

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 18 2004

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

Subject: **Formulation HS-652Q**
EPA Registration Number 47371-6
Application / Letter Dated February 18, 2004
EPA Received Date February 20, 2004

Dear Mr. Sloan:

The following amendment, submitted in connection with registration the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the following comments:

Proposed Amendment:

- revised labeling

Conditions:

Revise the label as follows:

1. Your product is categorized as a III for acute oral and dermal routes of exposure. You must add the following statement to the "Precautionary Statements"

"Harmful if swallowed or absorbed through skin. Avoid contact with skin, eye or clothing wash thoroughly with soap and water after handling and before eating, chewing gum or using tobacco".

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

2. Under "Storage & Disposal" for containers greater than 1 gallon, add the statement "store in original container areas inaccessible to children or persons unfamiliar with the use of product."

General Comments:

A stamped copy of the labeling accepted with conditions 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 Drusilla Copeland on (703) 308-6224.

Sincerely,



Velma Noble

Product Manager (31)

Regulatory Management Branch I

Antimicrobials Division (7510C)

Enclosure Stamped Label

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 or chemical resistant). Remove and wash contaminated clothing before reuse. 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 the 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 the 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 a Poison Control Center or doctor or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

(For container sizes of 5 gallon & larger)

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:**

MAY 18 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 47371-6

FORMULATION HS-652Q

One-Step Germicidal Cleaner and Deodorant

- DISINFECTANT
- PSEUDOMONACIDAL
- STAPHYLOCIDAL
- SALMONELLACIDAL
- BACTERICIDAL
- FUNGICIDAL
- MILDEWSTATIC
- *VIRUCIDAL

Active Ingredients:

Didecyl dimethyl ammonium chloride.....	7.5%
n-Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%)	
Dimethyl benzyl ammonium chloride.....	5.0%
Other Ingredients:	87.5%
Total:	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER (PELIGRO)

See (side) (back) (right) (left) panel for Precautionary Statements and First Aid.

EPA Reg. No. 47371-6

EPA Est. No. (insert EPA Est. No. here)

Net Contents (insert container size here)

H&S CHEMICALS DIVISION

c/o Lonza Inc.

17-17 Route 208

Fair Lawn, NJ 07410

4/10

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
- Staphylococcus aureus
- Salmonella choleraesuis

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

(Viruses:)

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

(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

Recommended for use in hospitals, nursing homes, schools, colleges, medical clinics, dental offices, office buildings, hotels, motels, airports, veterinary clinics, farm premises, poultry houses, federally inspected meat and poultry plants and households. Cleans, disinfects and deodorizes floors, walls, metal surfaces, painted surfaces, exterior bowl surfaces, empty basins, showers, conductive flooring, lavatory fixtures, plastic surfaces (such as polypropylene, polystyrene), and other hard, nonporous surfaces.

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

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

DILUTION: 1:256 ½ oz. per gallon of water
(488 ppm Active Quat)

DIRECTIONS FOR USE

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

DISINFECTION: Remove heavy soil deposits from surface. Then, thoroughly wet surface with a solution of 1/2 ounce of the concentrate per gallon of water. The solution can be applied with a cloth, mop, sponge, or coarse sprayer or by soaking. Let solution remain on surface for a minimum 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 the solution becomes diluted or visibly soiled.

(Note to reviewer: Only One of the following two statements will 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.

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 as a disinfectant.

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. Follow disinfection directions.

USDA: Use in federally inspected meat and poultry plants as a floor and wall cleaner in all departments. Food products and packaging materials must be removed from the room or carefully protected. Follow disinfection directions.

5/6

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.

MILDEWSTATIC INSTRUCTIONS: Will effectively control the growth of mold and mildew plus the odors caused by them when applied to hard, non-porous surfaces such as walls, floors, and table tops. Apply solution (1/2 oz. 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 PRE-CLEANED, 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 (HIV-1)(associated with AIDS).

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

Personal Protection: Disposable protective gloves, gowns, face masks, or eye coverings, as appropriate, must be worn during all cleaning of blood / body fluids, and during decontamination procedures.

Cleaning Procedures: Blood / body fluids must be thoroughly cleaned from surfaces and objects before application.

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

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

FARM PREMISE 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.

6/6

(If container size is 1 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 reuse empty container. Discard in trash or recycle.

(If container size is greater than 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

Do not store on side. Avoid creasing or impacting of side walls.

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray or mixture of 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 incineration, or, if allowed by state and local authorities by burning. If burned, stay out of way of smoke.

(Metal Containers:) Triple rinse (or equivalent), then offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(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.