

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT - 9 2003

Mr. Robert J. Sloan
Sr. Regulatory Services Associate
H & S Chemicals Division c/o Lonza, Inc.
17-17 Route 208
Fair Lawn, NJ 07410

Subject: **Formulation HS210-37**
EPA Registration Number 47371-54
Application Dated July 11, 2003
EPA Received July 14, 2003

Dear Mr. Sloan:

The following amendment, submitted in connection with registration under section of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with comments:

Proposed Amendment:

- revise first aid statement
- revise precautionary statements and storage and disposal

General Comments:

1. Revise Precautionary statement as follows:

DANGER Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Harmful if swallowed or inhaled. Avoid breathing vapor or spray mist. Wear protective eyewear (goggles, face shield, or safety glasses, and protective clothing and waterproof gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

2. Revise the "Veterinary" directions by deleting the statement beginning: "Rinse all surfaces that come in contact with food...with potable water.." and replacing with the following: "*Thoroughly scrub* ~~about~~ surfaces that come in contact with food.

SYMBOL								
SURNAME								
DATE								

including equipment used for feeding or watering, *with soap or detergent and rinse with potable water before reuse.*


- 3. Under Wisconsin only subheading make the following changes:
 - (a) # 4 correct to 9½ gallon of water....
 - (b) #6 change to read "Prepared fresh sanitizing at least daily or when visibly soiled or diluted".
 - (c) Under Beverage Plants: replace the word "should" with "must". Refer to PR 2000-5 for mandatory language.
 - (d) Under Storage Tank Sanitizing: Add the following text to the directions " 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".

- 4. Under Restaurant and Bar Use: add this statement as follows per DIS/TSS 17

It is necessary for removal of gross food particles and soil by a preflush, or pre-scrape and, when necessary, pre-soak treatment. In addition, instructions must be provided for thoroughly washing the surfaces or objects with a good detergent or compatible cleaner, followed by a potable water rinse prior to application of the sanitizing solution.

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 Drusilla Copeland on (703) 308-6224.

Sincerely,

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

Enclosure

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Corrosive. Causes irreversible eye damage and skin burns. Harmful if absorbed through skin. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing and gloves (rubber, chemical resistant). Harmful if swallowed. 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

(Note to reviewer: If 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.

PHYSICAL AND CHEMICAL HAZARDS

Do not store near heat or open flame.

Formulation HS210-37

Farm Disinfectant / Sanitizer

Active Ingredient:	
Didecyl dimethyl ammonium chloride	37.5%
Other Ingredients:.....	62.5%
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. 47371-54
EPA Est. No. *(insert EPA Est. No. here)*
Net Contents: *(insert container size here)*

MANUFACTURED BY:
H&S CHEMICALS DIVISION
c/o LONZA INC.
17-17 Route 208
Fair Lawn, NJ 07410

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Under the Federal Insecticide,
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registered under EPA Reg. No. **47371-54**

Bactericidal in the presence of 5% organic serum, according to current AOAC Use-dilution Test. Effective as a sanitizer, in the presence of 1,000 ppm water hardness, according to AOAC Germicidal and Detergent Sanitizer Test.

For use in hospitals, nursing homes, dairy farms, equine farms, hog farms, poultry and turkey farms, tack shops, kennels, pet shops, veterinary clinics, animal life science laboratories, restaurants and bars, beverage plants, federally inspected meat and poultry processing plants, egg processing plants and households.

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

- DISINFECTANT:** 1:700..... 1 oz per 5 ½ gallons
..... (535 ppm quat)
- SANITIZER:** 1:2500 1 oz. per 19 ½ gallons
..... 150 ppm quat)

DIRECTIONS FOR USE

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

GENERAL USE DIRECTIONS FOR DISINFECTING

Remove gross filth and heavy soil deposits then, thoroughly wet surfaces with a solution of 1 ounce per 5 ½ gallons water for a minimum contact time of 10 minutes. Can be applied with a mop, sponge, or cloth, as well as with a coarse sprayer or 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.

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.

Rinsing of floors 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.

FOR POULTRY AND SWINE HOUSE DISINFECTING

Prior to disinfection:

1. All animals, as well as feeds, must be removed from the premises. This includes emptying all troughs, racks, and other feeding and water appliances.
2. Remove all litter and droppings from floors, walls, and other surfaces occupied or traversed by animals.
3. Thoroughly clean all surfaces with detergent and rinse with water.

Disinfection procedures:

1. Thoroughly mix 1 ounce of the concentrate per 5 ½ gallons of water.
2. Saturate surfaces above the floor with the disinfectant solution for a period of 10 minutes. Follow standard pattern with overlapping sections so that all surfaces are wet, including rafters, beams, feed troughs, windows, ceiling, etc. Surfaces should be wet to point of run off.
3. Ventilate buildings, coops, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.
4. All treated equipment that will be in contact with feed or drinking water must be rinsed with potable water before using.

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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 HS210-37** per 5½ gallons 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.

FARM PREMISE USE:

Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with a use-solution of 1 oz. of **FORMULATION HS210-37** per 5½ gallons of water (or equivalent dilution) for a period of 10 minutes. 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. Ventilate buildings, cars, boats and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before reuse

SANITIZING DAIRY, MEAT AND POULTRY PROCESSING UTENSILS AND EQUIPMENT

For use as a sanitizer on hard, nonporous surfaces, dilute 1 oz. per 19 1/2 gallons of water to provide 150 ppm active quat. Prior to sanitizing, thoroughly clean all surfaces with detergent and rinse with water. The solution can be applied with a mop, sponge, or cloth, as well as spraying or soaking. Saturate or immerse in sanitizing solution for a minimum contact time of 1 minute. Allow the surface to completely drain and air dry before use. Do not rinse. A fresh solution should be prepared at least daily or more often if the solution becomes diluted or soiled.

DAIRY COWS: The udders, flanks, and teats of dairy cows can be washed with a solution of 1 oz. in 19 1/2 gallons of warm water. Do not rinse. Use a fresh towel for each cow. Avoid contamination of wash solution by dirt and soil. Do not dip used towel back into wash solution. When solution becomes visibly dirty, discard and provide fresh solution.

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

SANITIZING SHELL EGGS INTENDED FOR FOOD

To sanitize previously cleaned, food-grade eggs, in shell egg and egg product processing plants, (saturate with) (spray with) a solution of 1 oz. in 19 1/2 gallons of warm water (150 ppm quat). The solution should be warmer than the eggs, but not to exceed 130°F. Wet eggs thoroughly and allow to drain. Eggs sanitized with this product shall be subjected to a potable water rinse only if they are to be broken immediately for use in the manufacture of egg products. Eggs should be reasonably dry before casing or breaking. The solution should not be reused for sanitizing eggs.

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 oz. per 19 1/2 gallons of water (150 ppm quat) for at least 1 minute. Allow to drain and air dry. Do not rinse. Allow to air dry.

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FOR WISCONSIN 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 19 gallons of water (150 ppm quat). Immerse all utensils for at least two minutes or for a contact time specified by governing sanitary codes.
- 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.

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 ounce per 19 1/2 gallons of water (150 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 and air dry. Do not rinse.

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.

SANITARY FILLING: To sanitize bottle or cans in the final rinse application, proportion 1 ounce per 19 1/2 gallons of water (150ppm) into the final rinse water line of the container washer or rinser and for the filler and closing machine. Allow the solution to remain in contact with equipment for at least 1 minute, then air dry. Do not rinse.

STORAGE TANK SANITIZING: To sanitize beer fermentation and holding tanks. A solution of 1 ounce per 19 1/2 gallons of water (150 ppm quat) should be applied by coarse spray or used in combination with automated cleaning systems. Allow the solution to remain in contact with equipment for at least 1 minute. Drain thoroughly. Allow to air dry. 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.

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.

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