

47371-164

11-14-2000

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

NOV 14 2000

ATTENTION: Wendy Mc Combie  
Agent for Lonza

SUBJECT: Formulation HS-1210 Disinfectant/Sanitizer (50%)  
EPA Registration Number 47371-164  
Your Amendment Dated: August 13, 2000  
EPA Received Date: August 16, 2000

The amendment referred to above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A), is acceptable subject to the following comments.

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

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

A. Revise the heading for "Disinfection/\*Viricidal/Fungicidal Directions" to read: "Disinfection/\*Viricidal/Fungicidal/Deodorizing Directions". Also revise the following statement to read: "If surfaces are visibly dirty, preclean prior to disinfection / viricidal / fungicidal /deodorizing activity."

B. In the "Disinfection/\*Viricidal/Fungicidal/Deodorizing Directions" following the phrase "...machinery and equipment, garbage cans, and plastic surfaces." add the following statement: "For fungicidal activity use in areas such as locker rooms, dressing rooms, shower and bath areas, and exercise facilities."

C. In the "Disinfection/\*Viricidal/Fungicidal/Deodorizing Directions" following the phrase "...unless they are to be waxed or polished." add the following statement: "Food contact surfaces must be thoroughly rinsed with potable water."

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D. Revise the use dilution in the statement which begins: "Fungicidal against Trichophyton mentagrophytes and Candida albicans..." to read "1:1000 dilution" instead of "1:256 dilution".

E. Since that Agency was unable to identify the "Infectious Bronchitis Virus-Arkansas '99" revise the name of this organism so that it reads exactly as identified in the viricidal efficacy test: "Infectious Bronchitis Virus Arkansas strain (IBV)".

F. On page two, revise the sections for "Restaurant and Bar Use" 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 of...Drain thoroughly and air dry...*"

G. Add the following statement to the section with directions for "Bacterial Spot of Tomatoes Control": "After use, all surfaces which come in contact with food or crop must be rinsed with potable water." Add this statement prior to the instructions to rinse clothing and footwear.

H. You have provided directions for use in "Veterinary Clinics/Animal Life Science Laboratories/..." Delete the abbreviation "etc." from this section.

I. Based on your method of support for Product Specific Acute Toxicity the following profile has been assigned for this product:

Primary Skin	I
Primary Eye	I
Acute Oral	II
Acute Dermal	II
Acute Inhalation	II
Dermal Sensitization	non-sensitizer

You have used the "cite-all" method of support for the primary eye, dermal sensitization, and acute inhalation data requirements. In reviewing data in our files we have identified several studies performed on the active ingredients contained in this product that indicate that this product should be assigned Tox II for the inhalation route of exposure. This would require a change in the precautionary statements 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.

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Make the following revisions to the "Precautionary Statements." Revise the statement "Harmful or fatal if swallowed." to read "May be fatal if swallowed or absorbed through the skin." and revise to state "Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco."

Revise the "IF INHALED" statement to read as follows: "Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention."

J. Revise the one gallon or less "Storage and Disposal" statement to read "Wrap and discard in trash or recycle."

3. Submit two ( 2 ) copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, this registration will be subject to cancellation in accordance with FIFRA sec. 6 ( e ). Your release for shipment of this product bearing the amended labeling constitutes acceptance of these conditions.

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,



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

Enclosure: Stamped Label  
7510C:T.Lantz:11/9/00:47371-164

CONCURRENCES

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**FORMULATION HS-1210 DISINFECTANT / SANITIZER (50%)**  
**DISINFECTANT – SANITIZER – GERMICIDE – DEODORANT**  
**ONE - STEP**

DISINFECTANT 1:1000      2 oz. per 15 ½ gallons of water (500 ppm)  
 SANITIZER 1:3333      1 oz. per 26 gallons of water (150 ppm)  
 SANITIZER 1:2496      1 oz. per 19 ½ gallons of water (200 ppm)

Salmonellacidal    Bactericidal    Pseudomonacidal  
 Staphylococidal    Fungicidal    \*Virucidal

**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, painted surfaces, stainless steel surfaces, lavatory fixtures, showers, glazed porcelain, machinery and equipment, garbage cans, and plastic surfaces. If surfaces are visibly dirty, preclean prior to disinfection / virucidal / fungicidal activity. Prepare a solution of 2 oz. of product per 15 ½ gallons 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. Rinse or allow to air dry. The use solution is prepared fresh for each use then discarded. Rinsing of floors is not necessary unless they 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 preclean 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 a use-solution of 2 fluid oz. per 15 ½ gallons 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.

**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 of sanitizing solution.

Then use 1 oz. per 19 ½ - 26 gallons of water 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.

A concentrated, multi-purpose germicide and deodorant effective in a moderate amount of organic soil (5% serum) according to the AOAC Use-dilution Test. Disinfects and deodorizes hard nonporous surfaces in one labor saving step. Recommended for use in hospitals, nursing homes, dental offices, schools, colleges, office buildings, restaurants, bars, beverage plants, citrus plants, breweries, medical clinics, 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, federally inspected meat and poultry plants and households.

Bactericidal at 1:1000 dilution (2 oz. per 15 ½ gallons of water) against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Salmonella choleraesuis* according to the 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 '99 according to the virucidal qualification, modified in the presence of 5% organic serum at a 1:1000 dilution.

**ACTIVE INGREDIENTS:**

Didecyl dimethyl ammonium chloride.....	30.00%
n-Alkyl (C <sub>14</sub> 50%, C <sub>12</sub> 40%, C <sub>16</sub> 10%) dimethyl benzyl ammonium chloride.....	20.00%
INERT INGREDIENTS: .....	50.00%
TOTAL.....	100.00%

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

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

EPA Reg. No. 47371-164  
 EPA Est. No. *(as indicated on container)*

**ACCEPTED**  
 with **COMMENTS**  
 in EPA Letter Dated:

**NOV 14 2000**

Under the Federal Insecticide,  
 Fungicide, and Rodenticide Act as  
 amended, for the pesticide,  
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**DIRECTIONS FOR USE CONTINUED:**

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 and cooking utensils, wash with detergent, rinse thoroughly and immerse in a solution of 1 oz. per 19 ½ - 26 gallons of water (200-150 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 1 oz. per 19 ½ - 26 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.

**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 1 fluid oz. per 19 ½ - 26 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.

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(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: 1:1000

2 ounces per 15 1/2 gallons

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.

**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 1:250 (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 coarse trigger spraying, dipping or brushing. 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 and 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 2 oz. of product per 15 1/2 gallons 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
- Enterobacter aerogenes
- Escherichia coli
- Klebsiella pneumoniae
- Mycoplasma gallisepticum
- Proteus mirabilis
- Salmonella typhi
- Serratia marcescens
- Shigella flexneri
- Staphylococcus aureus phage 80
- Staphylococcus aureus phage 81
- Streptococcus pyogenes

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.

- Aspergillus glaucus
- Candida albicans
- 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 Disease virus
- Marek's Disease Virus
- Infectious Bronchitis Virus, Arkansas '99

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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 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.

**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.

*(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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*(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.

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**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.