

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT - 3 2003

Mr. Robert Sloan
Lonza Inc.
17-17 Route 208
Fair Lawn, NJ 07410

Subject: Lonza Formulation M-7
EPA Registration No. 6836-167
Amendment Date: July 2, 2003
EPA Receipt Date: July 7, 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 Statements per PR Notice 2001-1

Conditions

Revise the label as follows:

1. Revise the "Precautionary Statements" by adding the phrase, *"protective clothing"* to the 4th statement and the statements, *"Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling."* Also, delete the statement, "Avoid contamination of food."
2. Revise 1st paragraph under the directions by qualifying the surface, tile, as hard nonporous by stating *"glazed"* tile. Also, specify appliance *exteriors*.
3. Under "Disinfecting," revise the second sentence by stating *"prepare 5 oz gallon of water and thoroughly wet surfaces with a cloth, sponge, brush, mop or mechanical sprayer."* Also, revise the last sentence by stating *"allow surfaces to air dry or rinse with clear water or wipe with a damp cloth."*
4. Delete the Memorandum of Understanding text on this label since this product is not approved for use in hospitals.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

General Comments

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

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)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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) and protective gloves (rubber or chemical resistant) when handling. Harmful if swallowed. Avoid contamination of food.

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.

(If container size is 5 gallons or greater, use the following Environmental Hazards statements;)

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.

LONZA FORMULATION M-7**DISINFECTANT-CLEANER-DEODORANT
PLEASANTLY MINT SCENTED****Active Ingredient:**

Alkyl (C₁₄, 58%; C₁₈, 28%; C₁₂, 14%)

dimethyl benzyl ammonium chloride2.0%

Other Ingredients:.....98.0%

Total:.....100.0%

Contains methyl salicylate

KEEP OUT OF REACH OF CHILDREN**DANGER**

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

EPA Reg. No. 6836-167

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

Net Contents (*Insert container size here*)

Manufactured by:

LONZA INC.

17-17 Route 208

Fair Lawn, NJ 07410

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 3 - 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 6836-167

THIS DISINFECTANT is effective against a wide variety of gram-positive and gram-negative bacteria.

THIS DISINFECTANT is also an excellent deodorant. It is especially effective in controlling odors that are bacterial in origin.

THIS DISINFECTANT mixes readily with water and makes a clear, stable solution. In use dilution, it is non-corrosive and non-staining to plastic, vinyl, synthetics, enamel, tile and most common metals. Has a pleasant mint odor.

DIRECTIONS FOR USE

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

FOR RESTROOMS AND GENERAL DISINFECTION of hard, non-porous inanimate surfaces such as glass, metal, plastic, glazed porcelain, linoleum, tile, leather, vinyl, and enamel and finished wood surfaces. Apply this product on walls, floors, appliances and furnishings in schools, public rooms, homes, pet quarters and industrial and commercial offices and areas.

CLEANING AND DEODORIZING. Whenever practical, flush away gross soils with water. For cleaning and deodorizing, use 5 to 8 oz. of THIS PRODUCT per gallon of water. Cleaning may be accomplished with a clean mop, sponge, squeegee, wet vacuum system or a coarse mechanical spraying device. After cleaning, remove suspended soils with a clear water rinse, vacuum pickup or by wiping with a clean mop, sponge, squeegee or cloth.

DISINFECTING. Before disinfecting, preclean surfaces as directed above. Then, prepare 5 ounces of THIS DISINFECTANT per gallon of water and thoroughly wet the surfaces to be disinfected. The disinfecting solution must contact the surface for 10 minutes for proper disinfection. If desired, the surfaces may then be rinsed with clear water or wiped with a damp cloth.

FOR CLEANING AND DEODORIZING OF GARBAGE CANS, GARBAGE TRUCKS, INDUSTRIAL WASTE RECEPTACLES AND OTHER GARBAGE HANDLING EQUIPMENT. It is especially important to preclean in order for the disinfectant to perform properly. Then apply a wetting solution of 8 ounces of THIS PRODUCT per gallon of water.

FOR CLEANING OF WALLS, FLOORS AND INDUSTRIAL WORK AREAS. Use 5-8 ounces per gallon of water. The use of rubber gloves is recommended for personnel doing continuous hand cleaning.

KILLS: *Salmonella choleraesuis* ATCC 10708 and *Staphylococcus aureus* ATCC 6538.

When applied as directed to precleaned hard, non-porous surfaces, this disinfectant also kills the following organisms at 5 ounces per gallon: *Candida albicans*, *Escherichia coli*, *Streptococcus pyogenes*, *Enterobacter aerogenes*, *Shigella sonnei*.

(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 preclean 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, use the following storage and disposal statements:)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Discard in trash or recycle.

(If container size is greater than 1 gallon, use the following storage and disposal statements:)

STORAGE AND DISPOSAL

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

(Metal container:) 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.