

6836-31

10/21/2010

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

Joanna Holcombe
Sr. Commercial Regulatory Services Associate
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OCT 21 2010

Subject: Lonza Sanitizer - Cleaner 45-7
EPA Registration No. 6836-31
Application Date: July 22, 2010
EPA Receipt Date: July 23, 2010

Dear Ms. Holcombe,

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

Proposed Amendment

1.
 - Update of Storage and Disposal language per PR Notice 2007-4
 - Update Company address;
 - Revise "Wisconsin State Board of health Directions for eating establishments"
 - Add optional barcode "country of origin"
- 2.
- 3.
4. **General Comments**

A stamped copy of the accepted labeling is enclosed. Submit 1 copy of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,

A handwritten signature in black ink, appearing to read 'V. Noble', with a long horizontal stroke extending to the right.

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

LONZA SANITIZER-CLEANER 45-7

Sanitizer - Cleaner
for Equipment and Utensils
in Food Processing, Dairy Industry, Bars
Restaurants, Institutional Kitchens, and Farms

Active Ingredients:

Alkyl (60%, C ₁₄ ; 30%, C ₁₆ ; 5%, C ₁₂ ; 5%, C ₁₈)	
dimethyl benzyl ammonium chloride.....	1.28%
Alkyl (68%, C ₁₂ ; 32%, C ₁₄)	
dimethyl ethylbenzyl ammonium chloride	1.28%
Other Ingredients	97.44%
Total:.....	100.00%

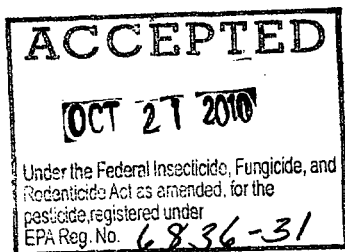
KEEP OUT OF REACH OF CHILDREN

DANGER

See (left) (right) (back) (side) panel for Precautionary Statements and First Aid.

EPA Reg. No. 6836-31
 EPA Est. No. (insert EPA Establishment No. here)
 Net Contents (insert container size here)
 [Country of origin (insert country)]
 [Manufactured in (insert country)]
 [Barcode]

Manufactured by:
 LONZA INC.
 90 Boroline Road, Allendale, NJ 07401



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**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, safety glasses), protective clothing and protective gloves (chemical or rubber). Harmful if swallowed or absorbed through the skin. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash 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 the first 5 minutes, then continue rinsing eye.

IF ON SKIN OR CLOTHING: 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 the poison control center or doctor. Do not give anything by mouth to an unconscious person.

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.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

(Note to reviewer: For container sizes of 5 gallons or larger, the following Environmental Hazards statements will be used:)

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.

Use **LONZA SANITIZER-CLEANER 45-7** for sanitizing and cleaning of hard nonporous equipment and utensils in food processing, dairy industry, bars, restaurants, institutional kitchens and farms.

Use on sink tops, countertops, refrigerated storage and display equipment and other stationary hard nonporous surfaces.

LONZA SANITIZER-CLEANER 45-7 is recommended wherever the maintenance of sanitary, clean conditions is indicated.

SANITIZING EFFECTIVENESS:

LONZA SANITIZER-CLEANER 45-7 is effective at 200 ppm active quat in waters up to 750 ppm hardness (calculated as CaCO₃). This activity has been confirmed by the Germicidal and Detergent Sanitizers Method ("The Chambers Method"); Methods of Analyses, AOAC, Thirteenth Edition as follows:

Escherichia coli ATCC NO. 11229 Staphylococcus aureus ATCC No. 6538

LONZA SANITIZER-CLEANER 45-7 contains a nonionic wetting agent to promote rinsing thus assuring film-free, spot-free equipment and utensils.

NOTE: Do not mix with soap or anionic detergents.

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DIRECTIONS FOR USE

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

Prior to application, remove gross food particles and soil by a pre-flush, or pre-scrape and, when necessary, pre-soak. Then thoroughly wash or flush objects with a good detergent or compatible cleaner followed by a potable water rinse before application of the sanitizing solution.

Apply a one (1) oz. per gallon of water use-dilution (200 ppm active quat) of **LONZA SANITIZER-CLEANER 45-7** with a cloth, mop, sponge, or coarse (mechanical) spray device until thoroughly wetted or by immersion. Treated surfaces must remain wet for one (1) minute followed by adequate draining. Do not rinse.

Prepare a fresh solution daily or when use-solution becomes visibly dirty.

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

Sanitize dishes, silverware, glasses, cooking utensils and other similar size food processing equipment by immersion.

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 potable water.
4. Sanitize in a solution of 1 oz. of **LONZA SANITIZER-CLEANER 45-7** to 1 gallon of water (200 ppm active quaternary). 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 40 CFR 180.940 (a)).

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(Note to reviewer: For Nonrefillable Containers for commercial, industrial, and institutional uses – all sizes – No Reuse Rinsate Statement for Public Health Use products. Chapter 13, Table 6 of the Label Review Manual states that for “All products in containers that could be burned,” the registrant has the option to “Remain silent on burning;” therefore, no incineration language is provided for plastic containers.)

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 ¼ 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.

(For metal containers only: DO NOT cut or weld metal containers.)