

6836-89

1-7-2004

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 7 2004

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

Subject: 205M Sanitizer  
EPA Registration No. 6836-89  
Amendment Date: October 8, 2003  
EPA Receipt Date: October 9, 2003

Dear Mr. Sloan,

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

- Update the First Aid statements, Precautionary Statements, and Storage/Disposal Statements

**Conditions**

Revise the label as follows:

1. Revise the "Sanitizing Food Processing Equipment and Other Hard Surfaces", the "Restaurants and Bar Rinse", and the "Food Processing Equipment and Dairies" directions by stating "*Equipment and utensil must be thoroughly preflushed, presoaked, or prescraped to remove gross food particles. Thoroughly wash equipment and utensils with soap or compatible detergent and rinse with potable water.*"
2. Revise the "Restaurants/Bar Rinse" and the "Food Processing Equipment and Dairies" directions by stating "*Allow sanitized surfaces and utensils to drain and air dry.*"

**General Comments**

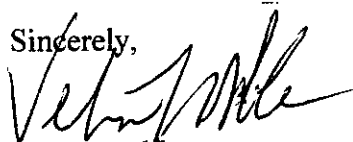
A copy of the stamped label acceptable with conditions is enclosed. Submit three (3) copies of the final printed label before releasing this product for shipment.

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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)

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DATE							

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HIGHLY REGULATED COPY

**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. Harmful if swallowed or absorbed through the skin. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and protective gloves (rubber, chemical resistant) when handling. Wash thoroughly with soap and water after handling. Remove and wash contaminated 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 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 duct 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: If container size is 5 gallons or greater, use the following Environmental Hazards statements.)*

**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.

**205M SANITIZER**

SANITIZER-DEODORIZER  
WITH ORGANIC SOIL TOLERANCE  
INSTITUTIONAL, INDUSTRIAL, SCHOOL  
DAIRY AND OTHER FARM USE  
FOR FOOD HANDLING AND PROCESSING AREAS,  
RESTAURANTS, BARS AND DAIRIES

**Active Ingredients**

Octyl decyl dimethyl ammonium chloride .....	2.250%
Didecyl dimethyl ammonium chloride .....	1.350%
Dioctyl dimethyl ammonium chloride .....	0.900%
Alkyl (C <sub>14</sub> , 50%; C <sub>12</sub> , 40%; C <sub>16</sub> , 10%) dimethyl benzyl ammonium chloride .....	3.000%
<b>Other Ingredients</b> .....	<b>92.500%</b>
<b>Total:</b> .....	<b>100.000%</b>

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

SEE LEFT PANEL FOR ADDITIONAL  
PRECAUTIONARY STATEMENTS

EPA Registration No. 6836-89  
EPA Est. No. *(insert EPA Est. No. here)*  
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:

JAN 7 2004

Under Insecticide,  
Fungicide Act as  
Fungicide,  
Under EPA Reg. No

6836-89

Regular, effective cleaning and sanitizing of equipment, utensils, and work or dining surfaces minimize the probability of contaminating food during preparation, storage or service which could harbor hazardous microorganisms. 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 disease 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 shall be washed, rinsed 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 shall be washed, rinsed and sanitized at intervals throughout the day on a schedule based on food temperature, type of food, and amount of food particle accumulation.

### **DIRECTIONS FOR USE**

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

**SANITIZING OF FOOD PROCESSING EQUIPMENT AND OTHER HARD SURFACES IN FOOD CONTACT LOCATIONS.** For sanitizing food processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage and display equipment and other hard non-porous surfaces. No potable water rinse is required.

Wash and rinse all articles thoroughly, then apply a solution of 1 oz. **205M SANITIZER** in 4 gallons of water (150 ppm active). Surfaces should remain wet for at least one minute followed by adequate draining and air drying. Fresh solution should be prepared daily or when use solution becomes visibly dirty. For mechanical application, use solution may not be reused for sanitizing applications.

Apply to sink tops, countertops, refrigerated storage and display equipment and other stationary hard surfaces by cloth or brush. No potable water rinse is required.

Dishes, silverware, glasses, cooking utensils and other similar size food processing equipment can be sanitized by immersion in a 1 oz./4 gallon solution of **205M SANITIZER**. No potable water rinse is required.

At 1 oz./4 gallons, **205M SANITIZER** fulfills the criteria of Appendix F of the Grade "A" Pasteurized Milk Ordinances 1978 Recommendations of the U.S. Public Health Services in waters up to 800 ppm of hardness calculated as  $\text{CaCO}_3$  when evaluated by the AOAC Germicidal and Detergent Sanitizer Method against *Escherichia coli* and *Staphylococcus aureus*.

## **U.S. PUBLIC HEALTH SERVICE FOOD SERVICE SANITIZATION RECOMMENDATIONS**

**CLEANING AND SANITIZING.** Equipment and utensils shall be thoroughly preflushed or prescraped and when necessary, presoaked to remove gross food particles and soil.

1. Thoroughly wash equipment and utensils in a hot detergent solution.
2. Rinse utensils and equipment thoroughly with clean water.
3. Sanitize equipment and utensils by immersion in a 1 oz./4 gallon solution of **205M SANITIZER** (150 ppm active) for at least 60 seconds at a temperature of 75°F. This dilution is equivalent to a solution containing 50 ppm available chlorine.
4. For equipment and utensils too large to sanitize by immersion, apply a 1 oz./2 gallon solution of **205M SANITIZER** (300 ppm active) by rinsing, spraying or swabbing until thoroughly wetted.
5. Allow sanitized surface to drain and air dry. Do not rinse.

**205M SANITIZER** meets the requirements of 21 CFR 178.1010.

**DIRECTIONS FOR RESTAURANTS AND BAR RINSE.** For dishes, glassware, silverware, cooking utensils, wash with 1 oz./4 gallon of **205M SANITIZER** and immerse in a solution containing 1 oz./4 gallon of **205M SANITIZER**. No rinse is required.

**DIRECTIONS FOR FOOD PROCESSING EQUIPMENT AND DAIRIES.** Clean and rinse equipment thoroughly, then apply sanitizing solution containing 1 oz. / 4 gallons of water. No rinse is required.

### **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 **205M SANITIZER** per 4 gallons of water. (150 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 to reviewer: If container 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 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 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:**

(Plastic Containers:) Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by 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 puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.