

6836-31

11/17/2003

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

Subject: Lonza Sanitizer Cleaner 45-7
 EPA Registration No. 6836-31
 Amendment Date: August 18, 2003
 EPA Receipt Date: August 19, 2003

Dear Mr. Sloan,

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

- Update First Aid Statements per PR Notice 2001-1

Conditions

Revise the label as follows:

1. Update the "Precautionary Statements" to read:

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, and using tobacco. Remove contaminated clothing and wash before reuse.

2. Bold the subheadings (if in eyes/in on skin or clothing/if swallowed) under First Aid and the "Note to Physician" heading.

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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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)

CONCURRENCES

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SURNAME								
DATE								

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Avoid contamination of food.

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.

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)

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

ACCEPTED
RECOMMENDATIONS
in 1998 Label Dated:

NOV 17 2003

Manufactured by Lonza Inc.
Fair Lawn, NJ 07410
EPA Reg. No. 6836-31
EPA Est. No. 6836-31

LONZA SANITIZER-CLEANER 45-7
EPA REG. NO. 6836-31
EPA DRAFT LABEL 8/5/03

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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.

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 clean 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.

NOTE: A clean potable water rinse following sanitization is not permitted under Section HFS 196.13 of the Wisconsin Administrative Code.

(If container size is 1 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 reuse empty container. Wrap container and put in trash.

(If container size is greater than 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 way 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.