

47371-9

10/8/2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT - 8 2003

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

Subject: Formulation HS-128Q
EPA Registration No. 47371-9
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.

Proposed Amendment

- Update First Aid Statements, Precautionary Statements and Storage and Disposal statements as required by the applicable PR Notices and the EPA Label Review Manuel

Conditions

1. Delete the reference to the use of this product as a deodorizer. You have neglected to provide specific directions for use of this product as a deodorant.
2. On page four Directions for use for Sanitizing Eating and Drinking Utensils in eating Establishments Item 3 should state:
 - 3) Rinse with potable water
3. Revise the Storage and Disposal Statements for container sizes 1 gallon or less as follows:

Store in original container in areas inaccessible to children. Do not reuse empty container. *Wrap* and discard in trash or recycle.

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. Wear eye protection (goggles, safety glasses or face shield) and protective gloves (rubber or chemical resistant) when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash 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.

(For container sizes of 5 gallons or larger)

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-128Q

DISINFECTS-DEODORIZERS-SANITIZES

BACTERICIDAL *VIRUCIDAL FUNGICIDAL

Active Ingredients:

- n-Alkyl (C₁₄ 60%, C₁₆ 30%, C₁₈ 5%, C₁₂ 5%)
dimethyl benzyl ammonium chloride 3.38%
- n-Alkyl (C₁₂ 68%, C₁₄ 32%)
dimethyl ethylbenzyl ammonium chloride 3.38%
- Other Ingredients:..... 93.24%
- Total:..... 100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Reg. No. 47371-9

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

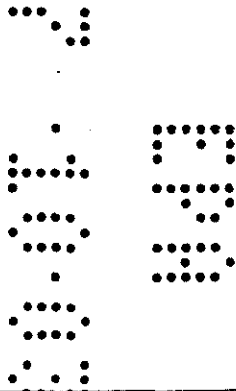
Net Contents *(insert container size here)*

H&S Chemical Division
c/o Lonza Inc.
17-17 Route 208
Fair Lawn, New Jersey 07410

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. **47371-9**



An effective, multi-purpose disinfectant, cleaner, Staphylocidal, Pseudomonacidal, Bactericidal, Fungicidal, and *Virucidal against Herpes virus Type I, Adenovirus Type 3, Influenza A/73 (Victoria), and Vaccinia on pre-cleaned hard nonporous environmental surfaces.

Bactericidal against:
Pseudomonas aeruginosa
Staphylococcus aureus
Salmonella choleraesuis
Aeromonas salmonicida
Enterobacter aerogenes
Enterobacter cloacae
Escherichia. coli
Klebsiella pneumoniae
Listeria monocytogenes
Proteus mirabilis
Pseudomonas putida
Shigella sonnei
Shigella flexneri
Staphylococcus aureus phage 80 & 81
Staphylococcus epidermidis
Streptococcus pyogenes
Vibrio anguillarum

Mold & Mildewcidal against:
Alternaria tenuis
Fusarium oxysporum
Geotrichum candidum
Penicillium digitatum
Phytophthora infestans
Rhizopus nigricans
Trichoderma harzianum
Trichophyton mentagrophytes

For use in hospitals, nursing homes, schools & colleges, office buildings, restaurants, bars, commercial and industrial institutions, veterinary clinics, hotels and motels, animal life science laboratories and medical and dental offices.

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

DISINFECTANT: 1:128 1 oz. per gallon of water (528 ppm Quat)
SANITIZER: 1:384 1 oz. per 3 gallons of water (175 ppm Quat)

DIRECTIONS FOR USE

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

FOR DISINFECTING: Remove gross filth and heavy soil deposits, then thoroughly wet surfaces with solution of 1 ounce per gallon of water. Apply with a mop, sponge, cloth, coarse sprayer or by soaking. Let solution remain on surface for a minimum contact time of 10 minutes. Wipe dry with a clean cloth or sponge or allow to air dry. The use solution is prepared fresh for each use then discarded. Rinsing is not necessary unless floors are to be waxed or polished.

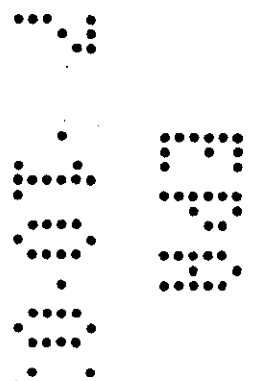
(Note to reviewer: Only One of the following two statements will be used:)

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.

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.

TO CONTROL MOLD AND MILDEW: To control mold and mildew on hard non-porous surfaces wash visible soil from the surface. Then apply 1 ounce per gallon solution with mop, sponge, cloth or mechanical sprayer so as to wet all surfaces thoroughly. Let air dry. Repeat application every 7 days or more often if growth recurs.



VETERINARY PRACTICE / ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP / KENNELS DISINFECTION DIRECTIONS:

For cleaning and disinfecting hard nonporous surfaces: equipment used for feeding or watering animals, utensils, instruments, cages, kennels, stables, catteries. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 1 oz. of **FORMULATION HS-128Q** per gallon of water (or equivalent dilution) for a period of 10 minutes. Wipe or allow to air dry. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. Rinse all surfaces that come in contact with food, including equipment used for feeding or watering, with potable water before reuse. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

FISHERIES, MILK, CITRUS, ICE CREAM, AND POTATO PROCESSING PLANTS: Applied routinely as a disinfectant on walls and floors will reduce or eliminate odors in the processing area. Use on filling equipment to reduce or eliminate bacteria associated with condensation on equipment and pipes.

For use as a sanitizer on conveyors and equipment to reduce or eliminate odors in the processing area. Also, for use on filling equipment to reduce bacteria associated with condensation on equipment and pipes.

FOR SANITIZING: For use on hard nonporous surfaces such as, counter tops, eating utensils, and drinking glasses. For heavily soiled areas, a pre-cleaning is required. Then use 1 ounce per 3 gallons of water for a minimum contact time of 1 minute in a single application. Can be applied with a mop, sponge, cloth or coarse sprayer or by soaking. The use solution is prepared fresh for each use then discarded. Drain thoroughly. Do not rinse.

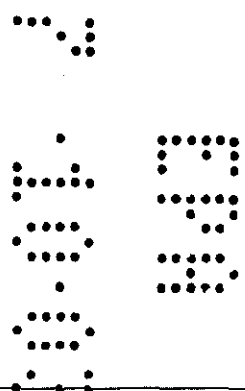
Before use as a sanitizer in federally inspected meat and poultry plants and dairies, food products and packaging materials must be removed from the room or carefully protected. A potable water rinse is not required following use of this compound on previously cleaned hard surfaces provided that the surfaces are adequately drained before contact with food so that little or no residue remains

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 (1 ounce per 3 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 lukewarm water. Fill equipment with solution of 1 ounce per 3 gallons of water (175 ppm 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. The product is to be proportioned into the final rinse water line of the container washer or rinser in concentration of 175 ppm. A sanitizing solution of 175 ppm active quat should be used in an external application for the filler and closing machine.



STORAGE TANK SANITIZING: Recommended for sanitizing beer fermentation and holding tanks. A solution of 175 ppm quat should be applied manually 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.

For Wisconsin Use Only

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 (A commercial cleaner or detergent may be recommended.)
- 3) Rinse with clean water.
- 4) Sanitize in a solution of 1 fluid ounce per 3 gallons of water (175 ppm quat). 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 drain-board to air dry
- 6) Fresh sanitizing solution should be prepared at least daily or when visibly soiled or diluted.

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

(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.

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.

