

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 4 2003

Mr. Robert Sloan
Lonza Inc
17-17 Route 208
Fair Lawn, NJ

Subject: Lonza Formulation 68-16
EPA Registration No. 6836-37
Amendment Date: September 5, 2003
EPA Receipt Date: September 8, 2003

Dear Mr. Sloan,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

- Update First Aid and Precautionary Statements

Conditions

Revise the label as follows:

1. The term, institutional, refers to hospitals, nursing homes, medical and dental facilities. The use of this term in your product label seems to be more in line with commercial than institutional since you state hospitals and nursing homes as specific sites. Commercial facilities refers to office buildings, motels, hotels, and athletic facilities. You should revise your label by deleting "institutional" and replace it with "commercial."
2. Revise the "When encountering heavy organic soil ... of water" statement to read "*When encountering heavy organic soil load in hospital, nursing homes, schools, commercial and industrial uses, preclean surfaces. Then use 2 oz per gallon of water.*"

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.

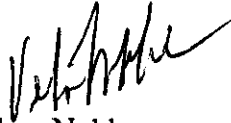
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

215

Should you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



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

Enclosure: Stamped Label

CONCURRENCES

SYMBOL							
▶							
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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. Wear protective eyewear (goggles, safety glasses or face shield) and protective gloves (rubber or chemical resistant) when handling. Harmful if swallowed or absorbed through the skin. Avoid contamination of food. 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 shock, respiratory depression and convulsion may be needed.

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.

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

DEC 4 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 6836-37

LONZA FORMULATION 68-16

**Heavy Duty Germicide
with Organic Soil Tolerance**

Cleaner – Disinfectant – Deodorizer – Fungicide -
Virucide* - Sanitizer

For Hospital and Institutional Use

Active Ingredients:

Octyl Decyl Dimethyl Ammonium Chloride.....	4.50%
Dioctyl Dimethyl Ammonium Chloride.....	2.25%
Didecyl Dimethyl Ammonium Chloride.....	2.25%
Other Ingredients:.....	91.00%
Total:	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Reg. No.6836-37

EPA Est. No. *(Insert EPA Establishment No. here)*

Net Contents *(insert container size here)*

MANUFACTURED BY:
LONZA INC.
17-17 Route 208
Fair Lawn, N.J. 07410

LONZA FORMULATION 68-16 is a germicide with an organic soil tolerance. Its disinfecting action has been verified in the AOAC Use-Dilution Test against *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa* in the presence of 5% blood serum as a source of organic matter. This means that one-step disinfection and cleaning can be achieved when used as directed.

Cross-contamination is of major housekeeping concern not only in hospitals, but in schools, institutions, and industry. **LONZA FORMULATION 68-16** is formulated for this problem area. It cleans, disinfects, and is virucidal when used as directed. Its hard surface disinfecting action will reduce the hazard of cross-contamination.

LONZA FORMULATION 68-16 is a proven "one-step" cleaner - disinfectant - sanitizer - fungicide - virucide in the presence of moderate amounts of organic soil when used as directed.

The broad spectrum activity of **LONZA FORMULATION 68-16** has been evaluated at 1 oz. per gallon of water in the presence of 5% serum and found to be effective against the following organisms by the AOAC Use-Dilution test:

Pseudomonas aeruginosa
Staphylococcus aureus
Salmonella choleraesuis

*Virucidal Performance

At 1 oz. per gallon use-level, **LONZA FORMULATION 68-16** was evaluated in the presence of 10% serum and found to be effective against the following viruses:

Herpes Simplex Type 1 (a member of the Herpes viruses that cause chicken pox, severe brain infections, and infectious mononucleosis)
 Influenza A₂ / Hong Kong (the Hong Kong flu virus)
 Vaccinia (representative of the pox viruses),

Use **LONZA FORMULATION 68-16** on walls, floors and other hard (inanimate) non-porous surfaces such as tables, chairs, countertops, sinks and bedframes.

Sanitizing-Non-Food Contact Surfaces (Walls, floors, tables, etc.). At ¾ oz. per 3½ gallons of water use-level, **LONZA FORMULATION 68-16** is an effective sanitizer in waters of up to 400 ppm hardness against *Staphylococcus aureus* and *Klebsiella pneumoniae* in the presence of 5% serum on hard porous and non-porous environmental surfaces.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Apply with a cloth, mop or sponge or coarse (mechanical) spray device so as to thoroughly wet surfaces. For heavily soiled areas, a preliminary cleaning is required.

Prepare a fresh solution daily or more often if the use solution becomes visibly diluted or dirty.

DISINFECTION / VIRUCIDAL DIRECTIONS: For disinfection of hard, nonporous surfaces, add 1 oz. per gallon of water. Treated surfaces must remain wet for 10 minutes. Wipe dry with a clean cloth or sponge or allow to air dry.

When encountering *heavy organic soil in hospitals, nursing homes, schools, institutional and industrial uses*, use 2 oz. per gallon of water.

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

TO SANITIZE - To sanitize porous or nonporous, non-food contact surfaces, add ¾ oz. per 3½ gallons of water. Treated surfaces must remain wet for 60 seconds. Wipe dry with a clean cloth or sponge or allow to air dry.

AOAC Fungicidal Test

LONZA FORMULATION 68-16 is an effective fungicide against *Trichophyton mentagrophytes* (the athlete's foot fungus) when used on surfaces in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities, etc. Follow Disinfection directions.

(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.

(If container size is 1 gallon or less, the following storage and disposal statements will be used:)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not reuse empty container. Discard in trash or recycle.

(If container size is greater than gallon, the following storage and disposal statements will be used:)

STORAGE AND DISPOSAL

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

Pesticide Storage

Do not store on side. Avoid creasing or impacting of side walls.

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray or mixture of 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 way of smoke.

(Metal Containers:) Triple rinse (or equivalent), then offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

