AREAS* Schools, Commercial Areas and Industries. At 2.5 oz. per gallon, use level, the activity of **LONZA DC-102** has been evaluated by the AOAC Use-Dilution method, and found to be effective against a broad spectrum of gram positive and gram negative organisms as represented by:

- Serratia marcescens
- Salmonella typhi
- Staphylococcus aureus
- Salmonella enterica
- Escherichia coli
- Streptococcus pyogenes
- Streptococcus faecalis
- Enterobacter aerogenes
- Shigella dysenteriae
- Brevibacterium ammoniagenes



NON-MEDICAL USE AREAS** At 5 oz. per gallon use level, the activity of **LONZA DC-102** has been evaluated in the presence of both 5% blood serum, and 400 ppm hard water, against Staphylococcus aureus, Salmonella enterica and Escherichia coli.

MEDICAL USE AREAS* ~~Hospitals and Nursing Homes.~~ At 5 oz. per gallon use level. At this dilution, **LONZA DC-102** is effective against Pseudomonas aeruginosa.

(Note to reviewer: Only One of the following two statements will 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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.~~

~~OR~~

~~This product is not for use on medical device surfaces.~~

FUNGICIDAL CONTROL At 2.5 oz. per gallon use level, **LONZA DC-102**, when used on surfaces, in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities. Fungicidal activity has been demonstrated in the presence of both 5% blood serum, and 400 ppm hard water against Trichophyton mentagrophytes (the athlete's foot fungus). Follow non-medical disinfection directions.

MOLD AND MILDEW CONTROL At 2.5 oz. per gallon use-level, **LONZA DC-102** will effectively inhibit the growth of mold and mildew, and the odors caused by them, when applied to hard, nonporous surfaces (as indicated in general instructions above). Allow to dry on surface and repeat when mildew growth returns.

SANITIZING NON-FOOD CONTACT SURFACES (such as floor, walls, tables) At 1 oz. per gallon use level prepared in water up to 600 ppm hardness, **LONZA DC-102** is an effective sanitizer against Staphylococcus aureus and Klebsiella pneumoniae, on hard, porous and nonporous, environmental surfaces. Apply use solution with sponge, mop, cloth or mechanical sprayer. Allow to remain wet for 60 seconds. Allow surfaces to air dry or wipe excess liquid with cloth, mop, or sponge.

(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.