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U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (H7505C) 401 "M" St., S.W Washington, D.C. 20460

6836-3<u>0</u>1

JAN 29 2002

NOTICE OF PESTICIDE:

x Registration

__ Reregistration

Term of Issuance:
Conditional

EPA Reg. Number

Name of Pesticide Product

Lonza Formulation FC-600

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Lonza, Inc.

17-17 Route 208

Fair Lawn, NJ 07410

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide \ct.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

- 1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
- 2. Make the following label changes:
 - a. Revise the EPA Registration Number to read, "EPA Reg. No. 6836-301".

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of this product constitutes acceptance of these conditions.

A stamped label is enclosed for your records. Submit three (3) copies of your final printed labeling before distributing or selling the product. If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Signature of Approving Official:

Velma Noble

Product Manager 31

Regulatory Management Branch I Antimicrobials Division (7510C) Date

JAN 29 2002

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING. Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield or safety glasses). 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.

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 reviewer: If the container is 5 gallons or larger, the following Environmental Hazards statements will be used:)

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:

JAN 29 2002

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pessicide, registered under EPA Reg. No. 6836-301

LONZA FORMULATION FC-600

Food Contact Surface Sanitizer

For Institutional and Industrial Use

For School, Dairy, Restaurant, Food Handling and Processing Areas, Bar and Institutional Kitchen Use, Retail Food Establishments

An effective sanitizer for use on food contact surfaces

An effective one-step sanitizer for use on non-food contact surfaces

KEEP OUT OF REACH OF CHILDREN

WARNING

SEE (SIDE)(LEFT)(RIGHT)(BACK) PANEL FOR PRECAUTIONARY STATEMENTS AND FIRST AID

EPA Reg. No. 6836-XXX EPA Est. No. (as listed on the container) Net Contents (insert container size here)

> LONZA INC. 17-17 Route 208, Fair Lawn, NJ 07410

Lonza Formulation FC-600 EPA Reg. No. 6836-xxx EPA revised draft label 11-29-01 (Note to reviewer: Language in () is optional)

PAGE 1 of 4

(Note to reviewer: The following is all optional marketing language.)

This product contains no phosphorous.

Lonza Formulation FC-600 improves labor results by effectively controlling odors.

Cross-contamination is of major (food safety) concern. Lonza Formulation FC-600 has been formulated to aid in the reduction of cross-contamination in restaurants, schools, institutions, and industry.

Lonza Formulation FC-600 is an economical concentrate that can be used with a mop and bucker, trigger sprayers, sponge, or by (immersion) (soaking).

Lonza Formulation FC-600 is a complete, chemically balanced sanitizer that provides (clear) (translucent) use solutions even in the presence of hard water.

Use Lonza Formulation FC-600 as a commercial sanitizer on dishes, glassware, and utensils at 150ppm active.

Use Lonza Formulation FC-600 as a sanitizer in bottling and beverage dispensing equipment.

Use Lonza Formulation FC-600 in restaurants, bars, cafeterias, institutional kitchens, convenience stores, food storage areas, institutional facilities, retail food establishments, food processing plants and dairies.

Use Lonza Formulation FC-600 on washable hard nonporous surfaces including food preparation and storage areas, dishes, glassware, silverware, cooking utensils, plastic and other hard nonporous cutting boards and chopping blocks, coolers, ice chests, refrigerator meat and vegetable and egg bins, Tupperware[®], kitchen equipment such as food processors, blenders, cutlery and other utensils, counters (countertops), slurpy machines, beverage (stovetops), machines. stoves sinks. appliances. refrigerators, tables, picnic tables, highchairs, refrigerated storage and display equipment, bottling or pre-mix dispersing equipment, and other hard nonporous surfaces made of metal, stainless steel, enamel, Formica, vinyl, glazed porcelain, glazed ceramic, fiberglass, sealed stone and plastic.

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

At 1.0 ounce per gallon of water (or equivalent dilution) (150 ppm) Lonza Formulation FC-600 fulfills the criteria of Appendix F of the Grade "A" Pasteurized Milk Ordinances 1999 Recommendations of the U.S. Public Health Services in waters up to 600 ppm of hardness calculated as CaCO₃ when evaluated by the AOAC Germicidal and Detergent Sanitizer Method.

LONZA FORMULATION FC-600 meets EPA's Sanitizer Test standards for non-food contact sanitizers at 1 oz. per gallon of water (1:128 dilution) (150 ppm active) modified in the presence of 600 ppm hard water plus 5% organic serum.

LONZA FORMULATION FC-600 eliminates 99.9% of Staphylococcus aureus and Klebsiella pneumoniae in 60 seconds (one minute).

Lonza Formulation FC-600 meets AOAC Germicidal & Detergent standards for sanitizing previously cleaned foodcontact surfaces.

Lonza Formulation FC-600 is an effective food contact sanitizer, in water up to 600 ppm hardness at 1.0 oz. per gallon of water (or equivalent dilution) (150 ppm active) in 60 seconds by reducing 99.999% of:

Escherichia coli Escherichia coli 0157:H7 (pathogenic strain) Listeria monocytogenes Staphylococcus aureus Salmonella typhi Yersinia enterocolitica

Regular, effective cleaning and sanitizing of equipment, utensils, and work or dining surfaces minimizes the probability of contaminating food during preparation, storage or service which could harbor hazardous microorganisms. Effective cleaning will remove soil and prevent the accumulation of food residues that may decompose or support the rapid development of food poisoning organisms or toxins. Application of effective sanitizing procedures reduces the number of those disease causing organisms which may be present on equipment and utensils after cleaning, and reduces the potential for the transfer, either directly through tableware such as glasses, cups and flatware or indirectly through food.

To prevent cross-contamination, wash, rinse and sanitize kitchenware and food-contact surfaces of equipment after use and following any interruption of operation during which time contamination may have occurred.

Wash, rinse and sanitize equipment and utensils used for the preparation of foods on a continuous or production-line basis at intervals throughout the day on a schedule based on food temperature, type of food, and amount of food particle accumulation.

> ACCEPTED > with COMMENTS > in EPA Letter Dated:

JAN 2 9 2002

Under the Federal Insecticide, (Note to reviewer: Language in () is optionaine, and Rodenticide Act as amended, for the pessicide, registered under EPA Reg. No. 6836-301

Lonza Formulation FC-600 EPA Rea. No. 6836-xxx EPA revised draft label 11-29-01

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	DILUTION CHART		
	Product	Water	
	1 oz.	1 gailon	
_	7.82 mL	1 liter	_

DIRECTIONS FOR USE

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

To Sanitize Food Processing Equipment and Other Hard Nonporous Food Contact Surfaces:

Use Lonza Formulation FC-600 to sanitize food utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage and display equipment and other hard nonporous surfaces.

Prior to application, remove gross food particles and soil by a pre-flush, or pre-scrape and, when necessary, presoak. 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.

Apply a use-solution of 1.0 oz. of Lonza Formulation FC-600 per gallon of water (or equivalent dilution) to precleaned hard nonporous surfaces, thoroughly wetting surfaces with a clean cloth, mop, sponge, coarse sprayer or by immersion. Surfaces must remain wet for at least one minute (60 seconds) followed by adequate draining and air drying. Prepare fresh solution daily or more often if use-solution becomes visibly dirty. For mechanical application, use-solution may not be reused for sanitizing applications.

To Sanitize Beverage Dispensing Equipment:

- 1. Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing.
- Fill equipment with a use-solution of 1.0 oz. of Lonza Formulation FC-600 per gallon of water (or equivalent dilution).
- Allow solution to remain in equipment for at least 60 seconds
- 4. Drain thoroughly and air dry before reuse.

U.S. PUBLIC HEALTH SERVICE FOOD SERVICE SANITIZATION RECOMMENDATIONS

CLEANING AND SANITIZING. Equipment and utensils must be thoroughly preflushed or prescraped and when necessary, presoaked to remove gross food particles and soil.

Thoroughly wash equipment and utensils in a hot detergent solution.

Rinse utensils and equipment thoroughly with clean water. Sanitize equipment and utensils by immersion in a 75°-85°F use-solution of 1.0 oz. of Lonza Formulation FC-600 per gallon of water (or equivalent dilution) for at least 60 seconds. (This dilution is equivalent to a solution containing 50-ppm available chlorine.)

For equipment and utensils too large to sanitize by immersion, apply a use solution of 1.0 oz. of Lonza Formulation FC-600 per gallon of water (or equivalent dilution) by rinsing, spraying or swabbing until thoroughly wetted. Allow sanitized surface to drain and air dry. DO NOT RINSE.

WISCONSIN STATE BOARD OF HEALTH DIRECTIONS FOR EATING ESTABLISHMENTS

- Scrape and pre-wash utensils and glasses whenever possible.
- 2. Wash with a good detergent or compatible cleaner.
- 3. Rinse with clean water.
- Sanitize in a solution of 1.0 oz. of Lonza Formulation FC-600 per gallon of water (or equivalent dilution) (150 ppm active). Immerse all utensils for at least two minutes or for contact time specified by governing sanitary code.
- Place sanitized utensils on a rack or drain board to air dry.

TO SANITIZE NON-FOOD CONTACT SURFACES:

(Add) (Mix) 1 oz. of Lonza Formulation FC-600 per gallon of water to sanitize hard nonporous surfaces. Treated surfaces must remain wet for 60 seconds. Wipe dry with a sponge, mop or cloth or allow to air dry.

ACCEPTED with COMMENTS in EPA Letter Dated:

JAN 2 9 2002

Under the Federal Insecticide,
Fangicide, and Rodenticide Act as amended, for the pesdcide,
registered under EPA Reg. No. 6836-30/

Lonza Formulation FC-600 EPA Reg. No. 6836-xxx EPA revised draft label 11-29-01 (Note to reviewer: Language in () is optional)

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(Note to reviewer if the 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 store on side. Avoid creasing or impacting of side walls. Do not reuse empty container, Discard in trash (or recycle).

(Note to reviewer: If container size is greater than 1 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 sidewalls.

PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or in an approved waste disposal facility. 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 other procedures approved by state and local authorities.

ACCEPTED with COMMENTS in EPA Letter Dated:

JAN 2 9 2002

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 6836-361