

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

NOTICE OF PESTICIDE:

x Registration Reregistration EPA Reg. Number:

Date of Issuance:

JAN - 2 2001

6836-290

Term of Issuance:

Conditional

Name of Pesticide Product:

Lonza Formulation DC-103F RTU

Sanitizer

(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 commection with this registration must be submitted to and accepted by the Registration Division prior to se 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

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:

- Submit and/or cite all data required for registration/ reregistration of your product under FIFRA 1. 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:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 6836-290".
 - On page 2, right column, 2nd paragraph, the surface, "tiles," must be qualified as hard, nonb. porous by stating "glazed tiles."
 - On Page 3, the following directions must be added to the label for toilet bowel c. sanitization:

Empty water in toilet bowl or urinal and apply Lonza Formulation DC-103F RTU Sanitizer to toilet bowl surfaces including under the rim with cloth, sponge, wiper/sprayer. Allow to surfaces to remain wet for 60 seconds (one minute) and flush.

Signature of Approving Official:

JAN - 2 2001

Product Manager 31

Regulatory Management Branch I

Antimicrobials Division (7510C)

EPA Form 8570-6

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d. The "Sanitizing Food Contact Surface Directions" must be revised to comply with DIS/TSS-17:

Prior to application, remove gross food particles and soil by a pre-wash, prescrape, or pre-flush, and when necessary pre-soak. Thoroughly wash or flush equipment or utensils with a good detergent or compatible cleaner followed by a potable water rinse before applying sanitizer.

Apply Lonza Formulation DC-103F RTU Sanitizer to pre-cleaned hard, non-porous surfaces with cloth, mop, sponge, or sprayer or by immersion. Surfaces must remain wet for 60 seconds (1 minute). Drain thoroughly and allow to air dry before reuse.

- e. On page 4, Add the statement, "allow to air dry," as the last sentence to the "Vehicles" instructions.
- 3. The acute toxicology studies submitted to support the registration of Bardac 205M RTU, 6836-EIO, will also support the registration of this product. The following is the acute toxicology profile for this product:

Acute oral toxicity	IV
Acute dermal toxicity	IV
Acute inhalation toxicity	IV
Primary eye irritation	IV
Primary skin irritation	IV

Dermal sensitization Non-sensitizer

4. Submit two (2) copies of the revised final printed label for the record.

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. If you have any questions regarding this letter, please contact Jacqueline Campbell at (703) 308-6416.

Sincerely,

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

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Avoid contact with eyes or dothing. Wash thoroughly with soap and water after handling.

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.

(If container size is 5 gallons or larger, 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 mination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge Muent containing this product to sewer systems without previously ying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

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

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

Wastes resulting from the use of this product may be disposed of site or at an approved waste disposal facility.

CONTAINER DISPOSAL

(Plastic containers): Triple rinse (or equivalent). The offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by 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 dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

LONZA FORMULATION DC-103F RTU SANITIZER

Cleaner - Sanitizer - Deodorizer for Homes, Hospitals, Institutional and Industrial Use

Effective in the presence of 5% serum contamination

Formulated for Effective Poultry Premise Sanitation Formulated for Effective Swine Premise Sanitation Formulated for Effective Farm Premise Use

200 PFm

Active Ingredients:

Octyl decyl dimethyl ammonium chloride 0.0060% 0.0024% Dioctyl dimethyl ammonium chloride 0.0036% Didecyl dimethyl ammonium chloride Alkyl (50% C₁₄, 40% C₁₂, 10% C₁₆)

dimethyl benzyl ammonium chloride 0.0080% 99.9800% Inert Ingredients: 100.0000% Total:

1.02% AI

KEEP OUT OF REACH OF CHILDREN CAUTION

SEE LEFT/ SIDE/ RIGHT/ BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 6836-

EPA Est. No. (insert EPA Establishment 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:

JAN 2 - 2001

Under the Federal Insecticide, Fangicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 6836-290 This product contains no phosphorous.

When used as directed, LONZA FORMULATION DC-103F RTU SANITIZER will clean and 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.

Cross-contamination is of major housekeeping concern. LONZA FORMULATION DC-103F RTU SANITIZER has been formulated to aid in the reduction of cross-contamination not only in hospitals, but in schools, institutions and industry.

LONZA FORMULATION DC-103F RTU SANITIZER is recommended for use in federally inspected meat and poultry plants as a sanitizer for all surfaces not always requiring a rinse.

JNZA FORMULATION DC-103F RTU SANITIZER can be used with a mop and bucket, trigger sprayers, sponge or by soaking.

ZA FORMULATION DC-103F RTU SANITIZER improves labor results by effectively controlling malodors.

LONZA FORMULATION DC-103F RTU SANITIZER is recommended for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures and toilet bowls.

LONZA FORMULATION DC-103F RTU SANITIZER is for use in kitchens, bathrooms and other household areas.

LONZA FORMULATION DC-103F RTU SANITIZER is formulated for use in daily maintenance programs with a balance of detergents, biocides and malodor counteractants that deliver effective cleaning, sanitizing and malodor control.

ONZA FORMULATION DC-103F RTU SANITIZER will not leave it or soap scum.

NZA FORMULATION DC-103F RTU SANITIZER is a versatile tizer for Veterinarian, Animal Care and Farm Premise applications.

LONZA FORMULATION DC-103F RTU SANITIZER is an effective sanitizer-cleaner for use on food contact as well as non-food contact surfaces.

LONZA FORMULATION DC-103F RTU SANITIZER eliminates 99.9% of Staphylococcus aureus and Klebsiella pneumoniae in 60 seconds.

LONZA FORMULATION DC-103F RTU SANITIZER meets EPA's Sanitizer Test standards for non-food contact sanitizers.

LONZA FORMULATION DC-103F RTU SANITIZER for use in hospitals, homes, medical and dental offices, nursing homes, day care centers, nurseries, restaurants, bars, cafeterias, institutional kitchens, convenience stores, food storage areas, public rest rooms, institutions, schools, athletic facilities, camp grounds, food processing plants, USDA inspected food processing facilities, dairy farms, hog farms, poultry and turkey farms, kennels, pet animal quarters, zoos, pet shops, animal laboratories, transportation terminals, hotels and motels, business and office buildings, boats, ships, campers, trailers, mobile homes, cars, buses, trains, taxis, airplanes.

LONZA FORMULATION DC-103F RTU SANITIZER for use on the following washable hard, nonporous surfaces: floors, walls, countertops, stovetops, sinks, appliances, refrigerators, cabinets, highchairs, garbage cans, refrigerated storage and display equipment, tables, picnic tables, outdoor furniture, chairs, desks, telephones, doorknobs, shower stalls, tubs and tiles, whirlpool bathtubs, toilets, bathtubs, shower stalls, sinks, urinals, toilet bowls, toilet bowl surfaces, other bathroom fixtures, kennel runs, cages, conductive flooring and hard nonporous surfaces made of metal, glazed porcelain, glazed ceramic, fiberglass, plastic, porcelain lining, stainless steel, enameled surfaces, finished woodwork, Formica®, vinyl and plastic upholstery.

LONZA FORMULATION DC-103F RTU SANITIZER is recommended for Poultry Premise Sanitation (Hatcheries): Egg Receiving Area, Egg Holding Area; Setter Room, Tray Dumping Area, Trays, Buggies, Racks, Egg Flats, Chick Holding Room, Hatchery Room, Chick Processing Area, Chick Loading Area, Poultry Buildings, Ceilings, Sidewalls and Floors, Drinkers and other Poultry House related equipment, and all other hard nonporous surfaces in the Hatchery environment.

LONZA FORMULATION DC-103F RTU SANITIZER is recommended for Swine Premise Sanitation: Waterers and Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns and areas, Nursery blocks, Creep area, Chutes.

LONZA FORMULATION DC-103F RTU SANITIZER is a ready-touse sanitizer for hard nonporous non-food contact surfaces (200 ppm active) according to the method for Sanitizers - Non-Food Contact Surfaces, modified in the presence of 5% organic serum in 60 seconds against:

Klebsiella pneumoniae

Staphylococcus aureus

ACCEPTED with COMMENTS in EPA Letter Dated:

JAN 2 - 2001

Under the Federal Insecticide, Fangicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 6836-290

LONZA FORMULATION DC-103F RTU SANITIZER EPA REG. NO. 6836-DRAFT MASTER LABEL 09/15/00 5/6

DIRECTIONS FOR USE

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

(Alternate directions for 2 chamber solution / wiper cloth package)

Directions for Saturating the Wiper Cloth:

To thoroughly saturate the wiper cloth with the sanitizer solution, open the solution pouch and allow the liquid to flow into the wiper chamber. Allow the liquid to thoroughly saturate the wiper cloth. There should be no visible liquid left in the wiper cloth chamber. The wiper cloth is now ready for use.

SANITIZING NON-FOOD CONTACT SURFACE DIRECTIONS:

Apply LONZA FORMULATION DC-103F RTU SANITIZER as is to sanitize hard nonporous surfaces with a cloth, mop, sponge, wiper or sprayer.

Rub with a brush, sponge, wiper or cloth.

Treated surfaces must remain wet for 60 seconds (one minute). Allow to air dry.

For sprayer applications, use a coarse spray device. Spray 6 - 8 inches from surface. Avoid breathing spray.

SANITIZING FOOD CONTACT SURFACE DIRECTIONS:

Use LONZA FORMULATION DC-103F RTU SANITIZER (200 ppm active) for sanitizing and cleaning of equipment and utensils in food processing, dairy industry, bars, restaurants, institutional kitchens, meat and poultry processing plants.

For heavily soiled equipment or utensils, prewash with LONZA FORMULATION DC-103F RTU SANITIZER. Rinse with clean water then apply LONZA FORMULATION DC-103F RTU SANITIZER as is [with a cloth, sponge, or coarse mechanical spray device] until thoroughly wetted, or by immersion.

Treated surfaces must remain wet for 60 seconds (one minute).

DO NOT reuse mechanically applied use solution for sanitizing.

LONZA FORMULATION DC-103F RTU SANITIZER can be used in accordance with the U.S. Public Health Service food service sanitization recommendations

U.S. PUBLIC HEALTH SERVICE FOOD SERVICE SANITZATION RECOMMENDATIONS

CLEANING AND SANITIZING: Equipment and utensits shall be thoroughly pre-flushed or pre-scraped and when necessary, pre-soaked to remove gross food particles and soil.

- 1. Thoroughly wash equipment and utensils in hot detergent solution.
- 2. Rinse utensils and equipment thoroughly with clean water.
- 3. Sanitize equipment and utensils by immersion in LONZA FORMULATION DC-103F RTU SANITIZER (200 ppm active) for at least 60 seconds at a temperature of 75°F.
- 4. For equipment and utensils too large to sanitize by immersion, apply LONZA FORMULATION DC-103F RTU SANITIZER (200 ppm active) by rinsing, spraying or swabbing until thoroughly wetted.
- 5. Allow sanitized surface to drain and air dry.

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 using LONZA FORMULATION DC-103F RTU SANITIZER (200 ppm active). Immerse all utensils for at least two
 minutes or for contact time specified by governing sanitary code.
- 5. Place sanitized utensils on a rack or drain board to air dry.

ACCEPTED with COMMENTS in EPA Letter Dated:

JAN 2 - 2001

Under the Federal Insecticide, Fangicide, and Rodenticide Act as amended, for the pesticide,

LONZA FORMULATION DC-103F RTU SANITEGISTE under EPA Reg. No. 6836-290 EPA REG. No. 6836-

DRAFT MASTER LABEL 09/15/00

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Poultry and Swine Premise Sanitizer Directions:

Remove all animals and feeds from premises, vehicles, and enclosures such as coops and crates. Remove all litter, droppings and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Use LONZA FORMULATION DC-103F RTU SANITIZER to saturate surfaces with the sanitizing solution for 60 seconds. Immerse all halters, ropes and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings, cars, trucks, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. [Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.]

Hatcheries: Use LONZA FORMULATION DC-103F RTU SANITIZER to treat the following hard nonporous surfaces: hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces wet for 60 seconds or more. Then allow to air dry.

Vehicles: Clean all vehicles including mats, crates, cabs and wheels with high pressure water and LONZA FORMULATION DC-103F RTU SANITIZER. Use LONZA FORMULATION DC-103F RTU SANITIZER to treat all vehicles. Leave all treated surfaces wet for 60 seconds or more.

Shoe Bath Sanitizer Directions: To prevent tracking harmful organisms into animal areas, shoe baths containing one inch of fresh solution should be placed at all entrances to buildings and hatcheries. Scrape waterproof work boots and place in LONZA FORMULATION DC-103F RTU SANITIZER for 60 seconds prior to entering area. Change the solution in the bath daily or when solution appears diluted or soiled.

Dressing Plant Sanitizer Directions: Sanitize equipment, utensils, walls and floors in poultry and animal dressing plants. Sanitize offal rooms, exterior walls and loading platforms of dressing plants. Cover or remove all food and packaging materials. Remove all heavy soils prior to application. Saturate all surfaces with LONZA FORMULATION DC-103F RTU SANITIZER. Scrub to loosen all soils. Surfaces must remain wet for 60 seconds. A potable water rinse is not required before operations are resumed.

Veterinary Practice / Animal Care / Animal Laboratory / Zoos / Pet Shop / Kennels Sanitization Directions: For cleaning and sanitizing the following hard nonporous surfaces: utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with LONZA FORMULATION DC-103F RTU SANITIZER for 60 seconds. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

Farm Premise Use:

Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with LONZA FORMULATION DC-103F RTU SANITIZER for 60 seconds. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. Ventilate buildings, cars, boats and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried. [Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.]

ACCEPTED with COMMENTS in EPA Letter Dated:

Under the Federal Insecticide,
Fangicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 6836-290

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LONZA FORMULATION DC-103F RTU SANITIZER EPA REG. NO. 6836-DRAFT MASTER LABEL 09/15/00