

6836-89

11/12/2008



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

NOV 12 2008

Ms. Georgia Anastasiou
Lewis & Harrison
122 C Street, NW
Suite 740
Washington, DC 20001

Subject: 205M Sanitizer
EPA Registration No.: 6836-89
Amendment Date: August 12, 2008
EPA Receipt Date: August 14, 2008

Dear Ms. Anastasiou,

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

- Update Container Disposal instructions per PR Notice 2007-4
- Add marketing language, graphics, dilution rate charts
- Secondary container with use dilution precautionary statements

Conditions

Revise the label as follows:

- 1) Under the "Precautionary Statements" on page 2, revise the second to last statement by incorporating the phrase, "...and before eating, drinking, chewing gum, or using tobacco."
- 2) Revise the "Precautionary Statements" on page 2 by adding the use dilution precautionary labeling in italics underneath the statements.

"After product is diluted in accordance with the directions for use, causes moderate eye irritation. Avoid contact with eyes and clothing. Wash thoroughly with soap and water after handling and before eating drinking, chewing gum, or using tobacco."

- 3) Revise the 1st statement in the 1st paragraph on page 3 by deleting the term, hazardous, and replace it with "food poisoning." Also, delete "CONSUMER USE" which appears in the 3rd statement in this paragraph. The use of "hazardous" and "disease" are terms that imply heightened efficacy.

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2/17

4) Revise the statement, "Articles or surfaces too large ... swabbing," by deleting the term "should," and replacing it with, "**must**," such that the statement is in agreement with PR Notice 2000-5, Mandatory Labeling.

5) The refillable container statements do not meet the definition of refillable containers; therefore,
The refillable container instructions must be deleted.

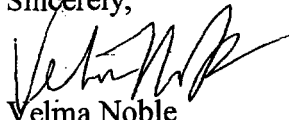
6) Revise the secondary container label by deleting the "Caution" signal word and stating "**DANGER**". A registered product cannot support two different Signal Words.

General Comments

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

Should you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416 or Velma Noble (703) 308-6233.

Sincerely,



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

Enclosure: Stamped Label

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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%
Diocetyl dimethyl ammonium chloride	0.900%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	3.000%
<u>Other Ingredients</u>	<u>92.500%</u>
Total:	100.000%

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)
[Country of origin: (insert country)]
[Manufactured in: (insert country)]

Manufactured by:
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

ACCEPTED
with COMMENTS
in EPA Letter Dated:
NOV 12 2008

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

6836-89

4
17

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 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: 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.

(Note to reviewer: The following is considered optional marketing language :)

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

Articles that can be immersed in solution must remain in solution for 60 seconds.

Articles or surfaces too large for immersing ~~should~~ be thoroughly wetted or flooded by rinsing, spraying or swabbing.

Allow all sanitized surfaces to drain and air dry.

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 CaCO_3 when evaluated by the AOAC Germicidal and Detergent Sanitizer Method against *Escherichia coli* and *Staphylococcus aureus*.

For use in *[insert name of automated dilution system here]* (automated) (dilution system).

(Note to reviewer: The following may be used only if the supplemental registrant has obtained a Kosher Certification.)



(Any Kosher Symbol such as:)

(Kosher)

5/6

(Note to reviewer: The following may be used only if the supplemental registrant has obtained an NSF listing. Allowed on back or side panel only.)



(NSF Listed)

(Insert 6-Digit NSF Listing Number here)

(Note to reviewer: The following is considered optional marketing language:)

205M Sanitizer is an effective sanitizer for use on food contact surfaces in 400 ppm hard water against:

(Note to reviewer: 150 ppm Al)

Escherichia coli
Staphylococcus aureus

205M Sanitizer is an effective sanitizer for use on food contact surfaces in 500 ppm hard water against:

(Note to reviewer: 200 ppm Al)

Campylobacter jejuni
Escherichia coli
Escherichia coli 0157:H7
Klebsiella pneumoniae
Listeria monocytogenes
Salmonella enterica
Shigella sonnei
Staphylococcus aureus
Yersinia enterocolitica

205M Sanitizer is an effective sanitizer for use on food contact surfaces in 1000 ppm hard water against:

(Note to reviewer: 400 ppm Al)

Escherichia coli
Staphylococcus aureus

DIRECTIONS FOR USE

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

Sanitizer (1:188)	2 oz per 2 7/8 gallons of water (0.68 oz per gallon of water) (400 ppm active quat)
Sanitizer (1:376)	2 oz per 5 3/4 gallons of water (0.34 oz per gallon of water) (200 ppm active quat)
Sanitizer (1:496)	2 oz per 7 3/4 gallons of water (0.25 oz per gallon of water) (150 ppm active quat)

(Note to reviewer. On a final printed label, only one of the following dilution rates will be used in the sanitization sections below)

For Food Contact Surfaces, Food Processing Equipment and Utensils in Dairies and Public Eating Establishments (40 CFR 180.940 (a)) and Food Contact Surfaces, Food Processing Equipment and Utensils in Food Processing Plants (40 CFR 180.940 (a6)):

2 oz. of 205M SANITIZER per 7 3/4 gallons of water (0.25 oz. of 205M Sanitizer per gallon of water) (150 ppm active quat)

or

2 oz. of 205M SANITIZER per 5 3/4 gallons of water (0.34 oz. of 205M Sanitizer per gallon of water) (200 ppm active quat)

or

2 oz. of 205M SANITIZER per 2 7/8 gallons of water (0.68 oz. of 205M Sanitizer per gallon of water) (400 ppm active quat)

or

2 oz. of 205M SANITIZER per 2 7/8 - 5 3/4 gallons of water (0.25 - 0.34 oz. of 205M Sanitizer per gallon of water) (150 - 200 ppm active quat)

or

2 oz. of 205M SANITIZER per 2 7/8 - 7 3/4 gallons of water (0.25 - 0.68 oz. of 205M Sanitizer per gallon of water) (150 - 400 ppm active quat)

or

2 - 4 oz. of 205M SANITIZER per 2 7/8 gallons of water (0.34 - 0.68 oz. of 205M Sanitizer per gallon of water) (200 - 400 ppm active quat)

8/15

TO SANITIZE FOOD CONTACT SURFACES:

or

TO SANITIZE FOOD CONTACT SURFACES, FOOD PROCESSING EQUIPMENT AND OTHER HARD SURFACES IN FOOD PROCESSING LOCATIONS, DAIRIES, RESTAURANTS AND BARS:

Use **205M SANITIZER** to sanitize hard nonporous surfaces of food processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage areas and display equipment and other hard surfaces.

Prior to application, remove gross food particles and soil by a pre-flush, pre-scrub or, 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 use-solution of *[insert appropriate dilution from box above here]* [or equivalent dilution] to pre-cleaned hard surfaces thoroughly wetting surfaces with a cloth, mop, sponge, coarse sprayer or by immersion. 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 for each use. For mechanical application, use- solution may not be reused for sanitizing applications but may be reused for other purposes such as cleaning.

Apply to sink tops, countertops, refrigerated storage and display equipment and other stationary hard nonporous surfaces by cloth, sponge or brush or coarse spray.

Immerse pre-cleaned glassware, dishes, silverware, cooking utensils and other similar size food processing equipment in a solution of *[insert appropriate dilution here]* (or equivalent dilution) for at least 60 seconds. Drain thoroughly [and allow to air dry] before reuse. Do not rinse.

TO SANITIZE FOOD PROCESSING EQUIPMENT, UTENSILS, AND OTHER FOOD CONTACT ARTICLES REGULATED BY 40 CFR § 180.940(a):

1. Scrape, flush, or presoak articles (whether mobile or stationary) to remove gross food particles and soil.
2. Thoroughly wash articles with an appropriate detergent or cleaner.
3. Rinse articles thoroughly with clean water.
4. Sanitize by immersing articles with a use-solution of *[insert appropriate dilution here]* (or equivalent dilution) for at least 60 seconds. Articles too large for immersing must be thoroughly wetted by rinsing, spraying, or swabbing.
5. Remove immersed items from solution to drain and then air dry. Non-immersed items must also be allowed to air dry. **Do not rinse.**

6/17

205M SANITIZER can be used in accordance with the U.S. Public Health Service food service sanitization recommendations.

U.S. PUBLIC HEALTH SERVICE

FOOD SERVICE SANITIZATION RECOMMENDATIONS

CLEANING AND SANITIZING: Equipment and utensils must be thoroughly pre-flushed or pre-scraped and, when necessary, pre-soaked to remove gross food particles and soil.

1. Thoroughly wash equipment and utensils in hot detergent solution.
2. Rinse utensils and equipment thoroughly with clean water.
3. Sanitize equipment and utensils by immersion in a use solution of *[insert appropriate dilution from box above here]* (or equivalent dilution) for at least 60 seconds at a temperature of 75°F.
4. For equipment and utensils too large to sanitize by immersion, apply a use-solution of *[insert appropriate dilution from box above here]* (or equivalent dilution) by rinsing, spraying or swabbing until thoroughly wet.
5. Allow sanitized surface to drain and air dry. Do not rinse.

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 *[insert a dilution of 200 ppm active or higher dilution from box above here]*
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 HFS 196, Appendix 7-204.11 of the Wisconsin Administrative Code (reference 40 CFR 180.940 (a)).

10
17

(Note to reviewer: For Nonrefillable Containers, Container is one gallon or less, Label has Household and Residential Uses only.)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls.

Nonrefillable container. Do not reuse or refill this container. (Wrap and) Discard in trash. Offer for recycling, if available.

(or)

Nonrefillable container. Do not reuse or refill this container. (Wrap and) Discard in trash. Offer for reconditioning, if appropriate

15
(Note to reviewer: For Nonrefillable Containers, Container is one gallon or less; Label has uses any uses other than Household and Residential).

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls.

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. (Wrap and) Discard in trash. Offer for recycling, if available.

(or)

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. (Wrap and) Discard in trash. Offer for reconditioning, if appropriate

12
15

(Note to reviewer: For Nonrefillable Containers, Container is over one gallon.)

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:

~~Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.~~

(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.

(For Bag-in-Box Containers:) Completely empty bag into application equipment. Offer for recycling, if available or dispose of empty bag in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(Note to reviewer: For Refillable Containers, Container is one gallon or less:)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls.

Refillable container. Refill this container with [this product] only. Do not reuse this container for any other purpose.

Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

FINAL CONTAINER DISPOSAL

Clean container promptly after emptying.

(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.

(For Bag-in-Box Containers:) Completely empty bag into application equipment. Offer for recycling, if available or dispose of empty bag in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

5/5
(Note to reviewer: For Refillable Containers, Container is over one gallon.)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Refillable container. Refill this container with [this product] only. Do not reuse this container for any other purpose. Cleaning before refilling is the responsibility of the refiller.

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.

FINAL CONTAINER DISPOSAL

Clean container promptly after emptying. Cleaning the container before final disposal is the responsibility of the person disposing of the container.

(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.

(For Bag-in-Box Containers:) Completely empty bag into application equipment. Offer for recycling, if available or dispose of empty bag in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(For Bag-in-Box Containers.)

For Bag - In - Box Containers:

How to use this package

This package is designed to be used with dilution control systems only. Open package and connect to dispense according to directions on box-top.

Trigger Sprayers:

Fill bottle from dispenser

Apply to surfaces as specified in directions above.

Mop Buckets:

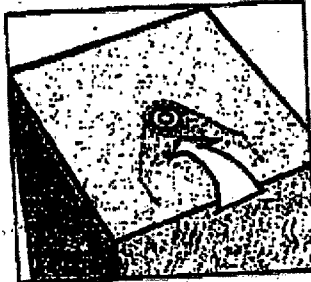
Fill bucket from dispenser

Set up "Wet Floor" signs

Mop floor surface as specified in directions above

OPENING INSTRUCTIONS

1. Position box with perforation up.
2. Press in circle.
3. Lift flap/ear along perforation.
4. Retrieve fitting on bag.
5. Remove clear dust-cap from bag fitting.
6. Twist dispenser connector onto bag fitting.
7. Place bag-in-box into position on dispenser shelf.
8. Close dispenser (if applicable).



INSTRUCCIONES PARA ABRIR

1. Ponga la caja con la perforación hacia arriba.
2. Empuje el círculo hacia adentro.
3. Levante la pesona arrancándola de la caja a lo largo de la perforación.
4. Saque el adaptador que está en la bolsa.
5. Quite la tapa transparente contra el polvo que tiene el adaptador de la bolsa.
6. Enrosque el conector dispensador al adaptador.
7. Ponga la "bag-in-box" (bolsa en caja) en posición en el mostrador de despacho.
8. Cierre el dispensador (si corresponde).

5/6

**PACKET LABEL TO BE USED WITH MASTER CONTAINER LABEL
FOR SANITIZATION**

*Note to reviewer: the following will be used for 0.68 oz of concentrate:
MIX EACH PACKET WITH 1 GALLON OF WATER*

205M SANITIZER

EPA Reg. No. 6836-89

EPA Est. No. *(insert EPA Est. No. here)*

Net Contents:

Active Ingredients:	
Octyl-decyl dimethyl ammonium chloride	2.25%
Dioctyl dimethyl ammonium chloride	0.90%
Didecyl dimethyl ammonium chloride	1.35%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	3.00%
Other Ingredients	92.50%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

See outer container for Precautionary Statements and Use directions

Disposal: Do not reuse packet. Wrap and put in trash.

Lonza Inc. 90 Boroline Road, Allendale, NJ 07401

[IF OTHER PACKET SIZES ARE DESIRED, NEW PACKET LABEL WILL BE IDENTICAL AND THE ONLY THINGS THAT WILL VARY ARE THE NET CONTENTS, AMOUNT OF WATER TO DILUTE WITH AND PPM ACTIVE QUAT. THOSE 3 ITEMS WILL HAVE TO MATCH OR BE EQUIVALENT TO THE DILUTION CHART THAT IS SHOWN ON PAGE 7.]

SECONDARY CONTAINER LABEL

(Note to reviewer: This secondary container label will be used only when the product is diluted at 0.68 oz. per gallon of water (400 ppm Al or less))

205M SANITIZER

EPA Reg. No. 6836-89

Active Ingredients:

Octyl decyl dimethyl ammonium chloride	2.25%
Dioctyl dimethyl ammonium chloride	0.90%
Didecyl dimethyl ammonium chloride	1.35%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	3.00%
Other Ingredients	92.50%
Total	100.00%

The product in this container is diluted as directed on the pesticide product label.

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Caution. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

Follow the directions for use on the pesticide label when applying this product.