

OCT - 9 2003

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

Subject: Lonza Formulation DC-103F RTU Sanitizer
EPA Registration No. 6836-290
Notification Date: September 8, 2003
EPA Receipt Date: September 10, 2003

Dear Mr. Sloan,

This letter acknowledges receipt of the following notification submitted in connection with registration under FIFRA section 3(c)9 and PR Notice 98-10.

- Replace "inert" with "other" in the ingredients statement
- Add "Have product container or label with you when calling poison control center, doctor, or going for treatment" to First Aid section per PR Notice 2001-1

General Comments

Based on the submitted materials, your notification is acceptable and apart of the records on file. If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



Velma Noble

Product Manager (31)

Regulatory Management Branch I

Antimicrobials Division (7510C)

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Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0080, Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number
281276

Application for Pesticide - Section I

1. Company/Product Number 6836-290	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) LONZA FORMULATION DC-103F RTU SANITIZER	PM# Team 31	
5. Name and Address of Applicant (Include ZIP Code) LONZA, Inc. 17-17 Route 208 Fair Lawn, NJ 07410 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

- Add the following sentence to the First Aid Statement: "Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment."
- Replace "Inert Ingredients" with "Other Ingredients" in the Ingredient Statement.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions	
6. Manner in Which Label is Affixed to Product			<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Robert J. Sloan	Title Sr. Regulatory Services Associate	Telephone No. (Include Area Code) (201) 794-2610
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Sr. Regulatory Services Associate	
4. Typed Name Robert J. Sloan	5. Date 9/8/03	

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Lonza

Document Processing Desk (NOTIF)
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U.S. EPA
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Lonza Inc
17-17 Route 208
Fair Lawn, NJ 07410, USA

Robert J. Sloan
Performance Chemicals
Regulatory Services

Phone: (201) 794-2610
Fax: (201) 696-3569
bob.sloan@lonza.com

Attention: Velma Noble (PM-31)

September 8, 2003

**LONZA FORMULATION DC-103F RTU SANITIZER
EPA Reg. No. 6836-290
Label Notification**

Dear Velma,

Lonza is submitting a **Notification of addition to an Advisory Statement** per PR Notice 98-10, section II.D. In addition, a **Non-notification change** (2) is shown on the proposed revised label.

Lonza is proposing the following changes:

1. Add the following sentence to the First Aid Statement: "Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment."
2. Replace "Inert Ingredients" with "Other Ingredients" in the Ingredient Statement.


In support of this Notification, enclosed are the following:

1. EPA Form 8570-1, Application for Pesticide Amendment, OPP ID No. 281276.
2. Three copies of the proposed revised label, with one copy highlighted for ease of review.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If you have any questions, please call me at 1-800-777-1875, ext. 2610.

Best regards
Lonza Inc



Robert J. Sloan
Sr. Regulatory Services Associate

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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

Active Ingredients:

Octyl decyl dimethyl ammonium chloride	0.0060%
Diocetyl dimethyl ammonium chloride	0.0024%
Didecyl dimethyl ammonium chloride	0.0036%
Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chloride	0.0080%
Other Ingredients:	99.9800%
Total:	100.0000%

KEEP OUT OF REACH OF CHILDREN

CAUTION

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

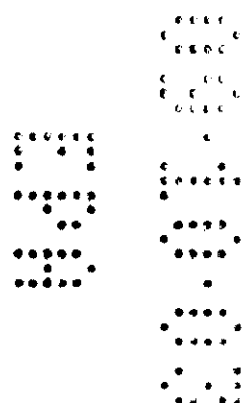
EPA Reg. No. 6836-290

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



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Avoid contact with eyes or clothing. 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. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

(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 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.

(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 on 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

EPA REG. NO. 6836-290

EPA DRAFT LABEL DATED 9/8/03

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.

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

LONZA 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.

LONZA FORMULATION DC-103F RTU SANITIZER will not leave grit or soap scum.

LONZA FORMULATION DC-103F RTU SANITIZER is a versatile sanitizer 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 glazed 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.

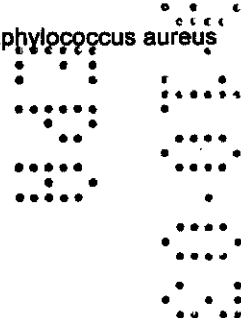
LONZA FORMULATION DC-103F RTU SANITIZER is recommended for Poultry Premise Sanitation (Hatcheries): Egg Receiving Area, Egg Holding Area; Setter Room, Tray Dumping Area, Trays, Buggies, Racks, Egg Flats, Chick Holding Room, Hatchery Room, Chick Processing Area, Chick Loading Area, Poultry Buildings, 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-to-use 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



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.

TOILET BOWL SANITIZATION DIRECTIONS:

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 surfaces to remain wet for 60 seconds (one minute) and flush.

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.

Prior to application, remove gross food particles and soil by a pre-wash, pre-scrape, 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 (one minute). Drain thoroughly and allow to air dry before reuse.

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

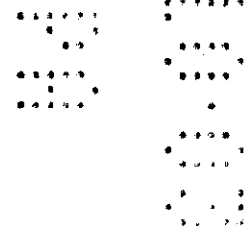
U.S. PUBLIC HEALTH SERVICE FOOD SERVICE SANITIZATION RECOMMENDATIONS

CLEANING AND SANITIZING: Equipment and utensils 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

1. Scrape and pre-wash utensils and glasses whenever possible.
2. Wash with a good detergent or compatible cleaner.
3. Rinse with clean water.
4. 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.



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. Allow to air dry.

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.]

