

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT - 8 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 HS210-15**  
EPA Registration Number 47371-53  
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:
2. "DANGER Corrosive. Causes irreversible eye damage. Harmful if swallowed. Harmful if absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. Wear protective eyewear (goggles, face shield, or safety glasses), "Wash thoroughly".....
3. Under the heading metal containers in the Container Disposal Statement add the word " puncture" as follows"...puncture or dispose of in a sanitary landfill".....


**CONCURRENCES**

SYMBOL								
SURNAME								
DATE								

- 4. 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* all surfaces that come in contact with food, including equipment used for feeding or watering, *with soap or detergent and rinse with potable water before reuse*".
- 5. Delete the claims for use as a disinfectant at 1:300 and as a sanitizer at 1:1000. The rates which have been previously approved for this product are at 1:288 and 1:992 respectively. Your 1:300 and 1:1000 rates are not in agreement with those previously accepted for this product.
- 6. Revise the Directions for Disinfecting to include the following statement: "Do not use on utensils, glassware, dishes or appliance interior surfaces as disinfectant".

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 Stamped Label

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER** Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed. 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 protective gloves (rubber or chemical resistant). 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. Measures against circulatory shock, respiratory depression and convulsion may be needed.

*(If container size is 5 gallons or larger, use the following Environmental Hazards statement)*

**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**

Is a cationic germicide. Do not mix with soap or anionic materials.

**FORMULATION HS210-15**

**FARM DISINFECTANT / SANITIZER**

Active Ingredient:

Didecyl dimethyl ammonium chloride ..... 15.0%

Other Ingredients: ..... 85.0%

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. 47371-53

EPA Est. No. (as indicated on container)

Net Contents: (insert container size here)

H&S CHEMICALS DIVISION  
c/o LONZA INC.  
17-17 Route 208  
Fair Lawn, NJ 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. 47371-53

Effective against *Pseudomonas aeruginosa*, *Salmonella choleraesuis* and *Staphylococcus aureus*, in the presence of 5% organic serum, according to current AOAC Use-dilution Tests. 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 and egg processing plants.

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

**DISINFECTANT: 1:300** ... 2 oz per 4 1/2 gallons water  
**SANITIZER: 1:1000** ... 2 oz. per 15 1/2 gallons of water

**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 2 oz. per 4 1/2 gallons water for a minimum contact time of 10 minutes in a single application. Can be applied with a mop, sponge, or cloth, as well 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.

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 preclean 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. Fill tank half way with water. Add required amount (2 oz. per 4 1/2 gallons of water). Mix thoroughly. Fill tank with water.
2. Spray all surfaces above the floor with the disinfectant solution. 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. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
4. Ventilate buildings, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.
5. All treated equipment that will be in contact with feed or drinking water must be rinsed with potable water before using.

**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 2 oz. of **FORMULATION HS210-15** per 4½ 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 2 oz. of **FORMULATION HS210-15** per 4½ 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 of hard, nonporous surfaces, dilute 2 ounces per 15 1/2 gallons of water to provide 150 ppm active quat. Prior to sanitizing, thoroughly clean all surfaces with detergent and rinse with water. Saturate or immerse in sanitizing solution for a 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 2 ounces in 15 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, spray with a solution of 2 ounces in 15 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 (2 ounces per 15 1/2 gallons of water) for at least 1 minute. Allow to drain and air dry. 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 2 ounces per 15 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. Allow 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:** Recommended for use in sanitizing bottles or cans in the final rinse application. Proportion into the final rinse water line of the container washer or rinse in concentration of 150 ppm. A sanitizing solution of 150 ppm active quat should be used in an external spraying application 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:** Recommended for sanitizing beer fermentation and holding tanks. A solution of 150 ppm should be applied by spraying 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. 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.