6836-57 10/06/2003
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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OCT 6 2003

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

Subject:

Barquat 42Z-10

EPA Registration No. 6836-57 Amendment Date: July 7, 2003 EPA Receipt Date: July 8, 2003

Dear Mr. Sloan,

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

• Update First Aid Statements per PR Notice 2001-1

Conditions

Revise the label as follows:

- 1. Revise the "Environmental Hazards" statement to be in agreement with the last stamped label by including the following statement: "This pesticide is toxic to fish."
- 2. Under "First Aid," bold the subheadings, If swallowed/If in eyes/If on skin or clothing, so the statements stand out on the label.
- 3. Revise the first section on page two to read: "...reduction of cross contamination on treated surfaces in these areas."
- 4. Revise the third section on page two to read: "...effective against Pseudomonas aeruginosa, Staphylococcus aureus and Salmonella choleraesuis" You may not list public health pests without identifying the genus and species.
- 5. Revise the last section on page two, left column by deleting "toilet bowls" as you have

CONCURRENCES									
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EPA Form 1320-1A (1/90)

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- 6. Revise the section on page two beginning "Apply use-solution of..." by revising to include the following statement: "Prepare fresh solution daily or more often if the use solution..."
- 7. Revise the section on page two beginning: "Rinse all surfaces that..." to end as follows: "Do not use on utensils, glassware, dishes or appliance interior surfaces."
- 8. Revise the "Disinfection of Barber Tools" directions on page three to end as follows: "...solution of Barquat 42Z-10 for a minimum contact time of 10 minutes."
- 9. Revise the "Disinfection of Poultry Equipment, Animal Quarters and Kennels" directions on page three to end as follows: "Immerse small utensils in this solution."

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 Tracy Lantz at (703) 308-6415.

Sincerely,

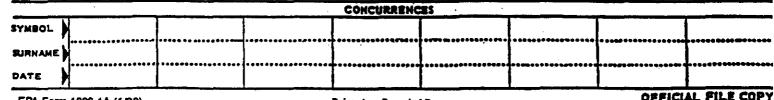
Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510C)

Enclosure: Stamped Label

7510C:T.Lantz:10/6/03:6836-57



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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 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

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						

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)

> Manufactured by: LONZA INC. 17-17 Route 208 Fair Lawn, NJ 07410

ACCEPTED
With COMMENTS
in EPA Letter Dated:

OCT 6 - 2003

Production of Federal Insecticide, and Rodennicide Act as posticide, and Rodennicide. The posticide, for the posticide, registered under EPA Reg. No. L 8 36 - 57

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 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, staph and salmonella.

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

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. Fresh solution should be prepared 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 and dishes 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 nonpourous 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

This product is not for use on medical device suffaces.

Barquat 42Z-10 EPA Reg. 6836-57 EPA DRAFT LABEL 5-7-03

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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 OR 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 should 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.

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. Small utensils should be immersed 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 recommended 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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(For container sizes of one gallon or less, use the following storage and disposal statements:)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Discard in trash or recycle.

(For container sizes greater than one gallon, use the following storage and disposal statements:)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and 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 pesticides, 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 Container:) 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 smoke.

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