

JUL 9 2003

Mr. Robert Sloan
Lonza Inc.
17-17 Route 208
Fair Lawn, NJ 07410

SUBJECT: Formulation HS-267Q
EPA Registration Number: 47371-37
Application Dated: April 8, 2003
Receipt Date: April 10, 2003

Dear Mr. Sloan:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, acceptable subject to the conditions listed below.

- Update as per PR Notices
- Add Storage and Disposal instructions for 1 gallon or less
- Add Directions for Use

Conditions

1. When compared to other similar products which have been registered by the Agency, it would appear that the signal word for this product should be DANGER. The file for this product includes toxicity data (accession # 40286402) which has been reviewed by the Agency (March 1988). The following toxicity categories have been assigned to this product based on this review: Primary Eye: II, Primary Skin: III, Acute Dermal: III, and Acute Oral: IV. Thus, based on this data and associated review, the signal word for this product will continue to be WARNING.

2. Revise the Precautionary Statements to be in agreement with this review as follows:

“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

SYMBOL	With skin. Wash thoroughly with soap and water after handling.							
SURNAME	7510C							
DATE	7/8/03							

3. Delete one instance of the site: "poultry farms" as it appears twice on page three.
4. Delete the surface "fiberglass" on page three as this is considered a porous surface.
5. Make the following revisions to page three: revise your label to state "*exterior surfaces of appliances,*" "*exterior surfaces of microwaves,*" and "*exterior surfaces of refrigerators*".

This issue was discussed with representatives from your company in a meeting with the Agency on 1/28/03. We continue to classify microwave oven and refrigerator interior surfaces as food contact surfaces. We are particularly concerned about the use of this product in residential settings where we believe that the user will not conduct a potable water rinse on interior surfaces of microwave ovens and refrigerators. If you desire that all surfaces of microwave ovens and refrigerators be treated in a commercial setting and are willing to limit the use on these surfaces by homeowners you should submit a new amendment and propose modified labeling to the Agency.

It is suggested that this label have separate surfaces and directions for use in commercial settings and residential settings. These directions would continue to indicate the necessity for a potable water rinse on food contact surfaces for commercial use and could include treatment of microwave ovens and refrigerators. The residential directions would limit the product to use on exterior surfaces of microwave ovens and refrigerators.

In addition, revise the statement on page four beginning: "Rinse all surfaces that come in contact with food..." to state "*exterior surfaces of appliances*".

6. Revise page four "Application" directions to begin: "*For disinfection remove heavy soil deposits...*" Also revise this section to state: "...per gallon of water. Apply with a cloth, mop...or by soaking. *For sprayer applications, use a coarse spray device. Spray 6-8 inches from the surface, rub with a brush, cloth or sponge. Do not breathe spray. Let solution remain on surface...*"

7. Your product claims fungicidal activity. Add the following set of fungicidal directions: "*For Fungicidal Activity: HS-267Q 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.*"

8. Revise the directions for use on toilet bowls (page four) to read: "To disinfect, *first preclean to remove heavy soil, then remove or expel over the inner trap...*"

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							


9. Delete the claim on page two: "cause of ringworm" as Trichophyton mentagrophytes is not the causative agent of ringworm.

General Comments

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 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:7/8/03:47371-37

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING. Causes eye and skin irritation. Avoid contact with eyes, skin, and clothing. 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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUL 9 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. **47371-37**

HS-267Q

One-Step Germicidal Cleaner and Deodorant

DISINFECTANT
STAPHYLOCIDAL
BACTERICIDAL
MILDEWSTATIC

PSEUDOMONACIDAL
SALMONELLACIDAL
FUNGICIDAL
*VIRUCIDAL

Active Ingredients:

Didecyl dimethyl ammonium chloride	1.875%
n-Alkyl (C ₁₄ 50%, C ₁₂ 40%, C ₁₆ 10%) dimethyl benzyl ammonium chloride....	1.248%
Other Ingredients:	<u>96.877%</u>
Total	100.000%

KEEP OUT OF REACH OF CHILDREN

WARNING / AVISO

EPA Reg. No. 47371-37
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)

Use HS-267Q 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 farms
 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:)

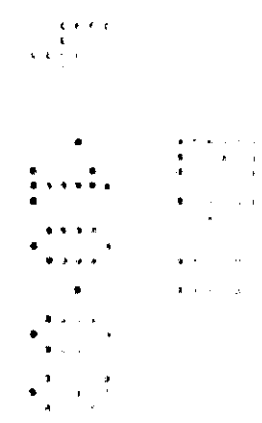
Use HS-267Q on washable hard, nonporous surfaces of:

Appliances
 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
 Garbage cans
 Highchairs
 Kennel runs
 Microwave ovens
 Outdoor furniture

Refrigerators
 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:

Fiberglass
 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: 1:64 2 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: Remove heavy soil deposits from surface. Then thoroughly wet surface with a solution of 2 ounces of the concentrate per gallon of water. The Apply with a cloth, mop, sponge, or coarse sprayer, or by soaking. 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, appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes.

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 pre-clean 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.

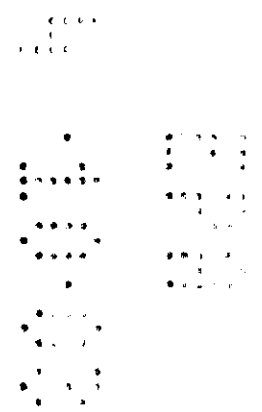
USDA: Use in federally inspected meat and poultry plants on all hard, nonporous surfaces in inedible product processing areas, non-processing areas, and / or exterior areas.

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 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 2 ounce 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.

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 [2 ounces (1/4 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.



***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-267Q.

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 2 oz. of HS-267Q 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. Rinse all surfaces that come in contact with food, including equipment used for feeding or watering, 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 (1 oz of HS-267Q per 24 oz of water) (4 to 6 oz of HS-267Q per gallon of water) to clean heavily soiled areas.

(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. 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

