AUG 0 6 1991

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

Attention: Joseph R. Robinson

Gentlemen:

Subject: 205M Sanitizer

EPA Registration No. 6836-89 Your Amendment Dated March 8, 1991

The amendment referred to above, submitted in connection with registration under FIFRA, is acceptable provided that you:

- 1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:
 - 4. In the first right upper panel:
 - 1) Revise the wording ". . . and the transmission of disease organisms to consumers and employees" to read ". . . which could harbor hazardous microorganisms."
 - 2) Revise the wording ". . . destroys those disease organisms . . " to read ". . . reduces the number of those disease organism . . . "
 - 3) Revise the wording "... and prevents the transfer of such organisms to consumers or employees" to read "... and reduces the potential for the transfer ... "
 - b. Delete the word "milk."
- Submit five (5) copies of your final printed labeling before yo' release the product for shipment.

CONCURRENCES									
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Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martha DeLaney at (703) 557-6982.

Sincerely yours,

John M. Lee

Product Manager (31)

Antimicrobial Program Branch Registration Division (H7505C)

Enclosure

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PRECAUTIONARY STATEMENTS BAZARDOUS TO BUMANS AND DOMESTIC ANDMALS

DANGER

Keep Out Of Reach of Children, Corrosive, Causes 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, Do not breathe spray mist. Avoid contamination of food.

STORAGE AND DISPOSAL

- Do not contaminate water, food, or feed by storage disposal.
- 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 carnot 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.

CONTAINED DISPOSAL

Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a semitary landfill, or incineration, or if ellowed by state and local authorities by burning. If burned, stay out of smoke.

Metal Container: 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.

(If container is 1 gallon or less, use this container disposal statement.)

Do not reuse ampty container (bottle, can, bucket). Wrap container and put in trash.

205M SANITIZER

SANITIZER-DECOORIZER
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	2.2501
Didecyl dimethyl ammonium chloride	1.350%
Dioctyl dimethyl ammonium chloride Alkyl (C., 50%; C., 40%; C., 10%)	0.900%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	3.000%
Inert Ingredients	92,500% 100,000%

KEEP OUT OF REACH OF CHILDREN

DANGER

STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Ramove and wash conteminated clothing before reuse.

If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution; or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

MOTE TO PHISICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration No.
EPA Establishment No.
Net Contents

6835-89 6835-IL-1

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

Regular, effective of equipment, utensils, a minimize the probabilism during preparation, st transmission of disease employees. Effective of employees. prevent the accumulation decompose or support the poisoning organisms or effective sanitizing disease organisms which and utensils after of transfer of such of employees, either direct glasses, cups and flatwe food. To prevent cross-cont food-contact surfaces or rinsed and sanitized as any interruption of o contamination may have o Where equipment and u preparation of foods or line basis, utensils ar of equipment shall be a at intervals throughout food temperature, t

DIRECTION OF Fed in a manner inconsistent

food particle accumulat:

SABITIZING OF FOOD PROBLEMS SURFACES IN FOOD senitizing food programment, food utersplanes, sink tops storage and display porous surfaces. ...

Wash and rinse all artisolution of 1 oz. 2050 water (150 ppm active) for at least one min draining and air drying prepared daily or who visibly dirty. For a solution may not a applications.

Apply to sink tops, storage and display eq hard surfaces by cloth device. No p-table water

Dishes, silverware, g other similar size foot sanitized by immersic solution of 205M SANTT is required.

At 1 oz./4 gallons, criterie of Appendix F Milk Ordinances 1978 Public Health Services hardness calculated as AOAC Germicidal and sagainst Escherichie col:

205M SANITIZER

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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	1.3501
Dioctyl dimethyl ammonium chloride Alkyl (C++, 50%; C++, 40%; C++, 10%)	0.9007
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₅ , 10%) dimethyl benzyl ammonium chloride	3.0001
Inert Ingredients	92,500%

KEEP OUT OF REACH OF CHILLREN

DANGER

STATEMENT OF PRACTICAL TREATMENT

In ase of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse.

If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution; or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

EVIL TO FINICIAE: Probable success! demage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and compulsion may be needed.

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

PA Registration No. PA Establishment No. Not Contents 6836-89 6836-IL-1

100.0001

Maintactured Ey": LONZA INC., 17-17 Route 208 Fair Laws, NJ 07410 Regular, effective cleaning and sanitizing of equipment, utensils, and work or dining surfaces minimize the probability of contaminating food during preparation, storage or service and the transmission of disease organisms to consumers and employees. 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 destroys those disease organisms which may be present on equipment and utensils after cleaning, and prevents the transfer of such organisms to consumers or employees, either directly through tableware such as glasses, cups and flatware or indirectly through the food.

To prevent cross-contamination, kitchenware and food-contact surfaces of equipment shall be washed, rinsed and samitized 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

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

SANITIZING OF POOD PROCESSING EQUIPMENT AND OTHER HAND SURPACES IN POOD 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). Sirfaces should remain wet for at least one minute followed by adequate draining and air drying. Fresh solution should be prepared daily or when the 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 or mechanical spray device. 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 or./4 gailons, 205M SANITIZER fulfills the criteria of Appendix F of the Grade "A" Pasteurized Milk Ordinances 1978 Recommendations of the U.S. Public Realth Services in water up to 800 ppm of hardness calculated as Calla when evaluated by the ACAC Germicidal and Detergint Sanitizer Method against Escherichia coli and Stohylococcus aureus.

U.S. PUBLIC BEALTH STRVICE POOD SERVICE SANITIZATION RECOMMENDATIONS

CLEARING AND SARITIZING. Equipment and utensils shall be thoroughly preflushed or prescraped and when necessary, prescaked to remove gross food particles and soil.

- Thoroughly wash equipment and utensils in a hot detergent solution.
- Rinse utensils and equipment thoroughly with clean water.
- Sanitize equipment and utensils by immersion in a 1 oz./4 gallon solution of 2094 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.
- Allow senitized surface to drain and sir dry, Do not ringe.

205M SARITIZER meets the requirements of 21 CFR 178,1010.

DIRECTIONS FOR EXSTAINANT AND MAR RIESE. 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 gallon of 205M SANITIZER to 1 gallon of water. No rinse is required.

WISCORSIE STATE BOARD OF BEALTH DIRECTIONS FOR EATING ESTABLISHMENTS

- 1. Scrape and pre-wash utensils and glasses whenever possible.
- Wash with a good detergent or competible cleaner.
- 3. Rinse with clean water.
- 4. Sanitize in a solution of 1 oz./4 gallon of 205M SANITIZER to 1 gallon 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 specific of all-dry.

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