

47371-1

11-25-2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 25 2003

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

Subject: Formulation HS-32Q
EPA Registration No. 47371-01
Amendment Date: June 4, 2003
EPA Receipt Date: June 4, 2003

Dear Mr. Robert J. Sloan,

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

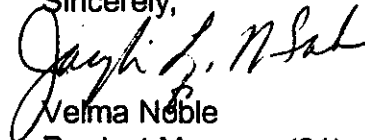
Proposed Amendment

- Response to Agency letter dated May 20, 2003

General Comments

A stamped copy of the accepted 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 Velma Noble at (703) 308-6233.

Sincerely,



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

CONCURRENCES

SYMBOL	7510(e)						
SURNAME	A. Peters						

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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 protective gloves (rubber, chemical resistant) when handling. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing 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 first 5 minutes, then continue rinsing eye. 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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF ON SKIN: 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.

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

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

(Note to reviewer: If the container size is 5 gallons or larger the following Environmental Hazards statements will be used:)

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.

FORMULATION HS-32Q

GERMICIDAL DETERGENT

CLEANER - DEODORANT - DISINFECTANT

For use in hospitals, nursing homes, schools, colleges, medical and dental offices, veterinary clinics.

Active Ingredients:

n-Alkyl (C ₁₄ , 60%; C ₁₆ , 30%; C ₁₂ , 5%; C ₁₈ , 5%)	
dimethyl benzyl ammonium chlorides.....	0.8%
n-Alkyl (C ₁₂ , 50%; C ₁₄ , 30%; C ₁₆ , 17%; C ₁₈ , 3%)	
dimethyl ethylbenzyl ammonium chlorides.....	0.8%
Other Ingredients:.....	98.4%
Total.....	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

SEE (SIDE) (LEFT) (RIGHT) (BACK) PANEL FOR PRECAUTIONARY STATEMENTS AND FIRST AID

EPA Reg. No. 47371-1

EPA Est. No. *(Insert EPA Est. No. Here)*

NET CONTENTS *(Insert size of container here)*

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

ACCEPTED
with **COMMENTS**
in EPA Letter Dated:
NOV 25 2000

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pest, etc.,
registered under EPA Reg. No.

47371-01

(Note to reviewer: The following is considered optional marketing language :)

- Formulation HS-32Q eliminates odors at their source.
- Concentrate (Concentrated)
- Disinfects (Disinfectant)
- Cleans (Cleaner)
- Deodorizes (Deodorizes)
- This product contains no (phosphates) or (phosphorous compounds).

FORMULATION HS-32Q is a (Hospital Use) disinfectant at 1:32 dilution (4 oz. per gallon of water), Bactericidal according to the current AOAC Use-Dilution Test Method and Virucidal* according to the virucidal qualification.

Formulation HS-32Q is effective against all of the following organisms:

(Bacteria)

- Pseudomonas aeruginosa (Pseudomonas)
- Staphylococcus aureus (Staph)
- Salmonella choleraesuis (Salmonella)

(Viruses)

- *HIV-1 (AIDS virus)

(Animal Viruses)

- *Canine Parvovirus (at 12 oz. per gallon)

(Fungi)

- Candida albicans
- Trichophyton mentagrophytes (athlete's foot fungus)

(AREAS OF USE:)

Use Formulation HS-32Q in:

Bathrooms, Kitchens

Dental offices, Hospitals, Medical Offices, Nursing Homes, Senior Residences

Day care centers, Nurseries

USDA inspected food processing facilities

Athletic facilities, 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.

Airplanes, Boats, Buses, Campers, Cars, Emergency vehicles, Ships, Taxis, Trailers, Trains, Transportation terminals.

Animal laboratories, Kennels, Pet animal quarters, Pet shops, Veterinary Clinics, Zoos

(TYPES OF SURFACES:)

Use Formulation HS-32Q on washable hard, nonporous surfaces:

Floors, walls, bathroom fixtures, doorknobs, garbage cans, exterior bowl surfaces, empty basins, showers, shower stalls, sinks, toilet bowl surfaces, tubs, urinals, athletic equipment, lavatory fixtures, Formica®, glazed ceramic, glazed porcelain, metal, plastic (such as polystyrene or polypropylene, sealed stone, sealed granite, sealed marble, stainless steel, vinyl or plastic upholstery, finished woodwork and painted surfaces,.

Dilution:

Disinfection: 1:32.....4 fl. oz. per gallon

DIRECTIONS FOR USE

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

DISINFECTION DIRECTIONS: Use 4 fl. oz. of Formulation HS-32Q per gallon of water, for a minimum contact time of 10 minutes, in a single application. Pre-clean all surfaces prior to disinfection. Thoroughly wet surfaces with a mop, sponge, cloth, coarse sprayer or by soaking. Wipe dry with a clean cloth or sponge or allow to air dry.

For sprayer applications, use a coarse spray device. Spray 6 - 8 inches from the surface; rub with a brush, sponge or cloth. Do not breathe spray.

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.

Prepare fresh solution daily or more often if the use solution becomes visibly diluted or dirty.

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amended, for the purpose of being
registered under FFA Reg. No.

47371-01

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(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.

FOR FUNGICIDAL ACTIVITY: Formulation HS-32Q 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.

TO CLEAN AND DISINFECT TOILET BOWLS AND URINALS:

To clean, squeeze around the bowl and under the rim. Leave for 10 minutes or overnight if possible. Swab, then flush.

To disinfect, first preclean to remove heavy soil, then remove or expel over the inner trap the residual bowl water prior to applying the use dilution. Use 4 fl. oz. of Formulation HS-32Q per gallon of water. Apply to exposed surfaces including under the rim with a cloth, mop sponge or coarse sprayer. Brush or swab thoroughly, allow to stand for 10 minutes and flush. Close cap on container after each use.

TO CLEAN AND DEODORIZE: Mix 4 oz. of Formulation HS-32Q per gallon of water to clean and deodorize surfaces. Apply using a cloth, mop, sponge or sprayer. Wipe or allow to air dry.

FLOOR AND WALL CLEANER

Use in USDA federally inspected meat and poultry plants as a floor and wall cleaner in all departments. Before use of this product, food products and packaging materials must be removed from the room or carefully protected. Apply with mop, cloth, or sponge at a dilution of 4 fl. oz. per gallon. After use of this compound, all surfaces in the area must be thoroughly rinsed with potable water.

***KILLS HIV 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 or body fluids, and in which the surfaces / objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS.

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

Cleaning Procedures: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of Formulation HS-32Q.

Contact Time: Leave surface wet for 5 minutes. Use a ten (10) minute contact time for disinfection against other viruses, bacteria, and fungi 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.

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VETERINARY PRACTICE / ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP / KENNELS DISINFECTION DIRECTIONS:

For cleaning and disinfecting hard nonporous surfaces: equipment used for animal food or water, 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 **FORMULATION HS-32Q** per gallon of water (or equivalent dilution) for a period of 10 minutes. Wipe or allow to air dry. 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. 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.

FOR CANINE PARVOVIRUS ACTIVITY:

Formulation HS-32Q is effective against Canine Parvovirus at 12 oz. per gallon. Follow Veterinary Practice / Animal Care / Animal Laboratory / Zoos / Pet Shop / Kennels Disinfection Directions.

(Note to reviewer: If the container size is one gallon or less, the following Storage and Disposal directions will be used :)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not reuse empty container. Rinse empty container thoroughly and discard in trash or recycle.

(Note to reviewer: If the container size is greater than one gallon, the following Storage and Disposal directions will be used:)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage

Keep product under locked storage, inaccessible to children. 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 incinerate, or if allowed by state and local authorities, burn. If burned, stay out of smoke.

(Fiber Drums With Liner:) 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.

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