

6836-83

6-12-2002

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Samantha Bates
Agent for LONZA, Inc.
Lewis & Harrison
122 C Street, NW
Suite 740
Washington, DC 20001

JUN 12 2002

Subject: Amendment per FIFRA
LONZA CS-201
EPA Registration No. 6836-83
Application Dated: December 14, 2001
EPA Received Date: December 17, 2001

Dear Ms. Bates:

The following amendment, submitted in connection with registration under 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the findings listed below.

Proposed Amendment

- Addition of new microorganism claim against *Campylobacter jejuni*

Efficacy

Efficacy testing conducted, beginning July 8, 2002, demonstrated the effectiveness of a 1:256 dilution in 500 ppm of hard water of the product when tested against *Campylobacter jejuni* ATCC 29428 at 25 +/- 2° C for an exposure of 30 seconds.

Label Comments

1. Revise the Precautionary Statements by adding "protective clothing" to the statement "Wear protective eyewear (goggles, face shield or safety glasses) and rubber gloves."

CONCURRENCES

SYMBOL	7510C							
SURNAME	Gray							
DATE	6-7-02							

General Comments

A stamped copy of the label is enclosed for your records. Please submit one(1) copy of the final printed label before releasing this product for shipment. Should you have any questions regarding this letter, please contact me at 703-308-6233.

Sincerely,



Velma Noble

Product Manager 31

Regulatory Management Branch I

Antimicrobials Division (7510 C)

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 eyewear (goggles, face shield or safety glasses) and rubber gloves. 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.

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.

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 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)

Manufactured by
LONZA INC.

17-17 Route 208, Fair Lawn, NJ 07410

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 12 2002
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 6836-83

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

In 600 ppm hard water (calculated as CaCO₃) against:

Escherichia coli

Staphylococcus aureus

In 500 ppm hard water (calculated as CaCO₃) against:

Escherichia coli 0157:H7 (pathogenic strain)

Listeria monocytogenes

Salmonella choleraesuis

Yersinia enterocolitica

LONZA CS-201 is an effective food contact sanitizer at 2 oz. per 4 gallons of water (or 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

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 of the U.S. Public Health Services.

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 CaCO₃). For all equipment a preliminary cleaning is required before sanitizing.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 12 2002

Under the Federal Insecticide,
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registered under EPA Reg. No. 6536-53

TO SANITIZE BULK MILK TANKS AND 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 1 - 2 oz. **LONZA CS-201** per 4 gallons of water (or equivalent dilution) (150 - 300 ppm active quat) 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:

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 1 - 2 oz. **Lonza Formulation CS-201** per 4 gallons of water (or equivalent dilution) (150 - 300 ppm active quat).
4. Allow solution to remain in equipment for at least 60 seconds.
5. 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.

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 (150 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.

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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.

ACCEPTED
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