

47371-141

10-24-2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 24 2003

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

Subject: Formulation HH-652Q  
EPA Registration No. 47371-141  
Amendment Date: July 25, 2003  
EPA Receipt Date: July 28, 2003

Dear Mr. Sloan,

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

- Update the First Aid statements per PR Notice 2001-1

**Conditions**

Revise the label as follows:

1. Based on records on file, this product relied on EPA Reg. No. 303-91 data to support its registration. Therefore, the "Precautionary Statements must be revised to read:  
  
Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, safety glasses or face shield), protective clothing, and protective gloves (rubber or chemical resistant). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash before reuse.
2. Revise the fungicidal claim by adding "*when used in areas such as shower and bath areas. Follow disinfection directions.*"
3. Revise the "Disinfection" heading to include "**Clean/Deodorize**" since it is efficacious as a one step cleaner, disinfectant, and deodorizer.
4. Revise the statement, "Do not use on utensils, glassware, and dishes," to include "*interior surfaces of appliances.*"

**CONCURRENCES**

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- 5. Add the statement, "Remove gross filth prior to disinfection," to the Toilet Bowls and Urinals" directions.
- 6. Under "Veterinary Practice" directions, revise the 9<sup>th</sup> statement (rinse with potable water) to read "Thoroughly wash all feeding and watering appliances with soap or detergent, then rinse with potable water before reuse."
- 7. Revise the "Pesticide Storage" statement to include: "Store in area inaccessible to children."

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703)308-6416.

Sincerely,



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

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**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER. CORROSIVE:** Causes irreversible eye damage and skin burns. Wear protective eyewear (goggles, safety glasses or a face shield) and protective gloves (rubber or chemical resistant). Wash thoroughly with soap and water after handling. Remove and wash contaminated 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 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 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.

**FORMULATION HH - 652Q**

**CLEANS DISINFECTS AND DEODORIZES**

Active Ingredients:	
Didecyl dimethyl ammonium chloride .....	9.22%
n-Alkyl (C <sub>14</sub> , 50%; C <sub>12</sub> , 40%; C <sub>16</sub> , 10%)	
Dimethyl benzyl ammonium chloride .....	6.14%
Other Ingredients:.....	84.04%
Total:.....	100.00%

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

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

EPA Reg. No. 47371-141  
EPA Est. No. (insert EPA Establishment No. here)  
Net Contents (insert container size here)

H&S CHEMICALS DIVISION  
c/o Lonza Inc.  
17-17 Route 208  
Fair Lawn, NJ 07410

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

OCT 24 2003

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 47371-141

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

Formulation HH-652Q is a concentrated multi-purpose germicide detergent effective in the presence of moderate amounts of soil.

Formulation HH-652Q cleans, deodorizes and disinfects in one labor-saving step.

Cleans, disinfects and deodorizes:

floors, walls, sinks, bathtubs, toilet bowls, urinals, toilet bowl surfaces, showers, lavatory fixtures, empty basins, refrigerators (exteriors), appliances, countertops, garbage cans, conductive flooring, plastic surfaces (such as polypropylene, polystyrene), glazed porcelain, metal surfaces, painted surfaces, painted woodwork and other hard, non-porous surfaces.

According to the AOAC Use-Dilution test method, Formulation HH-652Q is effective against the following pathogenic organisms at a 1:256 dilution modified in the presence of 5% organic soil (fetal bovine serum) and 400 ppm water hardness (calculated as CaCO<sub>3</sub>):

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

*Enterobacter aerogenes*  
*Enterobacter cloacae*  
*Escherichia coli* (*E. coli*)  
*Klebsiella pneumoniae*  
*Proteus mirabilis*  
*Proteus vulgaris*  
*Serratia marcescens*  
*Shigella flexneri*  
*Shigella sonnei*  
*Staphylococcus aureus* phage 80 & 81  
*Staphylococcus epidermidis*  
*Streptococcus pyogenes*

According to the AOAC fungicidal test method, Formulation HH-652Q is effective against the following pathogenic organisms at a 1:256 dilution modified in the presence of 5% organic soil (fetal bovine serum) and 400 ppm water hardness (calculated as CaCO<sub>3</sub>):

*Candida albicans*  
*Trichophyton mentagrophytes*

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Formulation HH-652Q is virucidal against the following pathogenic organisms at a 1:256 dilution modified in the presence of 5% organic soil (fetal bovine serum) and 400 ppm water hardness (calculated as CaCO<sub>3</sub>):

\*Adenovirus Type 2 &  
\*Adenovirus Type 4  
\*Herpes simplex Type 1  
\*Herpes simplex Type 2  
\*HIV-1 (AIDS virus)  
\*Influenza A / Michigan  
\*Rubella (German Measles)  
\*Vaccinia

\*Avian influenza A / Michigan  
\*Avian Infectious bronchitis virus (Avian IBV)  
\*Bovine parvovirus  
\*Bovine rhinotracheitis virus  
\*Canine parvovirus

**DILUTION: 1:256**

**½ oz. per gallon of water**

#### **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, then, thoroughly wet surface with a solution of 1/2 oz. of Formulation HH-652Q per gallon of water. Apply with a cloth, mop, sponge, or coarse sprayer or by soaking. Let solution remain on surface for a minimum of 10 minutes. 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 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.

#### **TOILET BOWLS AND URINALS:**

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 (½ oz. per gallon of water). Swab the bowl completely using a scrub brush or bowl 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, nonporous surfaces such as walls, floors, and table tops. Apply use solution (½ 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 more often if mildew growth reappears.

*(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 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.

**WAXED AND NO-WAX FLOORS:** Cleans floors bright with virtually no filming or dulling the gloss. Add ½ oz. (1 tablespoon) of Formulation HH-652Q to 1 gallon warm water, wash floor with sponge or mop and rinse.

**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 4 minutes at room temperature (20-25°C). 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.

**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 ½ oz. of FORMULATION HH-652Q 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.

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(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. Open dumping is prohibited.

**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.

