

47371-164

7/12/2000

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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

JUL 12 2000

Subject: Formulation HS-1210 (50%)
EPA Registration No. 47371-164
Notification Per PR Notice 98-10

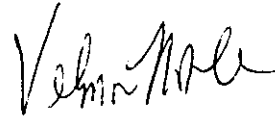
Attn: Ruth Trager
Manager, Regulatory Services

This will acknowledge receipt of your notification to change the designation of a non public health pest, correction of a typographical error in the dilution ratio, addition of the terminal sterilant paragraph, revision of company name and address to reflect transfer to Lonza Inc, and the deletion of the organisms *Aspergillus flavus* and *aspergillus fumigatus*, submitted under the provisions of FIFRA section 3 (c) 9. Based on a review of the submitted material, the following comments apply.

The application is acceptable and the notification has been made a part of the records for this file.

If you have any questions concerning the comments in this letter, you should contact Zenobia Jones at (703) 308-6198.

Sincerely,



Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510)

CONCURRENCES

SYMBOL	7510W						
SURNAME	Z. Jones						
DATE	7-7-00						

294

Please read instructions on reverse before completing form.

Form Approved. 'B No. 2070-0060.



United States Environmental Protection Agency Washington, DC 20460

Registration Amendment Other

OPP Identifier Number 256823

Application for Pesticide - Section I

1. Company/Product Number: 47371-164
2. EPA Product Manager: Velma Noble
3. Proposed Classification: [X] None [] Restricted
4. Company/Product (Name): FORMULATION HS-1210 (50%)
PM#: PM-31
5. Name and Address of Applicant: H&S CHEMICALS DIVISION, C/O LONZA INC., 17-17 ROUTE 208, FAIR LAWN, NJ 07410
6. Expedited Review: In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name

Section - II

Amendment - Explain below. Resubmission in response to Agency letter dated. Notification - Explain below. Final printed labels in response to Agency letter dated. "Me Too" Application. Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION AS PER PR NOTICE 98-10

- 1. Change in the designation of the non-public health pest Xanthomonas campestris pv. vesicatoria from the causative agent of "Citrus Canker Disease" to "Bacterial Spot of Tomatoes".
2. Correction of a typographical error in the dilution ratio. In order to achieve a 2000-ppm quat use-solution, the dilution ratio needs to be 1:250 and not 1:25.
3. Addition of the terminal sterilant paragraph
4. Revision of company name and address to reflect transfer to Lonza Inc.
5. Deleted the organisms Aspergillus flavus and Aspergillus fumigatus.

Section - III

1. Material This Product Will Be Packaged In: Child-Resistant Packaging, Unit Packaging, Water Soluble Packaging, 2. Type of Container: Metal, Plastic, Glass, Paper, Other (Specify)
3. Location of Net Contents Information: Label, Container
4. Size(s) Retail Container
5. Location of Label Directions: On Label, On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: Lithograph, Paper glued, Stenciled, Other

Section - IV

1. Contact Point: Name: RUTH TRAGER, Title: Manager, Regulatory Services, Telephone No.: 201-794-2466
Certification: I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete.
2. Signature: Ruth Trager
3. Title: Manager, Regulatory Services
4. Typed Name: RUTH TRAGER
5. Date: June 12, 2000
6. Date Application Received (Stamped)

FORMULATION HS-1210 DISINFECTANT/SANITIZER (50%)

DISINFECTANT - SANITIZER - DEODORANT

ONE-STEP

Salmonellacidal • Bactericidal • Pseudomonacidal

Staphylocidal • Fungicidal • *Virucidal

DISINFECTANT 1:1000 2 ounces per 15 1/2 gallons of water (500 ppm quat)
SANITIZER 1:3333 1 ounce per 26 gallons of water (150 ppm quat)
SANITIZER 1:2496 1 ounce per 19 1/2 gallons of water (200 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 heavy soil deposits from surface. Then thoroughly wet surface with a solution of 2 ounces per 15 1/2 gallons of water. Apply solution by cloth, mop, sponge, or coarse spray, or by soaking. Let solution remain on the surface for a minimum contact time of 10 minutes. Rinse or allow to air dry. Rinsing of floors is not necessary unless they are to be waxed or polished. Prepare a fresh solution daily or more often if solution becomes visibly dirty or diluted.

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.

SANITIZING: To sanitize previously cleaned and rinsed surfaces. Thoroughly wet surface with a solution of 1 ounce of concentrated per 19 1/2 - 26 gallons of water (200 - 150 ppm quat). Apply solution by cloth, mop, sponge, or coarse spray, or by soaking. Let solution remain on surface for a minimum of 1 minute. Do not rinse. Drain thoroughly. Prepare a fresh solution daily or more often if solution becomes visibly dirty or diluted.

USDA: For use in federally inspected meat and poultry plants as a sanitizer for all hard, non-porous surfaces not always requiring a rinse. Food packaging materials must be removed from the room or carefully protected. Follow the above directions for sanitization.

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 to 19 1/2 - 26 gallons of water (200 - 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.

RESTAURANT AND BAR USE: For sanitizing dishes, glassware, silverware, cooking utensils, wash with detergent, rinse thoroughly and immerse in a solution 1 ounce per 19 1/2 - 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. Fill equipment with solution of 1 ounce per 19 1/2 - 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, repeat the above procedure before processing a different product. Allow to drain completely before using.

BACTERIAL SPOT OF TOMATOES CONTROL: Effective against *Xanthomonas campestris* pv. *vesicatoria* (Bacterial Spot of Tomatoes Disease). Prepare a dilution ratio of 1:250 (2000 ppm quat). Treatments can be applied to field equipment, outer clothing, shoes, vehicles, tires, and any other equipment taken into infested areas. Apply solution by coarse spray, dipping, or brushing. Clothing should be laundered before reuse. Footwear should be rinsed before reuse.

FORMULATION HS-1210 (30%)
EPA REG. NO. 47371-164
EPA NOTIFICATION 6-12-00

A multi-purpose germicide effective in the presence of a moderate amount of organic soil (5% serum) according to the AOAC Use-dilution Test. Disinfects, cleans, and deodorizes in one labor-saving step. Effective against the following pathogens:

<i>Pseudomonas aeruginosa</i>	*Bovine rhinotracheitis virus
<i>Staphylococcus aureus</i>	*Bronchitis virus
<i>Salmonella choleraesuis</i>	*Newcastle virus
<i>Escherichia coli</i>	
<i>Salmonella typhi</i>	
<i>Serratia marcescens</i>	
<i>Klebsiella pneumoniae</i>	
<i>Streptococcus pyogenes</i>	<i>Aspergillus glaucus</i>
<i>Shigella flexneri</i>	<i>Candida albicans</i>
<i>Proteus mirabilis</i>	<i>Trichophyton mentagrophytes</i>
<i>Staphylococcus aureus</i> phage 80	
<i>Staphylococcus aureus</i> phage 81	
<i>Enterobacter aerogenes</i>	
<i>Mycoplasma gallisepticum</i>	

As a sanitizer for food contact surfaces the solution of 1 ounce per 19 1/2 - 26 gallons of water (200 - 150 ppm quat) is effective in 800 ppm hard water (Calculated as CaCO₃). Effective against:

Staphylococcus aureus *Escherichia coli*

Recommended for use in hospitals, nursing homes, schools, colleges, medical clinics, veterinary clinics, animal life science laboratories, equine farms, tack shops, pet shops, airport, kennels, poultry farms, turkey farms, dairy farms, hog farms, breeding/grooming establishments, dental offices, office buildings, restaurants, bars, beverage plants, citrus plants, breweries, federally inspected meat and poultry plants, and households.

Designed for floors, walls, metal surfaces, painted surfaces, stainless steel surfaces, lavatory fixtures, showers, glazed porcelain, machinery and equipment, garbage cans, plastic surfaces (such as polypropylene, polystyrene, etc.), and other hard, non-porous surfaces.

ACTIVE INGREDIENTS:

Didecyl dimethyl ammonium chloride 30.0%

n-Alkyl (C₁₄ 50%, C₁₂ 40%, C₁₆ 10%) dimethyl benzyl

ammonium chloride 20.0%

INERT INGREDIENTS: 50.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panel for additional precautionary and practical treatment statements.

EPA Reg. No. 47371-164

EPA Est. No. _____

NET CONTENTS _____

H&S CHEMICALS DIVISION

c/o Lonza Inc., 17-17 Route 208, Fair Lawn, NJ 07410

SANITARY FILLING: To sanitize bottles or cans in the final rinse application. This formula is to be proportioned into the final rinse water line of the container washer or rinser in concentration of 150 - 200 ppm quat. A sanitizing solution of 150 - 200 ppm active quat should be used in an external spraying application for the filler and closing machine.

STORAGE TANK SANITIZING: To sanitize beer fermentation and holding tanks. A solution of 150 - 200 ppm quat should be applied by coarse spray 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.

STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes call a physician. If swallowed, immediately drink a large quantity of water. Avoid alcohol. Get medical attention immediately.

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

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive: Causes eye and skin damage. Do not get in eyes or on skin. Was contaminated clothing before reuse. Wear goggles or face shield and rubber gloves when handling. Wash thoroughly with soap and water after handling. Harmful or fatal if swallowed. Avoid contamination of food.

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.

STORAGE AND DISPOSAL

Keep product under locked storage, inaccessible to children. Do not contaminate water, food, or feed by storage or disposal. 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 Protection Agency, or the Hazardous Waste representative at the nearest EPA Reg' 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 incinerate; or if allowed by state and local authorities, burn. If burned, stay out of smoke.

(FOR 1 GALLON OR LESS)

Do not reuse empty container. Rinse thoroughly, securely wrap in several layers of newspaper, and discard empty container in trash.

(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 in a sanitary landfill or incinerate 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 dispose of by other procedures approved by state and local authorities.

Handwritten initials: H b E

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FORMULATION HS-1210 DISINFECTANT/SANITIZER (50%)

FARM PREMISE, LIVESTOCK, TURKEY, AND POULTRY HOUSE DISINFECTANT

DILUTION: 1:1000

2 OUNCES PER 15 ½ GALLONS OF WATER

DIRECTIONS FOR USE

1. Remove all animals and feeds from premises, trucks, coops, crates, 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 poultry.
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, coops, cars, boats, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.
8. After treatment, thoroughly scrub feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

[To be used as a box insert and/or hang tag.]

