

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

AUG 31 2009

Ms. Joanna Holcombe
Lonza, Inc.
90 Boroline Road
Allendale, NJ 07401

SUBJECT: Lonza CS-201
EPA Registration No.: 6836-83
Amendment Date: June 1, 2009
EPA Receipt Date: June 2, 2009

Dear Ms. Holcombe,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

Proposed Amendment

- Update Storage and Disposal per PRN 2007-4
- Update Company Address and add optional statements

Conditions

Revise the label as follows:

- 1) The Environmental Hazards must be revised to be in agreement with the ADBAC and DDAC REDs by adding the statement, *"This pesticide is toxic to fish and aquatic invertebrates."*
- 2) Delete the 10th bullet under "Use Lonza CS-201" in left column on page 2 and "Sanitizing Udders, Flanks, and Teats of Dairy Cows" directions on page 6 because this use is under the Food and Drug Administrations purview not EPA.
- 3) Revise the 3rd claim in the right column on page 2 and "Directions for Sanitizing Food Processing Equipment, Utensils, and Food Contact Articles" heading by deleting FDA 40 CFR citation and stating *"40 CFR 190.840 (a)."*
- 4) Revise the 1st and 3rd statements in the first paragraph in the right column on page 3 by deleting the terms, hazardous, and disease and stating *"food poisoning."*

CONCURRENCES

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

5) The 5th statement, Articles or surfaces too large ... or swabbing, must be brought into compliance with PR Notice 2000-5, Mandatory Labeling, by deleting the term, should, and stating "must."

6) The Container Rule rescinded PR Notice 83-3 and 84-1 Part II in which Container Disposal statements are no longer separated by container size but by use pattern. Therefore, delete the "Storage and Disposal" statements for containers one gallon or less with uses other than household/residential

7) Revise the "Container Disposal" statements for the institutional/industrial/commercial uses to read:

Container Disposal: Nonrefillable container. Do not reuse or refill container. Clean container promptly after emptying.

(Containers 5 gallons or less [please note that the statements are the same for plastic and metal containers])

Triple rinse as follows: Fill container 1/4 full with water and recap. Agitate vigorously. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

(Container greater than 5 gallons [please note that the statements are the same for plastic and metal containers])

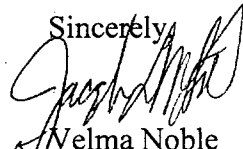
Triple rinse as follows: Fill container 1/4 full with water. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into the application equipment or mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

(For Bag in Box Containers): Proposed language acceptable.

General Comments

A stamped copy of the label 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 Velma Noble at (703) 308-6233.

Sincerely,

Velma Noble
Product Manager (31)

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Regulatory Management Branch I							
Antimicrobials Division (7510P)							
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103

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 clothing, eyewear (goggles, face shield or safety glasses) and protective gloves (rubber, chemical resistant). Harmful if swallowed. 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 first 5 minutes, then continue rinsing eye.

IF ON SKIN: 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 a poison control center or doctor.

Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling poison control center or doctor or going for treatment.

(Note to reviewer: If the container size is 5 gallons or greater, the following Environmental Hazards will be added :)

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:
AUG 31 2009

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

6836-83

LONZA CS-201

Multi-Purpose

No-Rinse Acid Cleaner - Sanitizer

Food Contact Surface Sanitizer

For Food, Dairy, Beverage, Meat, Poultry, Egg and
Seafood Processing and Farm Use

Removes Milkstone

Active Ingredients:

Octyl decyl dimethyl ammonium chloride.....	2.295%
Dioctyl dimethyl ammonium chloride	0.918%
Didecyl dimethyl ammonium chloride	1.377%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride.....	3.060%
Other Ingredients	92.350%
Total	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER

See [side] [back] [left] [right] panel for Precautionary
Statements and First Aid

EPA Reg. No. 6836-83

EPA Est. No. (as indicated on container)

Net Contents: (as indicated on container)

[Country of origin (insert country)]

[Manufactured in (insert country)]

[Barcode]

Manufactured by
LONZA INC.

90 Boroline Road, Allendale, NJ 07401

FOR INSTITUTIONAL AND INDUSTRIAL USE

Lonza CS-201 is a multi-purpose no-rinse acid cleaner and food contact surface sanitizer for dairies, dairy barns, cheese factories, breweries, food, meat, poultry, egg and seafood processing, farms, wineries, beverage plants, food handling and process areas, restaurants, bars and institutional kitchen use.

Milkstone and scale can build up on pipelines, storage tanks, tank trucks, silos and processing equipment in the dairy industry. Use of this product will remove milkstone and scale from dairy and cheese making equipment and help maintain the efficiency of the operation as well as eliminate bacterial growth.

Use Lonza CS-201:

- as a food contact sanitizer at a concentration of 150 – 400 ppm active.
- as a sanitizer in bottling, pre-mix and beverage dispensing equipment.
- as a sanitizer in sanitary filling of bottles and cans.
- as a sanitizer in beer fermentation and holding tanks.
- for cleaning and sanitizing of stainless steel and other hard surfaces found in restaurant and cafeteria kitchens for the removal of smut, soil, scale and rust from these surfaces.
- in sanitizing bottles or cans in the final rinse application and for external spraying of filling and closing machines.
- in restaurants, food service operations, dairies, breweries, beverage and food processing plants.
- in food processing plants, [federally] [USDA] inspected food processing facilities, dairy farms, egg processing plants, meat and poultry processing plants, meat and poultry producing establishments.
- ~~on trailers, tanks and boats of dairy cows.~~
- in federally inspected Meat & Poultry Plants as a food contact sanitizer. This product was authorized by USDA as category D2 under the prior authorization program and its formula has not been changed – a sanitizer for all surfaces not always requiring a rinse.

Lonza CS-201 not only sanitizes but also removes lime and scale in breweries and bottle washing.

Lonza CS-201 meets AOAC Germicidal & Detergent standards for previously cleaned food-contact surfaces.

Lonza CS-201 has been cleared by the ^{under} ~~FDA in 21 CFR~~ ⁴⁰ ~~§176.1010~~ for use on food processing equipment, utensils and other food-contact articles.

Use as a sanitizer on conveyor belts and equipment to reduce or eliminate odors in the processing area.

Use on filling equipment to reduce bacteria associated with condensation on equipment and pipes.

2/10

LONZA CS-201 is an effective food contact sanitizer at 1 oz. per 4 gallons of water (*or insert equivalent dilution*) (150 ppm active quat when evaluated by the AOAC Germicidal and Detergent Sanitizer Method in 500 ppm hard water (calculated as CaCO₃) against:

- Escherichia coli
- Escherichia coli 0157:H7 (pathogenic strain)
- Listeria monocytogenes
- Salmonella choleraesuis
- Shigella sonneii
- Staphylococcus aureus
- Vibrio cholerae
- Yersinia enterocolitica

LONZA CS-201 is an effective food contact sanitizer at 2 oz. per 4 gallons of water (*or insert equivalent dilution*) (300 ppm active quat) when evaluated by the AOAC Germicidal and Detergent Sanitizer Method in 500 ppm hard water (calculated as CaCO₃) against:

- Campylobacter jejuni
- Escherichia coli
- Escherichia coli 0157:H7 (pathogenic strain)
- Listeria monocytogenes
- Salmonella choleraesuis
- Shigella sonneii
- Staphylococcus aureus
- Vibrio cholerae
- Yersinia enterocolitica

Regular, effective cleaning and sanitizing of equipment, utensils, and work or dining surfaces which could harbor ~~harmful~~ microorganisms minimizes the probability of contaminating food during preparation, storage or service. Effective cleaning will remove soil and prevent the accumulation of food residues, which may decompose or support the rapid development of food poisoning organisms or toxins. Application of effective sanitizing procedures reduces the number of those ~~discrete~~ 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, kitchenware and food-contact surfaces of equipment must be washed, rinsed with potable water and sanitized after each use and following any interruption of operation during which time contamination may have occurred.

Where equipment and utensils are used for the preparation of foods on a continuous or production-line basis, utensils and the food-contact surfaces of equipment must be washed, rinsed with potable water and sanitized at intervals throughout the day on a schedule based on food temperature, type of food, and amount of food particle accumulation.

Articles that can be immersed in solution must remain in solution for 60 seconds.

Articles or surfaces too large for immersing ~~should~~ be thoroughly wetted or flooded by rinsing, spraying or swabbing.

Allow all sanitized surfaces to drain thoroughly (and air dry).

GRADE A PASTEURIZED MILK ORDINANCE:

At 1 – 2 oz. per 4 gallons of water (150 – 300 ppm active quat), **LONZA CS-201** fulfills the criteria of Appendix F of the Grade "A" Pasteurized Milk Ordinance revised 1999 recommendations of the U.S. Public Health Services.

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

(AREAS OF USE:)

Use Lonza CS-201 in:

- Kitchens
- Day care centers
- Nurseries

- Bagel Stores
- Bars
- Beer fermentation and holding tanks
- Bottling or pre-mix dispensing equipment
- Bottle Washing
- Cafeterias
- Cheese factories
- Citrus processing plants
- Coffee Shops
- Convenience stores
- Dairies
- Dairy Farms
- Dairy product dispensing equipment.
- Donut shops
- Drinking fountains
- Egg Processing plants
- Fast food operations
- Fisheries
- Fish processing plants
- Food establishments
- Food processing plants
- Food preparation areas
- Food storage areas
- Ice cream processing plants
- Institutional facilities
- Institutional kitchens
- Liquor stores
- Meat processing plants
- Meat producing facilities
- Milk processing plants
- Milk storage and handling systems
- Milk tanks [bulk]
- Milk pail inflations and tubing,

- Pizza parlors
- Poultry processing plants
- Poultry producing facilities
- Processing Plants [Milk, Citrus, Ice Cream]
- Restaurants
- USDA inspected food processing facilities
- Wineries

(TYPES OF SURFACES:)

Use Lonza CS-201 on washable hard, nonporous surfaces of:

- Appliances
- Beer fermentation and holding tanks
- Blenders
- Bottling or premix dispensing equipment
- Citrus processing equipment and holding tanks
- Coffee Pots
- Coffee Urns
- Cooking utensils
- Coolers
- Counters (countertops)
- Countertop laminates
- Chopping blocks, plastic and other nonporous
- Cutlery
- Cutting Boards, plastic and other nonporous
- Dishes
- Drinking fountains
- Eating Utensils
- Exhaust fans
- Food processors
- Glassware [glasses]
- Highchairs
- Ice Chests
- Ice Machines

- Kitchen equipment
- Microwave ovens
- Refrigerators
- Refrigerator bins used for meat, fruit, vegetables and eggs
- Refrigerated storage and display equipment
- Silverware
- Sinks
- Slurpy[®] Machines
- Stoves [stovetops]
- Tables [picnic tables]
- Tableware
- Tea dispensers
- Tupperware[®]
- Utensils
- Water dispensers [hot]

Other hard nonporous surfaces made of:

- Chrome
- Enamel
- Fiberglass sinks
- Formica[®]
- Glass
- Glazed ceramic
- Glazed enameled surfaces
- Glazed porcelain
- Laminated surfaces
- Metal
- Plastic [such as polystyrene or polypropylene]
- Sealed granite
- Sealed marble
- Sealed stone
- Stainless steel
- Woodwork, finished

Dilution Chart

Active Quat solution	2 gallons of water	4 gallons of water	10 gallons of water	20 gallons of water
150 ppm	½ oz.	1 oz.	2 ½ oz.	5 oz.
200 ppm	⅔ oz.	1 ⅓ oz.	3 ⅓ oz.	6 ⅔ oz.
300 ppm	1 oz.	2 oz.	5 oz.	10 oz.
400 ppm	1 ⅓ oz.	2 ⅔ oz.	6 ⅔ oz.	13 ⅓ oz.

DIRECTIONS FOR USE

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

LONZA CS-201 is an acid cleaner sanitizer for use on food processing and dairy equipment in water up to 500 ppm hardness (as CaCO₃). For all equipment a preliminary cleaning is required before sanitizing.

Before use in federally inspected meat and poultry food processing plants and dairies, food products and packaging materials must be removed from the room or carefully protected.

DIRECTIONS FOR SANITIZING FOOD PROCESSING EQUIPMENT, UTENSILS, AND FOOD CONTACT ARTICLES REGULATED BY ~~21 CFR Sec. 178.1010~~
(and / or)

TO SANITIZE FOOD CONTACT SURFACES:

(and / or)

TO SANITIZE BULK MILK TANKS:

(and / or)

TO SANITIZE STORAGE TANKS:

(and / or)

TO SANITIZE HARD, NONPOROUS SURFACES AND EQUIPMENT IN FOOD, DAIRY, BEVERAGE, MEAT, POULTRY, EGG, AND SEAFOOD PROCESSING PLANTS:

Remove gross filth and soil by preflush or prescrape or, when necessary, by presoak. Then wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing. Apply a use-solution of ___ oz. (insert appropriate dilution from dilution chart) of **Formulation CS-201** per ___ gallons of water [___ ppm quat] (insert appropriate ppm quat from dilution chart.) to precleaned hard surfaces, thoroughly wetting surfaces with a cloth, sponge, coarse sprayer or by immersion. Treated surfaces must remain wet for at least 60 seconds [one minute] followed by adequate draining [and air drying]. Do not rinse.

Prepare a fresh solution daily or more often if solution becomes visibly diluted, clouded or soiled.

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

TO SANITIZE DAIRY PRODUCT DISPENSING EQUIPMENT:

(and / or)

TO SANITIZE BEVERAGE DISPENSING EQUIPMENT:

1. Remove gross filth and soil by preflush or prescrape or, when necessary, by presoak.
2. Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing.
3. Fill equipment with a solution of ___ oz. (insert appropriate dilution from dilution chart) of **Formulation CS-201** per ___ gallons of water [___ ppm quat] (insert appropriate ppm quat from dilution chart.) Allow solution to remain in equipment for at least 60 seconds.
4. Drain thoroughly before reuse (and allow to air dry). Do not rinse.

For removable parts, immerse in use-solution for at least 60 seconds. [Allow to air dry.] Do not rinse.

For items too large to sanitize by immersion, apply use-solution by rinsing, spraying or swabbing until thoroughly wet for at least 60 seconds. Drain thoroughly before reuse. [Allow to air dry.] Do not rinse.

2/10

TO SANITIZE SANITARY FILLING EQUIPMENT:

Use to sanitize bottles or cans in the final rinse application. Wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing. Prepare a use-solution of *(insert appropriate dilution from dilution chart)* for final washer and rinser applications. Allow surfaces to remain wet for at least 60 seconds. Drain thoroughly before reuse [and allow to air dry.] Do not rinse.

~~**SANITIZING UDDERS, FLANKS AND TEATS OF DAIRY COWS:**~~

~~The udders, flanks and teats of dairy cows can be sanitized by washing with a solution of 1 oz LONZA CS-201 in 1 gallon of warm water (450 ppm active quat) and dried just prior to milking. Use a fresh towel for each cow. Avoid contamination of sanitizing solution by dirt and soil. Do not dip used towel back into sanitizing solution.~~

FOR WISCONSIN ONLY

SANITIZING EATING AND DRINKING UTENSILS IN EATING ESTABLISHMENTS

1. Scrape and pre-wash utensils and glasses whenever possible.
2. Wash with a good detergent or compatible cleaner.
3. Rinse with potable water.
4. Sanitize in a use-solution of *(insert appropriate dilution from dilution chart)*. 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.
6. Prepare a fresh sanitizing solution at least daily or when visibly soiled or diluted.

NOTE: A clean potable water rinse following sanitization is not permitted under Section HFS 196; Appendix 7-204.11 of the Wisconsin Administrative Code (reference CFR 180.940 (a)).

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 a use solution of *(insert appropriate dilution from dilution chart)* for at least 60 seconds at a temperature of 75°F.
4. For equipment and utensils too large to sanitize by immersion, apply a use-solution of *(insert appropriate dilution from dilution chart)* by rinsing, spraying or swabbing until thoroughly wet.
5. Allow sanitized surface to drain [and air dry]. Do not rinse.

~~(Note to reviewer: For Nonrefillable Containers, Container is one gallon or less, Label has any uses other than Household or Residential)~~

~~STORAGE AND DISPOSAL~~

~~Store in original container in areas inaccessible to children.~~

~~Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container 1/4 full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap [container] and put in trash or offer for recycling if available.~~

~~(or)~~

~~Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container 1/4 full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap [container] and put in trash or offer for reconditioning if appropriate.~~

(Note to reviewer: For Nonrefillable Containers, Container is over one gallon)

STORAGE AND DISPOSAL

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

Pesticide Storage:

Open dumping is prohibited. Store in original container in areas inaccessible to children.

Pesticide Disposal:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or 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:

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.

(Plastic Containers:) Triple rinse as follows: Fill container 1/4 full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

(Metal Containers:) Triple rinse as follows: Fill container 1/4 full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations. DO NOT cut or weld metal containers.

(For Bag in Box Containers:) Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

**1.0 OUNCE PACKET LABEL TO BE USED WITH MASTER CONTAINER LABEL
FOR SANITIZATION**

MIX EACH PACKET WITH [4 GALLONS] OF WATER [150 ppm active quat]

LONZA CS-201

EPA. Reg. No. 6836-83
EPA. Est. No. *(insert EPA Est. No. here)*
Net Contents: [1.0 fl. Oz].

Active Ingredients:

Octyl decyl dimethyl ammonium chloride.....	2.295%
Dioctyl dimethyl ammonium chloride.....	0.918%
Didecyl dimethyl ammonium chloride.....	1.377%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride.....	3.060%
Other Ingredients	92.350%
Total.....	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER

See outer container for Precautionary Statements and Use directions

Disposal: Do not reuse packet. Wrap and put in trash.

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

[IF OTHER PACKET SIZES ARE DESIRED, NEW PACKET LABEL WILL BE IDENTICAL AND THE ONLY THINGS THAT WILL VARY ARE THE NET CONTENTS, AMOUNT OF WATER TO DILUTE WITH AND PPM ACTIVE QUAT. THOSE 3 ITEMS WILL HAVE TO MATCH OR BE EQUIVALENT TO THE DILUTION CHART THAT IS SHOWN ON PAGE 5.]