

47371-36

12-22-2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

DEC 22 2003

Subject: Formulation HS-867Q
EPA Registration No. 47371-36
Amendment Date: November 4, 2003
EPA Receipt Date: November 12, 2003

Dear Mr. Sloan,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable.

- Update First Aid Statements per PR Notice 2001-1
- Update Precautionary Statements
- Update Storage and Disposal Statements

General Comments

In the previous Agency letter dated 10/17/03 you were asked to provide additional information to support a change in signal word from "Danger" to "Warning". Although the label now being stamped indicates a signal word of "Warning" your information regarding this formulation is currently in review to determine if "Warning" is the correct signal word for this product. This determination will be made via "similarity clinic" based on the toxicity data which you have cited for this product. We will notify you when this review is complete. Additional information and a revised label may be required at that time.

CONCURRENCES							
SYMBOL	7510c						
SURNAME	J. Park						
DATE	12/18/03						

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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A stamped copy of the accepted labeling 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 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:12/18/03:47371-36b

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING. Causes substantial but temporary eye injury. Harmful if absorbed through the skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield or safety glasses.) Remove contaminated clothing and wash before reuse. Avoid contact with skin. Wash thoroughly with soap and water after handling.

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 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.

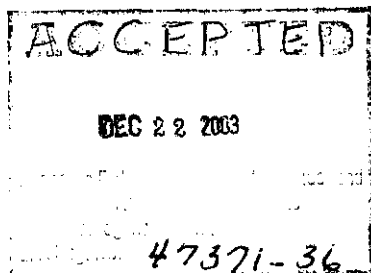
IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling poison control center or doctor or going for treatment.

(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.



HS-867Q

One-Step Germicidal Cleaner and Deodorant

DISINFECTANT
STAPHYLOCIDAL
BACTERICIDAL
MILDEWSTATIC

PSEUDOMONACIDAL
SALMONELLACIDAL
FUNGICIDAL
*VIRUCIDAL

Active Ingredients:

Didecyl dimethyl ammonium chloride	0.94%
n-Alkyl (C ₁₄ 50%, C ₁₂ 40%, C ₁₆ 10%) dimethyl benzyl ammonium chloride.....	0.62%
Other Ingredients:	98.44%
Total	100.000%

KEEP OUT OF REACH OF CHILDREN

WARNING / AVISO

EPA Reg. No. 47371-36

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 07410

A multi-purpose, germicidal detergent effective in the presence of a moderate amount of organic soil (5% serum).

Disinfects, cleans, and deodorizes in one labor saving step.

Effective against the following pathogens:

(Bacteria:)

Pseudomonas aeruginosa (Pseudomonas)
Staphylococcus aureus (Staph)
Streptococcus pyogenes (Strep)

Enterobacter aerogenes
Enterobacter cloacae
Escherichia coli
Klebsiella pneumoniae
Mycoplasma gallisepticum
Proteus mirabilis
Proteus vulgaris
Salmonella choleraesuis
Serratia marcescens
Shigella flexneri
Shigella sonnei
Staphylococcus aureus phage 80 & 81
Staphylococcus epidermidis

(Viruses:)

*Adenovirus Type 3
*Herpes simplex Type 1 (Herpes)
*HIV-1 (AIDS virus)
*Influenza A/Texas (Influenza)
*Rubella (German Measles)
*Vaccinia (Pox Virus)

(Animal Viruses:)

*Avian influenza
*Bovine rhinotracheitis virus
*Infectious bronchitis (Avian IBV)
*Newcastle disease virus

(Fungi:)

Aspergillus flavus
Aspergillus fumigatus
Aspergillus glaucus var tonophilus
Candida albicans
Trichophyton mentagrophytes (Athlete's Foot Fungus)
(Cause of ringworm)

Use **HS-867Q** in:

Bathrooms
Homes (households)
Kitchens

Dental offices
Hospitals
Medical Offices (Clinics)
Nursing homes

Day care centers
Nurseries

Bars
Cafeterias
Convenience stores
Federally inspected meat and poultry plants,
Food processing plants
Food storage areas
Institutional kitchens
Restaurants
(USDA) (Federally) inspected food processing facilities

Athletic facilities
Barber shops
Business and office buildings
Colleges
Correctional facilities
Dressing rooms
Exercise facilities
Factories
Hotels
Institutional facilities
Institutions
Locker rooms
Motels
Prisons
Public facilities
Public rest rooms
Schools
Shower and bath areas
Salons (Beauty)

Camp grounds
Play ground equipment

Animal laboratories
 Dairy farms
 Farms (Farm premises)
 Hog farms
 Kennels
 Poultry farms
 Pet animal quarters
 Pet shops
 Poultry houses
 Turkey farms
 Veterinary clinics
 Zoos

Airplanes
 Airports
 Boats
 Buses
 Campers
 Cars
 Emergency vehicles
 Mobile homes
 Ships
 Taxis
 Trailers
 Trains
 Transportation terminals

(TYPES OF SURFACES:)

Use HS-867Q on washable hard, nonporous surfaces of:

Appliances, exterior surfaces
 Basins (empty)
 Bathroom (lavatory) fixtures
 Bathtubs
 Cabinets
 Cages
 Chairs
 Coils and drain pans of air conditioning and refrigeration equipment and heat pumps
 Conductive flooring
 Counters (countertops)
 Desks
 Doorknobs
 Floors
 Fiberglass Bathtubs
 Fiberglass Sinks
 Garbage cans
 Highchairs
 Kennel runs
 Microwave ovens, exterior surfaces
 Outdoor furniture

Refrigerators, exterior surfaces
 Refrigerated storage and display equipment
 Showers
 Shower stalls
 Sinks (bathroom, kitchen)
 Stoves (stovetops)
 Tables, (picnic tables)
 Telephones
 Toilets
 Toilet bowls
 Toilet bowl surfaces
 Tubs
 Tiles, glazed
 Urinals
 Walls

Other hard nonporous surfaces made of:
 Formica®
 Glazed ceramic
 Glazed enameled surfaces
 Glazed porcelain
 Metal
 Painted surfaces
 Plastic (such as polystyrene or polypropylene)
 Sealed stone
 Stainless steel
 Upholstery, vinyl and plastic
 Woodwork, finished

DILUTION: 1:32

4 oz. per gallon of water
(488 ppm Active Quat)

[If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.]

AVISO: SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.

DIRECTIONS FOR USE

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

GENERAL USE DIRECTIONS

APPLICATION: For disinfection remove heavy soil deposits from surface. Then thoroughly wet surface with a solution of 4 ounces (1/2 cup) of the concentrate per gallon of water. Apply with a cloth, mop, sponge, or coarse sprayer, or by soaking. For sprayer applications, use a coarse spray device. Spray 6-8 inches from surface, rub with a brush, cloth or sponge. Do not breathe spray. Let solution remain on surface for a minimum of 10 minutes. Rinse or wipe dry with a clean cloth or sponge or allow to air dry.

Rinse all surfaces that come in contact with food such as countertops, exterior surfaces of appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware, dishes or appliance interior surfaces as a disinfectant.

Rinsing of floors is not necessary unless they are to be waxed or polished.

Prepare a fresh solution daily or more often if the solution becomes diluted or visibly soiled.

(Note for reviewer: For labels that list medical premises and 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 for use on medical device surfaces.

USDA: Use in federally inspected meat and poultry plants on all hard, nonporous surfaces in inedible product processing areas, non-processing areas, and / or exterior areas.

USDA: For use in federally inspected meat and poultry plants as a floor and wall cleaner for use in all departments. Food products and packaging materials must be removed from the room or carefully protected. All surfaces must be thoroughly rinsed with potable water.

TOILET BOWLS: To clean, apply diluted solution around the bowl and up under the rim. Stubborn stains may require brushing.

To disinfect, first preclean to remove the heavy soil, then remove or expel over the inner trap the residual bowl water. Pour in 3 ounces of the diluted solution. Swab the bowl completely using a scrub brush or mop, making sure to get under the rim. Let stand for 10 minutes or overnight, then flush.

DISINFECTION OF BARBER / BEAUTY / SALON

INSTRUMENTS AND TOOLS: Tools (such as combs, brushes, razors, scissors, and other shop tools) can be disinfected by immersing in a 4 ounce (1/2 cup) per gallon solution for a contact time of 10 minutes. Prepare a fresh solution daily or more often if the solution becomes diluted or visibly soiled.

FUNGICIDAL INSTRUCTIONS: HS-867Q is an effective fungicide against Trichophyton mentagrophytes (the athlete's foot fungus) in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities. Follow disinfection directions.

MILDEWSTATIC INSTRUCTIONS: Will effectively control the growth of mold and mildew plus the odors caused by them when applied to hard, nonporous surfaces such as walls, floors, and table tops. Apply solution [4 ounces (1/2 cup) per gallon of water] with a cloth, mop, sponge, or coarse sprayer, making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application weekly or when growth reappears.

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***KILLS HIV-1 (AIDS VIRUS) ON PRECLEANED, ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS** in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces / objects with blood / body fluids, and in which the surfaces / objects likely to be soiled with blood / body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OF SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS.

Personal Protection: Clean-up should always be done wearing protective gloves, gowns, masks and eye protection.

Cleaning Procedures: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of HS-867Q.

Contact Time: Leave surface wet for 5 minutes at 25°C (77°F) (room temperature). Use a 10-minute contact time for disinfection against all other viruses, fungi, and bacteria claimed.

Disposal of Infectious Materials: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

FARM PREMISE, LIVESTOCK, TURKEY AND POULTRY HOUSE DISINFECTANT:

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 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, 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 with disinfectant, thoroughly scrub feed racks, troughs, automated feeders, fountains, and waterers with soap and detergent, and rinse with potable water before reuse.

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 4 oz. of HS-867Q per gallon of water (or equivalent dilution) for a period of 10 minutes. Wipe or allow to air dry. Immerse all animal handling and restraining equipment as well as forks, shovels, and scrapers used to remove litter and manure. 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. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

HEAVY-DUTY CLEANING INSTRUCTIONS:

Use (2 oz of HS-867Q per 24 oz of water) (8 to 12 oz of HS-867Q per gallon of water) to clean heavily soiled areas.

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(Note to reviewer: If the container size is one 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 store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Wrap and discard in trash or recycle.

(Note to reviewer: If container is greater than one 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: Store in original container in areas inaccessible to children. 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 dispose of by other procedures approved by state and local authorities