

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

H & S Chemicals Division  
Lonza Inc.  
17-17 Route 208  
Fair Lawn, NJ 07410

FEB 18 2000

ATTENTION: Ruth Trager

SUBJECT: Formulation HS-1210 Disinfectant/Sanitizer 14.08%  
EPA Registration Number 47371-180  
Your Amendment Dated: November 19, 1999  
EPA Received Date: November 23, 1999

The amendment referred to above, submitted in connection with registration under FIFRA as amended, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

A. On the left column of the first page, in the Disinfection Directions revise the first sentence as follows: "For use on *the following precleaned* hard, nonporous surfaces: floors, walls, metal surfaces, stainless steel surfaces, *glazed* porcelain..."

B. On the left column of the first page make the following revisions as per DIS/TSS 17 in your directions "For Sanitizing Food Contact Surfaces." "For use on *the following* precleaned, hard, nonporous surfaces: chopping blocks, counter tops, eating utensils and drinking glasses. For heavily soiled areas, remove gross food particles *by preflush, prescrape, and presoak when necessary. Wash thoroughly with detergent or compatible cleaner then* rinse with potable water prior to application..."

Also make the following revision: "Can be applied with a cloth, sponge, mop, coarse trigger sprayer or by soaking. *Eating utensils and drinking glasses must be sanitized by immersion. Thoroughly wet all surfaces...Drain throughly and air dry. Do not rinse...*"

C. Revise the second sentence on the center panel of the first page to read as follows: "Disinfects and deodorizes *hard nonporous surfaces* in one labor saving step."

D. Revise the Ingredients Statement to include the phrase "Total.....100%"

CONCURRENCES

SYMBOL	7510C						
SURNAME	S. Trager						
DATE	2/17/00						

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

E. Revise the Precautionary Statements to include the following: "Wear protective eyewear (goggles, face shield, or safety goggles), *protective clothing* and rubber gloves." as well as "Harmful if swallowed."

F. On page two delete the abbreviation "USDA" and revise this section for federally inspected meat and poultry facilities to include "previously cleaned hard *nonporous* surfaces..."

G. On page two, revise the sections for "Restaurant and Bar Use" including the alternate language for the closed loop dilution system as follows: "For use as a sanitizer on dishes, glassware, silverware, and cooking utensils. *For heavily soiled areas, remove gross food particles by preflush, prescrape, and presoak when necessary. Wash thoroughly with detergent or compatible cleaner then rinse with potable water prior to application of this product...Then immerse in a solution...Drain throughly and air dry...*"

H. On page two, add the following to the directions for "Sanitizing in Fisheries, Milk, Citrus...Processing Plants": "*Follow directions for sanitizing food contact surfaces.*"

I. On page four, include the following information directly under the heading "Farm Premise Disinfectant Directions": "*For use in Equine, Dairy and Hog Farms.*"

J. You have provided directions for use in "Veterinary Clinics/Animal Life Science Laboratories/..." Include the site "Tack Shops" in this listing of sites which may house animals. Also make the following revisions to this set of directions: "For cleaning and disinfecting *the following* hard nonporous surfaces: equipment, utensils, instruments, cages, kennels, stables, catteries." deleting the word "including" and the abbreviation "etc." from the end of this statement. Your label must list specific surfaces. Include the following statement at the end of this section "*Thoroughly scrub all treated feed racks, automatic feeders, waterers and other equipment which dispenses food or water with soap or detergent, and rinse with potable water before reuse.*"

2. Submit two ( 2 ) copies of your final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for your records. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

DNE

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

Enclosure

7510C.T.Lantz.2/17/00.47371-180

CONCURRENCES

SYMBOL							
SURNAME							
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# FORMULATION HS-1210 DISINFECTANT / SANITIZER (14.08%)

germicide and deodorant

DISINFECTANT 1:256                    1/2 ounce per gallon of water (550 ppm)  
SANITIZER 1:938                        2 ounces per 14 1/2 gallons of water (150 ppm)  
SANITIZER 1:704                        2 ounces per 11 gallons of water (200 ppm)

## DIRECTIONS FOR USE

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

**DISINFECTION / \*VIRUCIDAL / FUNGICIDAL DIRECTIONS:** For use on hard, nonporous surfaces such as floors, walls, metal surfaces, stainless steel surfaces, porcelain, and plastic surfaces. Prepare a solution of 1/2 ounce of product per gallon of water. Apply use-solution with a cloth, sponge, mop, coarse trigger sprayer, or by soaking to thoroughly wet all surfaces. Let solution remain on the surface for a minimum contact time of 10 minutes. 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.

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.

**MOLD AND MILDEW CONTROL DIRECTIONS:** To control mold and mildew on hard, nonporous surfaces wash visible soil from the surface. Then apply 1/2 use-solution of 1/2 fluid oz. per gallon with a mop, sponge, cloth, or coarse trigger sprayer so as to wet all surfaces thoroughly. Let air dry. Repeat application every 7 days to control recurrence of growth.

**FISHERY, MILK, CITRUS, ICE CREAM & 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 odors in the processing area and bacteria associated with condensation on equipment and pipes. Follow Disinfection Directions above.

**FOR SANITIZING FOOD CONTACT SURFACES:** For use on pre-cleaned, hard, nonporous surfaces such as chopping blocks, counter tops, eating utensils, and drinking glasses. For heavily soiled areas, remove gross food particles and soil prior to washing and rinsing the surfaces. Rinse with potable water prior to application of sanitizing solution.

Then use 2 ounces per 11 - 14 1/2 gallons of water for a minimum contact time of 1 minute in a single application. *(alternate language for closed loop dilution center)* Then use product from the Closed Loop Dilution Center (200 ppm quat) for a minimum contact time of 1 minute in a single application.)

Can be applied with a cloth, sponge, mop, coarse trigger sprayer, or by soaking. Thoroughly wet all surfaces. The recommended use solution is prepared fresh for each use then discarded. Drain thoroughly. Do not reuse. For mechanical applications, use solution may not be reused for sanitizing applications.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

FEB 18 2000

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,

Formulation registered under EPA Reg. No. 47371-180 Page 1  
EPA Reg. No. 47371-180  
EPA Amendment 11/18/99

Pseudomonacidal    Staphylocidal  
Fungicidal            \*Virucidal

A concentrated, multi-purpose germicide and deodorant effective in 5% organic serum. Disinfects and deodorizes in one labor saving step. Recommended for use in hospitals, nursing homes, schools, colleges, veterinary clinics and animal life science laboratories, equine farms, tack shops, pet shops, airports, kennels, hotels and motels, poultry and turkey farms, dairy farms and hog farms, breeding and grooming establishments, and federally inspected meat and poultry plants.

Bactericidal at 1:256 dilution (1/2 ounce per gallon of water) against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Salmonella choleraesuis* according to AOAC Use-Dilution Test method, modified in the presence of 5% organic serum. (See reference sheet for complete list of pathogenic organisms).

Fungicidal against *Trichophyton interdigitale* and *Candida albicans* according to the AOAC fungicidal test, modified in the presence of 5% organic serum at a 1:256 dilution.

\*Virucidal against \*Bovine rhinotracheitis, \*Avian Infectious Bronchitis virus, and \*Newcastle virus according to the virucidal qualification, modified in the presence of 5% organic serum at a 1:256 dilution.

## ACTIVE INGREDIENTS:

Didecyl dimethyl ammonium chloride ..... 8.448%

n-Alkyl (C<sub>14</sub> 50%, C<sub>12</sub> 40%, C<sub>16</sub> 10%) dimethyl benzyl  
ammonium chloride ..... 5.632%

INERT INGREDIENTS: ..... 85.920%

## KEEP OUT OF REACH OF CHILDREN

## DANGER

(See side / right / back / left panel for additional precautionary and practical treatment statements.)

EPA Reg. No.47371-180

EPA Est. No. *(as indicated on container)*.

Net Contents: *(as indicated on container)*

H&S Chemicals Division  
c/o Lonza Inc., 17-17 Route 208, Fair Lawn, NJ

## 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 protective eyewear (goggles, face shield or safety glasses) and rubber gloves. Wash thoroughly with soap and water after handling. Harmful or fatal if swallowed. Remove contaminated clothing and wash before reuse.

### FIRST AID (STATEMENT OF PRACTICAL TREATMENT)

**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention.

**IF SWALLOWED:** Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin solution; or if these are not available, drink large quantities of water. Avoid alcohol.

**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 greater, use the following Environmental Hazards statements.)*

### ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not apply in marine and/or estuarine oil fields. 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/CHEMICAL HAZARDS

This pesticide is a cationic germicide. Do not mix with soap or anionic materials. Do not use or store near heat or flame.

*(If container size is greater than one gallon, use the following Storage and Disposal statements.)*

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

**PESTICIDE STORAGE:** Open dumping is prohibited. Do not reuse empty container.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

### 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.

*(If container size is one gallon or less, use the following Storage and Disposal statements):*

### STORAGE AND DISPOSAL

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

3/17

4/17

**DIRECTIONS FOR USE CONTINUED:**

**USDA:** 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 (2 ounces per 11 - 14-½ gallons of water) for at least 1 minute. Drain thoroughly. Do not rinse.

*(Alternate language for closed loop dilution system.)*

**RESTAURANT AND BAR USE:** For use as a sanitizer on dishes, glassware, silverware, cooking utensils, wash with detergent, rinse thoroughly and immerse in a sanitizing solution from Closed Loop Dilution Center (200 ppm quat) 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 2 ounces per 11 - 14 1/2 gallons of water (150-200 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 150-200 ppm active quat. A sanitizing solution of 150-200 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 150-200 ppm 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 SANITIZING IN FISHERIES, MILK, CITRUS, POTATO & ICE CREAM PROCESSING PLANTS:** 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.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
FEB 18 2000

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 47371-180

**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.
- 3) Rinse with clean water.
- 4) Sanitize in a solution of 2 fluid ounces per 11 - 14 1/2 gallons of water. 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.

*(Alternate language for closed loop dilution center.)*

**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.
- 3) Rinse with clean water.
- 4) Sanitize in a solution from the Closed Loop Dilution Center (200 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.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
FEB 13 2000

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide  
registered under EPA Reg. No. 47371-180

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FEB 18 2000

(The following label directions are required for poultry house disinfectants to permit their classification as non-food use products.)

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
EPA Reg. No. 47371-180

**POULTRY & TURKEY HOUSE DISINFECTANT DIRECTIONS**

Dilution: 1:256

1/2 ounce per gallon

1. Remove all poultry and feeds from premises, trucks, coops, and crates.
2. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
3. Empty all troughs, racks, and other feeding and water appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set or dried.
7. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

**FARM PREMISE DISINFECTANT DIRECTIONS:**

1. Remove all animals and feed from premises, vehicles, and enclosures.
2. 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.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. 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.
7. Ventilate buildings, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set, or dried.
8. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

**CITRUS CANKER CONTROL**

For prevention of Citrus Canker Disease through treatment of equipment. Effective against *Xanthomonas campestris* pv. *vesicatoria* (Citrus Canker Disease) at 2000 ppm active quat. Treat all equipment thoroughly at a dilution ratio of 1:25 (2000 ppm active quat). Treatments can be applied to field equipment, outer clothing, shoes, vehicles, tires, and any other equipment taken into infested areas. To prevent the spread of Citrus Canker by this artificial means of transportation, treatments are made by trigger spraying, dipping or brushing, using a maximum rate of 2000 ppm quat. Clothing should be either thoroughly rinsed or laundered before reuse. Footwear should be rinsed before reuse.

**VETERINARY CLINICS / ANIMAL LIFE SCIENCE LABORATORY / PET SHOP / KENNELS / BREEDING AND GROOMING ESTABLISHMENT DISINFECTION DIRECTIONS:** For cleaning and disinfecting hard nonporous surfaces including equipment, utensils, instruments, cages, kennels, stables, catteries, etc. 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. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 1/2 oz. of product per gallon of water (or equivalent dilution) for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

**BACTERICIDAL AGAINST:**

Effective against the following according to the AOAC Use-Dilution Test, modified in the presence of 5% organic serum.

- Pseudomonas aeruginosa
- Staphylococcus aureus
- Salmonella choleraesuis
- Aeromonas salmonicida
- Enterobacter aerogenes
- Escherichia coli
- Klebsiella pneumoniae
- Listeria monocytogenes
- Mycoplasma gallisepticum
- Proteus mirabilis
- Pseudomonas putida
- Salmonella typhi
- Serratia marcescens
- Shigella flexneri
- Staphylococcus aureus phage 80
- Staphylococcus aureus phage 81
- Streptococcus pyogenes
- Vibrio anguillarum

Effective against the following according to the AOAC Germicidal & Detergent Sanitizer Test, modified in the presence of 800 ppm water hardness (calculated as CaCO<sub>3</sub>)

- Escherichia coli
- Staphylococcus aureus

**FUNGICIDAL & MILDEWCIDAL AGAINST:**

Effective against the following according to the AOAC Use-Dilution Test, modified in the presence of 5% organic serum.

- Alternaria tenuis
- Aspergillus glaucus
- Candida albicans
- Fusarium oxysporum
- Geotrichum candidum
- Penicillium digitatum
- Phytophthora infestans
- Rhizopus nigricans (stolonifer)
- Trichoderma harzianum
- Trichophyton interdigitale

**VIRUCIDAL AGAINST:**

Effective against the following according to the virucidal qualifications modified in the presence of 5% organic serum.

- Avian Infectious Bronchitis virus
- Bovine rhinotracheitis virus
- Newcastle virus

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
FEB 18 2000

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 47371-180