

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 17 2003

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

Subject: Lonza RD-10
EPA Registration No. 6836-180
Amendment Date: July 17, 2003
EPA Receipt Date: July 21, 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 Statement" by adding the statement, "Wash thoroughly with soap and water after handling."
2. Under Disinfection directions, revise the first two paragraphs to read:

Always preclean surfaces with a suitable detergent and rinse well with water before disinfection.

General Disinfection: Use 1 oz per gallon of water

Hospital Disinfection: Use 1 1/2 oz per gallon of water

Apply appropriate use solution with a clean mop, sponge, cloth, or by coarse mechanical spraying device. Surfaces must remain wet for 10 minutes. Wipe dry with cloth, sponge, or mop or allow surfaces to air dry.

CONCURRENCES							
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SURNAME							
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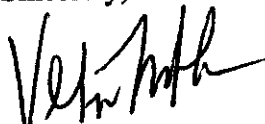
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General Comments

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

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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), protective clothing and protective gloves (rubber or chemical resistant). Harmful if swallowed. Remove and wash contaminated 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:

This product is toxic to fish.

(If container size is 5 gallons or larger, add the following Environmental Hazards statements.)

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 RD-10

- **DISINFECTANT**
- **SANITIZER**
- **DEODORANT**

FOR INDUSTRIAL, COMMERCIAL OR MEDICAL USE

Active Ingredient:

Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%)	
dimethyl benzyl ammonium chloride	10.00%
Other Ingredients:	90.00%
Total:	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Reg. No. 6836-180
EPA Est. No. *(insert EPA Est. No. here)*
Net Contents: *(insert container size here)*

Manufactured by:
LONZA INC.
17-17 RT. 208
FAIR LAWN, NJ 07410

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 17 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. **6836-180**

When used as directed, this product is an effective disinfectant, deodorant, and sanitizer.

When used as directed, this product mixes with water to form clear, stable use solutions that are non-corrosive and non-staining to most common metals, plastics, and tile.

This product may be used on floors, walls and finished woodwork.

Use on glass, metal, washable painted wood, vinyl, glazed porcelain, plastic, finished wood and other nonporous, hard surfaces.

This product fulfills the criteria of Appendix F of the Grade "A" Pasteurized Milk Ordinance 2003. Recommendations of the U.S. Public Health Service in waters up to 700 ppm of hardness calculated as CaCO₃ when tested by the A.O.A.C. Germicidal and Detergent Sanitizers - "Official Method".

* This disinfectant is effective at 1 oz./gal. 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.

* This disinfectant is an effective virucide against Influenza virus, Type A, Brazil at 1 oz./gal. on precleaned, hard nonporous surfaces.

DIRECTIONS FOR USE

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

DISINFECTION IN HOSPITALS, RESTAURANTS, COMMERCIAL AND INDUSTRIAL OFFICES, RESTROOMS AND WORK AREAS.

Always preclean surfaces with a suitable detergent and rinse well with water before disinfection. After cleaning, apply a solution containing 1 ounce of this product per gallon of water for usual disinfecting applications. For disinfecting contagious disease areas, use 1 1/2 ounces per gallon of water.

Apply with a clean mop, sponge, or by a coarse mechanical spraying device. Surfaces must remain wet for at least 10 minutes to assure proper germicidal action.

Prepare fresh solution daily or more often if solution when visibly soiled.

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.

(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.

SANITIZATION OF FOOD CONTACT SURFACES, GLASSWARE, SILVERWARE, DISHES, COOKING UTENSILS, MILK CANS, AND EQUIPMENT IN FOOD PROCESSING PLANTS, MEAT PLANTS, DAIRIES AND RESTAURANTS. Prior to application, remove gross food particles and soil by a pre-flush, or pre-scrape and, when necessary, pre-soak. Then thoroughly wash or flush objects with a good detergent or compatible cleaner followed by a potable water rinse before application of the sanitizing solution.

Then apply a sanitizing treatment of 1 ounce of THIS PRODUCT in 4 gallons of water (200 ppm active sanitizer) by immersion, flooding, flushing, spraying or with a clean cloth or mop. All surfaces must be thoroughly wet for at least 1 minute (60 seconds) for proper sanitization followed by adequate draining and air drying.. Do not rinse. Where possible, invert treated items (glassware, dishes, utensils, milk cans, etc.) and let them drain and air dry on a clean surface. Prepare fresh solutions daily or more often if solutions become diluted or soiled.

For mechanical application, use- solution may not be reused for sanitizing applications but may be reused for other purposes such as cleaning.

Apply to sink tops, countertops, refrigerated storage and display equipment and other stationary hard nonporous surfaces by cloth, sponge, brush coarse spray.

Sanitize dishes, silverware, glasses, cooking utensils and other similar size food processing equipment by immersion.

FLANK AND UDDER WASHING. Use 1 ounce per 4 gallons of water. Use a separate clean towel for each cow. Never dip a used towel back into the disinfectant solution. Prepare a fresh solution for each milking. Prepare solution in non-corrodible containers (stainless steel, plastic). Discard solutions if they become visibly soiled or turbid. To prevent residues in milk, allow udder to air dry or dry with clean towel before attaching to milker.

FOR DEODORIZING GARBAGE CANS, GARBAGE TRUCKS, INDUSTRIAL WASTE RECEPTACLES, AND GARBAGE HANDLING EQUIPMENT - Pre-clean with a suitable detergent and rinse well, then apply a wetting solution of 2 oz. of THIS PRODUCT per gallon of water. Wipe dry with a clean cloth or sponge or allow to air dry.

(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.