

6836-57

11/25/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

NOV 25 2009

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

SUBJECT: Barquat 42Z-10
EPA Registration No.: 6836-57
Amendment Date: November 19, 2009
EPA Receipt Date: November 19, 2009

Dear Ms. Holcombe,

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

Proposed Amendment

- Update Storage and Disposal per PRN 2007-4
- Add Pandemic H1N1 Claims

Conditions

Revise the label as follows:

- 1.) AOAC has updated the species nomenclature for *Salmonella choleraesuis* to *Salmonella enterica*. Revise the nomenclature on page 2 accordingly.
- 2.) Revise the "Personal Protection" statement by deleting the term, or, and stating "and." The personal protection items are not optional when cleaning or handling blood and body fluids.

General Comments

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

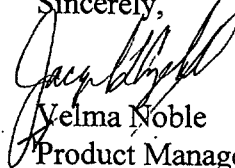
CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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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. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles or face shield) and protective gloves (rubber or chemical resistant) when handling. Harmful if swallowed. 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.

(if container is 5 gallons or larger, use the following Environmental Hazards statement:)

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. 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.

BARQUAT® 42Z-10

One-Step Disinfectant –

Virucide* - Deodorizer

For Hospital, Institutional, Industrial, School, Dairy and Other Farm Use

Active Ingredients:

Alkyl (C ₁₄ , 60%; C ₁₆ , 30%; C ₁₂ , 5%; C ₁₈ , 5%)	5.0%
Dimethyl Benzyl Ammonium Chloride	
Alkyl (C ₁₂ , 68%; C ₁₄ , 32%)	5.0%
Dimethyl Ethylbenzyl Ammonium Chloride	
Other Ingredients:	90.0%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Reg. No. 6836-57

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

Net Contents (insert container size here)

[Country of origin (insert country)]

[Manufactured in (insert country)]

[Barcode]

Manufactured by:

LONZA INC.

90 Boroline Road,
Allendale, NJ 07401

ACCEPTED
with COMMENTS
in EPA Letter Dated:
NOV 25 2009
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

Barquat 42Z-10

EPA Reg. 6836-57

EPA Stamped Label 10-6-03 w- 10-30-03 Notif Accepted 12-2-03, Draft 4-16-09, Rev. 11-19-09

Cross-contamination is of major housekeeping concern not only in hospitals, but in schools, institutions, and industry. BARQUAT 42Z-10 has been formulated to aid in the reduction of cross-contamination on treated surfaces in these areas.

BARQUAT 42Z-10 a one-step disinfectant cleaner that is effective against a broad spectrum of bacteria, is virucidal* (including HIV-1) when used as directed.

BARQUAT 42Z-10 kills germs in 10 minutes; effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella choleraesuis*.

BARQUAT 42Z-10 is for use in hospitals, medical and dental offices, nursing homes, public rest rooms, institutions, schools, colleges, veterinary clinics, animal life science laboratories, athletic facilities, food processing plants, food storage areas, kitchens, restaurants and bars, airports, transportation terminals, hotels and motels.

This product contains no phosphorous.

BARQUAT 42Z-10 is a no-rinse disinfectant cleaner that disinfects, cleans and deodorizes in one labor-saving step.

BARQUAT 42Z-10 can be used with a mop and bucket, trigger sprayers, sponge, or by soaking.

BARQUAT 42Z-10 provides effective cleaning strength that will not dull most metal-interlock floor finishes, and does not require a rinse prior to recoat.

BARQUAT 42Z-10 maximizes labor results by effectively controlling odors.

BARQUAT 42Z-10 Cleans, shines, deodorizes and disinfects hard nonporous surfaces.

BARQUAT 42Z-10 is for non-scratch cleaning of showers and tubs, shower doors and curtains and fixtures.

DIRECTIONS FOR USE

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

Apply use-solution of BARQUAT 42Z-10 with a cloth, mop or coarse mechanical spray device. When applied with a mechanical spray device, surface must be sprayed until thoroughly wetted. Treated surfaces must remain wet for 10 minutes. Wipe or allow to air dry. Prepare fresh solution daily or more often if the use solution becomes visibly dirty.

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, dishes or appliance interior surfaces as a disinfectant.

DISINFECTION IN HOSPITALS, NURSING HOMES AND OTHER HEALTH CARE INSTITUTIONS, INDUSTRY AND SCHOOLS.

For disinfecting floors, walls, countertops, bathing areas, lavatories, tables, chairs, garbage pails, bathroom fixtures and other hard nonporous surfaces. Add 1 oz. BARQUAT 42-Z10 per gallon of water.

At this use-level, BARQUAT 42Z-10 is effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella choleraesuis*, *Staphylococcus aureus* - Methicillin Resistant (MRSA), *Enterococcus faecalis* - Vancomycin Resistant (VRE), Hepatitis B Virus (HBV) and Human Immunodeficiency Virus Type 1 (HIV-1).

(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.

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This product, when used on hard, nonporous, surfaces at 1 oz. per gallon of water for a 10 minute contact (5% organic soil), is effective against Hepatitis B Virus (HBV). This product also kills Human Immunodeficiency Virus Type 1 (HIV-1) after a 30 second contact time.

***KILLS HIV-1 and HBV ON PRE-CLEANED ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS** in health care 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 HIV-1 or HBV.

SPECIAL INSTRUCTIONS FOR CLEANING OR DECONTAMINATING AGAINST HIV-1 AND HBV OF SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS.

PERSONAL PROTECTION: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gown, masks or eye coverings.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant.

CONTACT TIME: Leave surfaces wet for 30 seconds for HIV-1 and 10 minutes for HBV. Use a 10 minute contact time for all other bacteria listed.

DISPOSAL OF INFECTIOUS MATERIAL: Blood and other body fluids must be autoclaved and disposed of according to federal, state and local regulations for infectious medical waste disposal.

DISINFECTION OF BARBER TOOLS

Pre-cleaned barber tools (such as combs, brushes, razors, and scissors) can be disinfected by immersing in a 1 oz./gallon solution of BARQUAT 42Z-10 for a minimum contact time of 10 minutes.

DISINFECTION OF POULTRY EQUIPMENT, ANIMAL QUARTERS AND KENNELS. Poultry brooders, watering founts, feeding equipment and other animal quarters (such as stalls and kennel areas) can be disinfected after thorough cleaning by applying a solution of 1 oz. BARQUAT 42Z-10 per gallon of water with a mop, cloth or brush. Immerse small utensils in this solution.

Prior to disinfection, all poultry, other animals and their feeds must be removed from the premises vehicles and enclosures such as coops and crates. Remove all litter, droppings and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with the disinfecting solution for 10 minutes. 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.

After disinfection, ventilate building, coops and other closed spaces. Do not house poultry, or other animals, or employ equipment until treatment has been absorbed, set or dried.

Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

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(Note to reviewer: For Nonrefillable Containers for commercial, industrial, and institutional uses – all sizes – No Reuse Rinsate Statement for Public Health Use products)

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 and 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.

(For metal containers only: DO NOT cut or weld metal containers.)

(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.