

47371-6

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

SEP 10 2009

Ms. Joanna Holcombe
Lonza, Inc.
90 Boroline Road
Allendale, NJ 07401

SUBJECT: Formulation HS-652Q
EPA Registration No.: 47371-6
Amendment Date: June 11, 2009
EPA Receipt Date: June 15, 2009

Dear Ms. Holcombe,

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

Proposed Amendment

- Update Storage and Disposal per PRN 2007-4
- Update Company Address and add optional statements

Conditions

Revise the label as follows:

- 1) The Environmental Hazards must be revised to be in agreement with the ADBAC RED by adding the statement, "*This pesticide is toxic to fish and aquatic invertebrates.*"
- 2) The nomenclature for Herpes Simplex Type 1, Influenza A/Texas, Rubella, Vaccinia, Avian influenza, and Avian infectious bronchitis on page 2 is incomplete. You need to indicate that the microorganisms are viruses by stating "*Herpes Simplex Virus Type 1, Influenza A/Texas Virus, Rubella Virus, Vaccinia Virus, Avian Influenza Virus, and Avian infectious bronchitis Virus.*"
- 3) Revise the last claim in the right column on page 2 to be in compliance with PR Notice 2000-5, Mandatory Labeling, by deleting the term, recommended.
- 4) The Personal Protection statement under "HIV-1" instructions on page 3 must be revised by deleting the term, or, and stating "*and*" because the personal protection equipment is not optional

when cleaning blood/body fluids

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

- 5) The "Disposal of Infectious Materials" statement under the "HIV-1" instructions on page 3 must be brought into compliance with PR Notice 2000-5, Mandatory Labeling, by deleting the term, should, and stating "must."
- 6) Revise the 5th step under "Farm Premise and Poultry House" on page 3 to be in compliance with PR Notice 2000-5, Mandatory Labeling, by deleting the term, recommended.
- 7) The Container Rule rescinded PR Notice 83-3 and 84-1 Part II in which Container Disposal statements are no longer separated by container size but by use pattern. Delete the "Storage and Disposal" Instructions for containers one gallon or less with uses other than household or residential.

General Comments

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

Sincerely,



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

Enclosure: Stamped Label

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. CORROSIVE: Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through the skin. Avoid contact with skin, eyes, or 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 and before eating, chewing gum or using tobacco.

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.

ENVIRONMENTAL HAZARDS

(For 5 gallon & larger)

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
Date: _____

SEP 10 2009

47371-6

FORMULATION HS-652Q

One-Step Germicidal Cleaner

- 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)*

[Country of origin (insert country)]

[Manufactured in (insert country)]

[Barcode]

H&S CHEMICALS DIVISION

c/o Lonza Inc.

90 Boroline Road

Allendale, NJ 07401

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 enterica

- 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 1/2 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 AND CLEANING: 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 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.

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.

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, nonporous surfaces such as walls, floors and table tops. Apply solution (1/2 ounce 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, 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.

(Note to reviewer: For Nonrefillable Containers, Container is one gallon or less, Label has any uses other than Household or Residential)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children.

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap [container] and put in trash or offer for recycling if available.

(or)

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap [container] and put in trash or offer for reconditioning if appropriate.

(Note to reviewer: For Nonrefillable Containers, Container is over one gallon)

STORAGE AND DISPOSAL

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

Pesticide Storage:

Open dumping is prohibited. Store in original container in areas inaccessible to children.

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:

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.

(Plastic Containers:) Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

(Metal Containers:) Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations. DO NOT cut or weld metal containers.

(For Bag in Box Containers:) Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.