

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 09 2001

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

Subject: Formulation HS-1210 Disinfectant/Sanitizer (14.08%)  
EPA Registration No. 47371-180  
Amendment Date: 8/13/00  
EPA Receive Date: 8/16/00

Attention: Ms. Wendy McCombie

The amendment, referenced above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A) to update the product label and add claims for *Campylobacter jejuni*, Marek's Disease Virus, and Infectious Bronchitis Virus-Arkansas 99 is acceptable provided you address the following comments before you release this product for shipment.

The submitted data in MRID No. 451918-01 demonstrated the effectiveness of this product against *Campylobacter jejuni* at the use dilution of 1:256 in the presence of 5% organic soil load for 10 minutes.

The addition of Marek's Disease Virus and Infectious Bronchitis Virus-Arkansas 99 to the label is acceptable.

Label Recommendations

In several applications for use, this product is not a "one-step" disinfectant or sanitizer as stated at the top of the label. Prior cleaning is recommended for any areas where there is visible soil prior to treatment. For food contact sanitization, all surfaces must be cleaned before treatment. For disinfection of food contact surfaces, a potable water rinse is required after treatment. Therefore, the term, "one-step" must be removed from the top of the label. It can only be placed in areas where the statement is true.

CONCURRENCES

SYMBOL	7570c						
SURNAME	Campbell						
DATE	2/15/01						

In an effort to maintain consistency under the food contact sanitizing directions, the directions for the beverage plants, sanitary filling, storage tank sanitizing, and fisheries/milk/citrus plants must include either the phrase, "do not rinse," or the statement, "a potable water rinse is not required following use of this compound on previously cleaned hard, nonporous surfaces."

Based on a review of the data matrix, this product is relying on the acute toxicology data of 47371-27. Therefore the acute toxicology profile for this product is as follows:

Acute Oral	II
Acute Dermal	II
Primary Eye Irritation	I
Primary Skin Irritation	I

The "Precautionary Statements" need to be revised to reflect the following:

Corrosive. Causes irreversible eye damage and skin burns. *May be fatal if absorbed through skin.* Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves. *May be fatal if swallowed.* Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

You have used the "cite-all" method of support for the acute inhalation data requirements. In reviewing data in our files, we have identified a study performed on the active ingredients contained in this product which indicate that this product should be assigned Toxicity Category II. This would require a change in the precautionary statement regarding inhalation exposure to require the user to wear a mask and/or respirator. Although we are not asking for a change at this time, you must address the inhalation concerns by one of the following methods: 1) Submit an inhalation study for review, 2) cite a specific inhalation study, 3) provide a scientific rationale as to why toxicity category II for inhalation is not appropriate for this product. Please respond within 30 days as to how you plan to address this issue.

A stamped label is enclosed for your records. Please submit one (1) copy of the final printed label before you release this product for shipment. If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



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

Enclosure: Efficacy Data Evaluation  
Stamped Label

**FORMULATION HS-1210 DISINFECTANT / SANITIZER (14.08%)**  
**ONE-STEP DISINFECTANT**  
**SANITIZER - GERMICIDE - DEODORANT**

DISINFECTANT 1:256            ½ ounce per gallon of water (550 ppm)  
 SANITIZER 1:938            2 ounces per 14-½ gallons of water (150 ppm)  
 SANITIZER 1:704            2 ounces per 11 gallons of water (200 ppm)

Pseudomonacidal    Staphylocidal    Fungicidal    \*Virucidal  
 Salmonellacidal    Bactericidal

**DIRECTIONS FOR USE**

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

**DISINFECTION / \*VIRUCIDAL / FUNGICIDAL / DEODORIZING DIRECTIONS:** For use on hard, nonporous surfaces such as floors, walls, metal surfaces, painted surfaces, stainless steel surfaces, lavatory fixtures, showers, glazed porcelain, machinery and equipment, garbage cans and plastic surfaces. For fungicidal activity use in areas such as locker rooms, dressing rooms, shower and bath areas, and exercise facilities. If surfaces are visibly dirty, preclean prior to disinfection / virucidal / fungicidal / deodorizing activity. Prepare a solution of ½ 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. Food contact surfaces must be thoroughly rinsed with potable water.

*(Note to reviewer: For labels that list medical premises and / or metal and / or stainless steel surfaces, one of the following statements must 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 to be used on medical device surfaces.

**MOLD AND MILDEW CONTROL DIRECTIONS:** To control mold and mildew on hard, nonporous surfaces wash visible soil from the surface. Then apply a use-solution of ½ 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 DISINFECTION DIRECTIONS:** 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.

A concentrated, multi-purpose germicide and deodorant effective in 5% organic serum. Disinfects and deodorizes hard nonporous surfaces 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 (½ oz. 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 mentagrophytes* 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 Disease virus, Marek's Disease Virus and Infectious Bronchitis Virus - Arkansas strain (IBV) 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>12</sub> 50%, C<sub>12</sub> 40%, C<sub>16</sub> 10%) dimethyl benzyl ammonium chloride ... 5.632%  
 INERT INGREDIENTS: ..... 85.920%  
 TOTAL..... 100.000%

**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)

ACCEPTED  
 with COMMENTS  
 in EPA Letter Dated:  
 FEB 9 2001

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

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

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**DIRECTIONS FOR USE CONTINUED:**

**FOR SANITIZING FOOD CONTACT SURFACES:** For use on the following precleaned, smooth, 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 of sanitizing solution.

Then use 2 ounces per 11 – 14-½ gallons of water (200 – 150 ppm quat) 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. Eating utensils and drinking glasses must be sanitized by immersion. Thoroughly wet all surfaces. The recommended use solution is prepared fresh for each use then discarded. Drain thoroughly and air dry. Do not rinse. For mechanical applications, use solution may not be reused for sanitizing applications.

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 nonporous 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. 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 of 2 ounces per 11 – 14-½ gallons of water (200 – 150 ppm quat) for at least 1 minute. Drain thoroughly and air dry. 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. 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 sanitizing solution from Closed Loop Dilution Center (200 ppm quat) for at least 1 minute. Drain thoroughly 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 lukewarm water. Fill equipment with solution of 2 ounces per 11 - 14 1/2 gallons of water (200 - 150 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. Follow directions for sanitizing food contact surfaces.

FEB 9 2001

**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.

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47371-180

**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.

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

**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:**

For use in Equine, Dairy and Hog farms

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.

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**BACTERIAL SPOT OF TOMATOES CONTROL**

For prevention of Bacterial Spot of Tomatoes through treatment of equipment. Effective against *Xanthomonas campestris* pv. *vesicatoria* (Bacterial Spot of Tomatoes) at 2000 ppm active quat. Treat all equipment thoroughly at a dilution ratio of 1:7 (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 Bacterial Spot of Tomatoes by this artificial means of transportation, treatments are made by trigger spraying, dipping or brushing. After use, all surfaces that come in contact with food or crop must be rinsed with potable water. Clothing should be 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 / TACK SHOP DISINFECTION DIRECTIONS:** For cleaning and disinfecting the following hard nonporous surfaces: equipment, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feeds from premises, animal transportation vehicles, crates. 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 ½ 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. Thoroughly scrub all treated feed racks, automatic feeders, waterers and other equipment that dispenses food or water with soap or detergent and rinse with potable water before reuse.

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**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  
Campylobacter jejuni  
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 & MILDEWICIDAL 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 mentagrophytes

**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  
Marek's Disease Virus  
Infectious Bronchitis Virus, Arkansas strain (IBV)

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**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), protective clothing 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**

**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. Call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice.

**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.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

**ENVIRONMENTAL HAZARDS**

This pesticide is toxic to fish. Do not apply in marine and/or estuarine oil fields.  
*(If container size is 5 gallons or greater, add the following Environmental Hazards statements.)*

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.

*(Note to reviewer: 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 children. Do not reuse empty container. discard in trash or recycle.

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47371-180

*(Note to reviewer: 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**

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or 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 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.