

OCT 8 2003

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

Subject: Formulation HS-8451P
EPA Registration No. 47371-32
Amendment Date: July 9, 2003
EPA Receipt Date: July 10, 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, Precautionary Statements and Storage and Disposal statements as required by the applicable PR Notices and the EPA label review Manual

Conditions

Revise the Precautionary Statements to read exactly as follows:

1. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (*goggles or face shield or safety glasses*), Harmful if absorbed through the skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Harmful if swallowed.
2. Delete the reference to the use of this product as a deodorant. You have neglected to provide specific directions for use of this product as a deodorant.
3. On page two Directions for use for Sanitizing Eating and Drinking Utensils Item 3 should state:
3) Rinse with potable water

CONCURRENCES

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

General Comments

A stamped copy of the labeling accepted with conditions 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 or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely



Velma Noble

Product Manager (31)

Regulatory Management Branch I

Antimicrobials Division (7510C)

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. To protect eyes wear goggles or face shield and to protect skin, wear rubber gloves when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Harmful if swallowed.

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.

(For 5 gallon containers or larger only.)

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.

**ACCEPTED
with COMMENTS
in EPA Letter Dated:**

OCT 8 - 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 47371-32

FORMULATION HS-8451P

- DISINFECTANT
- SANITIZER
- DEODORANT

A concentrated disinfectant for use in hospitals and nursing homes, schools and colleges, medical and dental offices, office buildings, restaurants and bars, federally inspected meat and poultry plants and beverage plants.

Active Ingredient:

n-Alkyl (C ₁₄ 50%, C ₁₂ 40%, C ₁₆ 10%)	
dimethyl benzyl ammonium chloride.....	10.0%
Other Ingredients:.....	90.0%
Total:	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

See (left) (side) (right) (back) panel for Precautionary Statements and First Aid

EPA Reg. No. 47371-32

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

Net Contents: (insert container size here)

H&S CHEMICALS DIVISION

c/o Lonza Inc.

17-17 Route 208

Fair Lawn, NJ 07410

A.O.A.C. Use-dilution Test

Kills *Salmonella choleraesuis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*.

An effective sanitizer for use on food contact surfaces; it also fulfills the criteria of *Appendix F of the Grade "A" Pasteurized Milk Ordinance 1999* recommendation of the U.S. Public Health Service in hard waters up to 500 ppm hardness (calculated as CaCO₃).

Use on floors, walls, metal surfaces, painted surfaces, exterior bowl surfaces, empty basins, showers, athletic equipment, garbage cans, lavatory fixtures and other hard nonporous surfaces.

DISINFECTANT: 1:128 1 oz. per gallon of water
SANITIZER: 1:512 1 oz. per 4 gallons of water

DIRECTIONS FOR USE

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

DISINFECTION: Remove gross filth and heavy soil deposits. Pre-clean all surfaces prior to disinfection. Thoroughly wet surfaces with a 1 oz. per gallon of water use solution for a minimum contact time of 10 minutes in a single application. Can be applied with a mop, sponge or cloth as well as with a coarse sprayer or by soaking. Wipe dry with a clean cloth or sponge or allow to air dry. 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 all surfaces that come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes as a disinfectant.

(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.

FOR SANITIZING: For use on hard nonporous surfaces such as counter tops, eating utensils and drinking glasses. Remove gross filth and heavy soil deposits. Pre-clean all surfaces prior to sanitizing. Thoroughly wet surfaces. Use 1 ounce per 4 gallons of water for a minimum contact time of 1 minute in a single application. Can be applied with a mop, sponge or cloth, as well as soaking. 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.

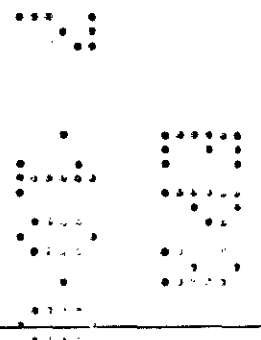
DIRECTIONS FOR SANITIZING EATING AND DRINKING UTENSILS IN EATING ESTABLISHMENTS:

- 1) Scrape and pre-wash utensils and glasses whenever possible.
- 2) Wash with a good detergent or compatible cleaner. (SEE FOOT NOTE #1)
- 3) Rinse with clean water.
- 4) Sanitize in a solution of 1 ounce to 4 gallons of water (200 ppm). 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) Fresh sanitizing solution should be prepared at least daily or more often if visibly soiled.

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

¹ *A commercial cleaner or detergent may be recommended. Also, one may use the statement: "Approved under the regulations of Wisconsin State Division of Health."*

RESTAURANT AND BAR USE: For use as a sanitizer on dishes, glassware, silverware, cooking utensils, wash with detergent, rinse thoroughly and immerse in a solution of 1 ounce per 4 gallons of water for at least 1 minute. Drain thoroughly. Do not rinse.



BEVERAGE PLANTS: For sanitizing of bottling or pre-mix dispensing equipment, after cleaning thoroughly rinse equipment with cold or luke warm water. Fill equipment with solution of 1 oz. per 4 gallons of water (200 ppm. of quat). 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 changeover between products, the system should be cleaned, rinsed and flushed with the sanitizing solution for at least 1 minute. Allow to drain completely before using.

SANITARY FILLING: Recommended for use in sanitizing bottles or cans in the final rinse application. This formulation is to be proportioned into the final rinse water line of the container washer or rinser in concentration of 200 ppm. A sanitizing solution of 200 ppm active quat should be used in an external spraying application for the filler and closing machine.

STORAGE TANK SANITIZING: Recommended for sanitizing beer fermentation and holding tanks. A solution of 200 ppm should be applied by spraying or used in combination with automated cleaning systems. 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.

(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. Discard in trash or recycle.

(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. Open dumping is prohibited.

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.

(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..

