



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 10, 2018

Kathryn Rosario
Regulatory Assurance Specialist
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

Subject: Label Amendment – Label revision & CSF update
Product Name: Lonza CS-201
EPA Registration Number: 6836-83
Application Date: May 01, 2018
Decision Number: 540814

Dear Ms. Rosario:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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

The Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 05/01/2018
- Alternate CSF 1 dated 05/01/2018
- Alternate CSF 2 dated 05/01/2018
- Alternate CSF 3 dated 05/01/2018

Any CSFs other than those listed above are superseded/no longer valid.

If you have any questions, please contact Mohammad Alavi by phone at (703) 347-0522, or via email at Alavi.mohammad@epa.gov.

Sincerely,



Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

Note to Reviewer:

[Items in brackets [AAA] are optional and may/may not be included on final label]

{Items in braces {AAA} are for information purposes and will not appear on final label}

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 [PELIGRO]

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)

[DOT symbols]

[Country of origin (insert country)]

[Manufactured in (insert country)]

[Barcode]

Manufactured by

Lonza Inc.

90 Boroline Road

Allendale, NJ 07401

ACCEPTED

07/10/2018

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under

EPA Reg. No. 6836-83

Lonza CS-201

EPA Reg. No. 6836-83

EPA Notification 2014-05-06

EPA Submission 2018-05-01

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.

{If the container size is 5 gallons or greater, use the following Environmental Hazards:}

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. 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.

{Note to reviewer: the following is considered optional marketing language:}

FOR INSTITUTIONAL AND INDUSTRIAL USE

Lonza CS-201 is a multi-purpose no-rinse acid cleaner and food contact surface sanitizer for:

<ul style="list-style-type: none">• dairies,• dairy barns,• cheese factories,• breweries,• food, meat, poultry, egg and seafood processing,	<ul style="list-style-type: none">• farms,• wineries,• beverage plants,• institutional kitchens• food handling and process areas of restaurants and bars
---	--

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.
- in sanitizing bottles or cans in the final rinse application and for external spraying of filling and closing machines.
- in 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.
- in federally inspected Meat & Poultry Plants as a food contact sanitizer.

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

Lonza CS-201 has been cleared under 40 CFR 180.940 (b) 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.

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 O157:H7 [pathogenic strain]
Listeria monocytogenes
Salmonella enterica
Shigella sonnei
Staphylococcus aureus
Vibrio cholerae
Yersinia enterocolitica

{Note to reviewer: the following is considered optional marketing language:}

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 O157:H7 [pathogenic strain]
- Listeria monocytogenes
- Salmonella enterica
- Shigella sonnei
- Staphylococcus aureus
- Vibrio cholerae
- Yersinia enterocolitica

Regular, effective cleaning and sanitizing of equipment, utensils, and work surfaces which could harbor food poisoning microorganisms minimizes the probability of contaminating food during preparation or storage. 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 food poisoning 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 must 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 2007 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:

{Note to reviewer: Each entry below also represents a graphic depicting the corresponding area of use. The graphics will only represent individual objects or outsides or insides of buildings as described below. No people, animal, or food will be depicted in graphics.}

Kitchens	Fish processing plants
Bagel Stores	Food processing plants
Beer fermentation and holding tanks	Food preparation areas
Bottling or pre-mix dispensing equipment	Food storage areas
Bottle Washing	Ice cream processing plants
Cheese factories	Institutional facilities
Citrus processing plants	Institutional kitchens
Dairies	Meat processing plants
Dairy Farms	Meat producing facilities
Dairy product dispensing equipment.	Milk processing plants
Donut shops	Milk storage and handling systems
Drinking fountains	Milk tanks [bulk]
Egg Processing plants	Milk pail inflations and tubing,
Fast food operations	Poultry processing plants
Fisheries	Poultry producing facilities
	Processing Plants [Milk, Citrus, Ice Cream]
	USDA inspected food processing facilities
	Wineries

{Note to reviewer: the following is considered optional marketing language:}

[TYPES OF SURFACES:]

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

{Note to reviewer: Each entry below also represents a graphic depicting the corresponding type of surface. No people, animal, or food will be depicted in graphics. Only exteriors of microwaves and refrigerators will be depicted. Toy graphics will be submitted to Agency for review.}

Appliances	Sinks
Beer fermentation and holding tanks	Stoves [stovetops]
Blenders	Tea dispensers
Bottling or premix dispensing equipment	Tupperware®
Citrus processing equipment and holding tanks	Utensils
Coffee Pots	Water dispensers [hot]
Coffee Urns	
Cooking utensils	Other hard nonporous surfaces made of:
Coolers	Chrome
Counters [countertops]	Enamel
Countertop laminates	Fiberglass sinks
Chopping blocks, plastic and other nonporous	Formica®
Cutlery	Glass
Cutting Boards, plastic and other nonporous	Glazed ceramic
Dishes	Glazed enameled surfaces
Exhaust fans	Glazed porcelain
Food processors	Laminated surfaces
Ice Chests	Metal
Ice Machines	Plastic [such as polystyrene or polypropylene]
Kitchen equipment	Sealed granite
Microwave ovens	Sealed marble
Refrigerators	Sealed stone
Refrigerator bins used for meat, fruit, vegetables and eggs	Stainless steel
Refrigerated storage and display equipment	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.	1⅓ oz.	3⅓ oz.	6⅔ oz.
300 ppm	1 oz.	2 oz.	5 oz.	10 oz.
400 ppm	1⅓ oz.	2⅔ oz.	6⅔ oz.	13 ⅓ oz.

*{If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.}
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. [If you do not understand the label, find someone to explain it to you in detail.]*

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 40 CFR 180.940 (b):

{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 **Lonza 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 **Lonza 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.

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.

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 for commercial, industrial, and institutional uses – all sizes – No Reuse Rinsate Statement for Public Health Use products}

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 and Metal Containers:} Triple rinse as follows: Fill container $\frac{1}{4}$ 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 only:} DO NOT cut or weld metal containers.

{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

{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 7.}

FOR SANITIZATION

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

LONZA CS-201

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.....	<u>92.350%</u>
Total.....	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

See outer container for Precautionary Statements and Use directions

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

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

Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

{Note to reviewer: The following are optional graphics and marketing language}

{Note to reviewer. The following may be used only if the supplemental registrant has obtained an NSF listing. Allowed on back or side panel only.}



{or}

[NSF Listed]

(Insert 6-Digit NSF Listing Number here)

{Note to reviewer. The following may be used only if the supplemental registrant has obtained an IFANCA Halal (Islamic Dietary) certification.}



[IFANCA Halal certified] {or} [Halal certified]

{Note to reviewer. The following may be used only if the supplemental registrant has obtained a Kosher Certification.}



[Any Kosher Symbol such as:]

[Kosher]