

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 3 2005

Mr. Robert Sloan  
Lonza Inc.  
90 Boroline Rd  
Allendale, NJ 07401

Subject: Formulation HS 3328  
EPA Registration No. 47371-104  
Amendment Date: May 9, 2005  
EPA Receipt Date: May 10, 2005

Dear Mr. Sloan,

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

- Add Packet Directions

**Conditions**

Revise the label as follows:

Revise the Barber Shop Directions to state:

*Preclean barber tools. Mix 1/2 oz. per gallon of water to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, razors, and scissors for 10 minutes. Rinse thoroughly and dry before resuse. Prepare a fresh solution daily or more often if solution becomes visibly soiled, cloudy, or diluted.*

*Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, dried, and kept in a clean non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.*

**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

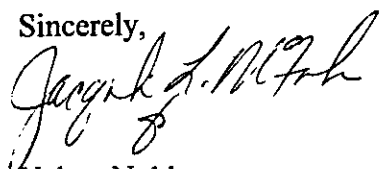
SYMBOL								
SURNAME								
DATE								

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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)

Enclosure: Stamped Label

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER. CORROSIVE:** Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles or face shield), protective clothing and protective gloves (rubber or chemical resistant) when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before use.

### 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. Measures against circulatory shock, respiratory depression and convulsion may be needed.

*(Note to reviewer: If the container size is 5 gallons or greater, 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.

FORMULATION HS-3328  
EPA Reg. No. 47371-104  
EPA DRAFT 05-05-05

## Formulation HS-3328

### DISINFECTANT-SANITIZER-DEODORIZER

#### Active Ingredients:

n-Alkyl (C <sub>14</sub> , 60%; C <sub>16</sub> , 30%; C <sub>18</sub> , 5%; C <sub>12</sub> , 5%)	
dimethyl benzyl ammonium chloride.....	7.04%
n-Alkyl (C <sub>12</sub> , 68%; C <sub>14</sub> , 32%)	
dimethyl ethylbenzyl ammonium chloride....	7.04%
Other Ingredients:.....	85.92%
Total.....	100.00%

### KEEP OUT OF REACH OF CHILDREN

## DANGER

See [side] [back] [left] [right] panel for Precautionary Statements and First Aid

EPA Reg. No. 47371-104

EPA Est. No. (as indicated on container)

Net Contents (as indicated on container)

H&S CHEMICALS DIVISION  
c/o Lonza Inc.  
90 Boroline Road  
Allendale, NJ 07401

ACCEPTED  
with COMMENTS  
EPA Letter Dated:

AUG 3 2005  
Under Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 47371-104

*(Note to reviewer: Language in [ ] is optional or interchangeable)*

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An effective, multi-purpose disinfectant - Staphylocidal, Pseudomonacidal and Salmonellacidal on nonporous, inanimate surfaces.

**Formulation HS-3328** is an effective sanitizer for use on food contact surfaces; it also fulfills the criteria of Appendix F, of the Grade "A" Pasteurized Milk Ordinance 2002, recommendation of the U.S. Public Health Service, in hard waters up to [500] [750] ppm hardness (calculated  $\text{CaCO}_3$ ).

**Formulation HS-3328** at 1 oz. per 5 1/2 gallons of water [alternate: 0.18 oz. per gallon of water, or 3.64 fl. oz. per 20 gallons of water, or equivalent dilution] is an effective sanitizer for use on food contact surfaces in 60 seconds at 200 ppm active and 750 ppm hard water against:

Escherichia coli  
Staphylococcus aureus

**Formulation HS-3328** at 1 oz. per 6 1/4 gallons of water [alternate: 0.16 oz. per gallon of water, or 3.19 fl. oz. per 20 gallons of water] [or equivalent dilution] is an effective sanitizer for use on food contact surfaces in 60 seconds at 175 ppm active and 500 ppm hard water against:

Escherichia coli  
Staphylococcus aureus

<b>DISINFECTANT 1:256</b>	(550 ppm active quat)
<b>SANITIZER 1:640</b>	(220 ppm active quat)
<b>SANITIZER 1:704</b>	(200 ppm active quat)
<b>SANITIZER 1:821</b>	(175 ppm active quat)

#### DIRECTIONS FOR USE

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

**DIRECTIONS FOR DISINFECTING:** For use in hospitals and nursing homes, federally inspected meat and poultry plants, restaurants and bars, beverage plants, barber shops, schools and colleges.

For use on hard, nonporous surfaces such as floors, walls, metal surfaces, glazed porcelain, and plastic surfaces (such as polypropylene, polystyrene, etc.).

Remove gross filth and heavy soils. Pre-clean all surfaces then thoroughly wet surfaces with Formulation HS-3328. Use 1/2 oz. per gallon of water for a minimum contact time of 10 minutes in a single application. Can be applied with a mop, sponge, trigger sprayer or by soaking. The recommended use solution is prepared fresh for each use, then discarded. Rinsing is not necessary, unless floors are to be waxed or polished.

Rinse food contact surfaces such as counter tops, tables, picnic tables, appliances and / or stove tops with potable water prior to reuse. Do not use on glasses, dishes or utensils as a disinfectant.

**DISINFECTION OF BARBER TOOLS:** Barber tools (such as combs, brushes, razors and scissors) can be disinfected by immersing in a 1/2 oz. per gallon solution for a minimum of 10 minutes. Prepare fresh solution daily.

(Note to reviewer: Only One of the following two statements will be used:)

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

or

This product is not for use on medical device surfaces.

**(Note to reviewer:** On a final printed label, only one of the dilution rates below will be used in the sanitizing direction sections.

[1 oz. per 5 [- 5 ½] gallons [0.18 [- 0.20] oz. per gallon] [3.64 [- 4.00] fl. oz. per 20 gallons] of water [or equivalent dilution] [200 [- 220] ppm active quat]

or

[1 oz. per 5 - 6 1/4 gallons (0.16 - 0.20 oz. per gallon) (3.19 - 4.00 fl. oz. per 20 gallons) of water (or equivalent dilution) (175 - 220 ppm active quat)]

or

[1 oz. per 5 ½ gallons] [0.73 oz. per 4 gallons] [2.73 fl. oz. per 15 gallons] [the contents of this packet] [3.64 fl. oz. per 20 gallons] [or equivalent dilution] (200 ppm quat]

**DIRECTIONS FOR SANITIZING:** For use on hard, nonporous surfaces such as eating utensils and drinking glasses.

Remove gross particles and soil by a pre-flush, pre-scrub, or when necessary, a pre-soak treatment. Thoroughly pre-clean all surfaces with a good detergent or compatible cleaner and rinse with potable water prior to sanitizing. Then, use [insert appropriate dilution rate here from box] for a minimum contact time of 1 minute in a single application. Can be applied with a mop, sponge, trigger sprayer or by soaking. Apply by soaking to dishes, glasses and eating utensils. For sprayer applications, use a coarse spray device. Spray 6 - 8 inches from the surface, rub with a brush, cloth or sponge. Do not breathe spray. The recommended use solution is prepared fresh for each use then discarded. Drain thoroughly. Do not rinse.

Before use as a sanitizer in federally inspected meat and poultry plants and dairies, food products and packaging materials must be removed from the room or carefully protected.

**RESTAURANT AND BAR USE:** For use as a sanitizer on dishes, glassware, silverware, cooking utensils, Remove gross particles and soil by a pre-flush, pre-scrub, or when necessary, a pre-soak treatment. Thoroughly pre-clean all surfaces with a good detergent or compatible cleaner and rinse with potable water prior to sanitizing. Immerse in a solution of [insert appropriate dilution rate here from box] for at least 1 minute. Do not rinse. Allow to air Dry. Prepare a fresh solution at least daily or when use solution becomes visibly dirty.

**BEVERAGE PLANTS:** For sanitizing of bottling or pre-mix dispensing equipment. Wash surfaces with a good detergent or compatible cleaner and rinse with potable water prior to sanitizing. Fill equipment with solution of [insert appropriate dilution rate here from box]. Allow the solution to remain in contact with equipment for at least 1 minute or until operations resume at which time the sanitizing solution should be drained from the system.

To insure the removal of flavors, it is suggested that during change over between products, the system should be cleaned, rinsed, and flushed with the sanitizing solution for 1 minute. Allow to drain completely before using.

**SANITARY FILLING:** Recommended for use in sanitizing bottles or cans in the final rinse application. Wash surfaces with a good detergent or compatible cleaner and rinse with potable water prior to sanitizing. Formulation HS-3328 is to be proportioned into the final rinse water line of the container washer or rinser in concentration of [insert appropriate dilution rate here from box]. A sanitizing solution of [insert appropriate dilution rate here from box] should be used for the filler and closing machine.

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**STORAGE TANK SANITIZING:** Recommended for sanitizing beer fermentation and holding tanks. Wash surfaces with a good detergent or compatible cleaner and rinse with potable water prior to sanitizing. A solution of [insert appropriate dilution rate here from box] should be applied by spraying or used in combination with automated cleaning systems. For sprayer applications, use a coarse spray device. Spray 6-8 inches from the surface, rub with a brush, cloth or sponge. Do not breathe spray. Drain thoroughly. Do not rinse. For mechanical operations or automated systems, the used sanitizing solution may not be reused for sanitizing, but may be reused for other purposes such as cleaning.

**DIRECTIONS FOR SANITIZING EATING AND DRINKING UTENSILS IN EATING ESTABLISHMENTS:**

- 1) Remove gross particles and soil by a pre-flush, pre-scrape, or when necessary, a pre-soak treatment.
- 2) Thoroughly pre-clean all surfaces with a good detergent or compatible cleaner and
- 3) Rinse with potable water prior to sanitizing.
- 4) Immerse in a solution of [insert appropriate dilution rate here from box]. Immerse all utensils for at least two minutes or for a contact time specified by governing sanitary code.
- 5) Place sanitized utensils on a rack or drainboard to air dry.
- 6) Prepare a fresh solution at least daily or when use solution becomes visibly dirty.

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

(Note to reviewer: If the container size is one gallon or less, the following Storage & Disposal statements will be used:)

**STORAGE AND DISPOSAL**

Store in original container in areas inaccessible to children. Do not reuse empty container. Discard in trash or recycle.

(Note to reviewer: If the container size is greater than one gallon, the following Storage & 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 incinerate, or if allowed by state and local authorities, burn. If burned, stay out of smoke.

(Fiber drums with liners) Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then, dispose of liner in a sanitary landfill, or by incineration, if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

(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.

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(Note to reviewer: Language for packets:)

TEAR HERE

## FORMULATION HS-3328

### Active Ingredients:

n-Alkyl (C14 60%, C16 30%, C18 5%, C12 5%)  
dimethyl benzyl ammonium chloride .....7.04%  
n-Alkyl (C12 68%, C14 32%) dimethyl  
ethylbenzyl ammonium chloride .....7.04%  
Other Ingredients .....85.92%

EPA Reg No. 47371-104-

EPA Est. No. (insert Establishment number here)

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

See box label for Precautionary Statements and First Aid.

(Note to reviewer: The following Directions for Use may or may not appear on the packet, depending on whether space allows. It is not required text for small containers. Other similar sanitizing directions from pages 3 or 4 may be substituted. )

### **[DIRECTIONS FOR USE:**

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

This product is not for use on medical device surfaces.

**DIRECTIONS FOR SANITIZING:** For use on hard, nonporous surfaces such as eating utensils and drinking glasses. Remove gross particles and soil by a pre-flush, pre-scrape, or when necessary, a pre-soak treatment. Thoroughly preclean all surfaces with a good detergent or compatible cleaner and rinse with potable water prior to sanitizing. Then use [0.73 oz. (the contents of this packet) per 4 gallons] [2.73 fl.oz. oz. (the contents of this packet) per 15 gallons of water] (200 ppm quat) for a minimum contact time of 1 minute in a single application. Can be applied with a mop, sponge, trigger sprayer or by soaking. Apply by soaking to dishes, glasses and eating utensils. For sprayer applications, use a coarse spray device. Spray 6 – 8 inches from the surface; rub with a brush, cloth or sponge. Do not breathe spray. The recommended use solution is prepared fresh for each use then discarded. Drain thoroughly. Do not rinse.]

Refer to box label for complete directions for use.

**Net Contents 0.73 fl. oz. (21.59 ml.)**

**Net Contents 2.73 fl. Oz. (80.73 ml.)**

**SOLD BY:**

Lonza Inc.

90 Boroline Road

Allendale, NJ 07401

(Note to reviewer: Additional language for outside box:)

- Do not open box with knife
- Tear off panel at perforation
- Remove packets through opening
- Packets can be opened by tearing across pouring spout where indicated
- It is not safe or healthy to open [packet] by using your teeth or a knife.