

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Eliot Harrison  
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Lewis & Harrison  
122 C Street, NW Ste. 740  
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OCT 29 2001

Subject: Lonza CS-201  
EPA Registration No. 6836-83

Amendment Date: July 30, 2001  
EPA Receipt Date: July 31, 2001

Amendment Date: May 1, 2001  
EPA Receipt Date: May 2, 2001

Dear Mr. Harrison:

The following amendments, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable with the conditions listed below:

- Update basic and three alternate formulations
- Add organisms, *Escherichia coli*, *Salmonella choleraesius*, *Yersinia enterocolitica*, and *Listeria monocytogenes*, to label.
- Minor label revisions: update first aid per PR Notice 91-2, add use sites, update precautionary statements and storage/disposal statements per label manual.

General Comments

Product Chemistry

The Confidential Statements of Formulas for the basic and three alternate formulations dated August 23, 2001 are acceptable. They are in compliance with PR Notice 91-2 and in agreement with the label.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Efficacy

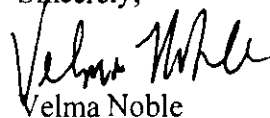
The submitted efficacy data in MRID Nos. 453983-01 and 453983-02 supported Lonza CS-201 as a food contact sanitizer when diluted at 1:512 concentration in the presence of 500 ppm hard water for 30 seconds against *S. choleraesuis* (ATCC 10708), *E. coli* 157:H7 (ATCC 35150), *Y. enterocolitica* (ATCC 9610), and *L. monocytogenes* (ATCC 7644).

Label Comments

1. Based on the active ingredient concentration of a chemically similar product, 6836-75, the "precautionary statements" must be revised by deleting skin irritation and replacing it with "skin burns" and adding the following sentences, "*Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.*"
2. Under the directions for use for each use site, add "*(150 ppm active quat)*" after the use solution, 1 oz/4 gallons of water.
3. Under the directions for "sanitizing milk tanks and hard nonporous surfaces and equipment in food, dairy beverage, meat, poultry, egg, and seafood processing plants," add the following steps, "*Remove gross filth and soil by preflush or pre-scrape when necessary presoak. Then, wash surfaces with a compatible detergent and rinse with potable water prior to sanitizing*" as the first two sentences."
4. The instruction, "*Remove gross filth and soil by preflush or pre-scrape when necessary presoak.*" needs to be included as the first sentence under step 1 for the sanitize dairy product dispensing equipment directions.

A stamped label is enclosed for your records. Please submit one (1) copy of the final printed label before you release this product for shipment. 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)

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER:** Corrosive. Causes irreversible eye damage and skin irritation. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed.

**FIRST AID**

Call a poison control center or doctor for treatment advice.

**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.

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

**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:

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Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. **6836-83**

**LONZA CS-201**

No-Rinse Acid Cleaner - 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%
Diocetyl dimethyl ammonium chloride .....	0.918%
Didecyl dimethyl ammonium chloride .....	1.377%
Alkyl (C <sub>14</sub> , 50%; C <sub>12</sub> , 40%; C <sub>16</sub> , 10%) dimethyl benzyl ammonium chloride .....	3.060%
Inert Ingredients .....	92.350%
Total .....	100.000%

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

EPA Reg. No. 6836-83  
EPA Est. No. 6836-IL-1  
Net Contents: (as indicated on container)

Manufactured by:  
LONZA INC., 17-17 Route 208, Fair Lawn, NJ 07410

**LONZA CS-201** is an effective food contact sanitizer at 1 oz. per 4 gallons of water (*or equivalent dilution*) when evaluated by the AOAC Germicidal and Detergent Sanitizer Method:

In 600 ppm hard water (calculated as CaCO<sub>3</sub>) against:

Escherichia coli

Staphylococcus aureus

In 500 ppm hard water (calculated as CaCO<sub>3</sub>) against:

Escherichia coli 0157:H7 (pathogenic strain)

Listeria monocytogenes

Salmonella choleraesuis

Yersinia enterocolitica

**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 600 ppm hardness (as CaCO<sub>3</sub>). For all equipment a preliminary cleaning is required before sanitizing.

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

Apply a use-solution of 1 oz. **LONZA CS-201** per 4 gallons of water (*or equivalent dilution*) to pre-cleaned 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:**

1. Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing.
2. Fill equipment with a solution of 1 oz. **Lonza Formulation CS-201** per 4 gallons of water (*or equivalent dilution*).
3. 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.

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

**GRADE A PASTEURIZED MILK ORDINANCE:**

At 1 oz. / 4 gallons, **LONZA CS-201** fulfills the criteria of Appendix F of the Grade "A" Pasteurized Milk Ordinance revised 1999 of the U.S. Public Health Services.

**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 4 gallons of warm water 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.

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(Note to reviewer: if container size is one 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 one 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 side walls.

**PESTICIDE DISPOSAL**

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

(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 dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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