

6836-270

05/06/2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY - 6 2004

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

Subject: Barquat 42Z-10F
EPA Registration No. 6836-270
Amendment Date: February 3, 2004
EPA Receipt Date: February 9, 2004

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, precautionary, storage and disposal statements

Conditions

Revise the label as follows:

1. Since this product is substantially similar to EPA Reg No. 6836-57, the Precautionary statements must be revised to reflect the following:

Corrosive. *Causes irreversible eye damage and skin burns.* Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles or faceshield), protective clothing, and rubber gloves. *Harmful if swallowed.* Wash thoroughly with soap and water after handling. *Remove contaminated clothing and wash before reuse.*

2. On page 2, 3rd claim on left panel: Revised the claim by deleting the term, germs, and replacing it with "*bacteria.*" Also, delete the organism, *Streptococcus pyogenes*, and replace it with *Salmonella choleraesuis*.

On March 26, 2004, the Agency develop guidance on the use of the term, "germs," on antimicrobial product labels. A product label must be registered as a general purpose disinfectant with an additional label claim against one of the two classes of organisms, Pathogenic fungi, *Trichophyton mentagrophytes*, or Viruses.

3. Since this product can be used on farms, veterinary clinics, and animal life science laboratories, you must develop specific directions for this type of use site.

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Remove all animals and feeds from premises, animal transportation vehicles, crates, enclosures such as coops and crates. Remove all liter, droppings, and manure from the floors, walls, and surfaces of 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 a use solution of 3-1/2 oz. of concentrate per 4 gallons of water for a period of 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. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waters with soap or detergent, and rinse with potable water before reuse.

4. On page 2, 9th claim on left panel: delete toilet bowls from the claim because the label does not support directions on how to disinfect toilet bowls.

5. Since the label makes a deodorizing claim, add the following directions:

Deodorizing: Apply 0.6 oz per gallon of water to hard nonporous surfaces. Allow surfaces to air dry.

6. Revise the "Sanitizing Food Processing Equipment and other hard surfaces in Food Contact Locations" by stating

Use product to sanitize hard, nonporous surfaces of food processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sinks, counters, refrigerated storage and display equipment and other hard, nonporous surfaces.

Prior to application, remove gross food particles and soil by a pre-flush or pre-scrub and when necessary presoak. Then thoroughly wash or flush objects with a good detergent or compatible cleaner then follow with a potable water rinse.

Apply use solution of 1 oz per 4 gallons of water (200 ppm active) to hard, nonporous surfaces by thoroughly wetting surfaces with cloth, mop, sponge, sprayer, or by immersion. Surfaces must remain wet for 60 seconds (one minute). Allow surfaces to drain and air dry. No potable water rinse is required.

Prepare a fresh solution daily or more often if the use solution becomes visibly soiled or diluted. For mechanical applications, the use solution may not be reused for sanitizing applications.

7. Revise the "Farm Use" heading to read "Sanitizing Dairy Cows Udders, Flanks, and Teats."

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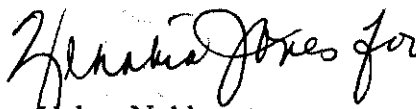
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General Comments

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.

If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



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

Enclosure: Stamped Label

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes eye damage and skin irritation. May be fatal if swallowed. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Wash thoroughly with soap and water after handling.

(If container size is 1 gallon or less, the following storage and disposal statements will be used:)

STORAGE AND DISPOSAL

Do not store on side. Store in an area inaccessible to children and pets. Avoid creasing or impacting of side walls. Do not reuse empty container. Wrap container and put in trash.

(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.

(For container sizes of 5 gallons or larger, use the following Environmental Hazards Statement:)

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. 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-10F

Disinfectant-Sanitizer-Deodorizer for Hospital, Institutional, Industrial, School, Dairy and Other Farm Use and for the Control of Mollusks and Algal, Bacterial and Fungal Slimes in Once-Through and Closed-Cycle Fresh and Sea Water Cooling Systems

Active Ingredients:

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

KEEP OUT OF REACH OF CHILDREN

DANGER

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.

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY AND FIRST AID STATEMENTS

EPA Reg. No. 6836-270

EPA Est. No. 6836-IL-1

Net Contents (insert appropriate size here)

This formulation is cleared for use by the Federal Food, Drug, and Cosmetic Act for use on food contact surfaces

Manufactured by:

LONZA INC., 17-17 Route 208, Fair Lawn, NJ 07410

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 6 - 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 6836-270

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

BARQUAT 42Z-10F is a disinfectant cleaner that is effective against a broad spectrum of bacteria and inhibits the growth of mold and mildew and their odors when used as directed.

BARQUAT 42Z-10F kills germs in 10 minutes; effective against *Pseudomonas*, *Staphylococcus aureus* and *Streptococcus pyogenes*.

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

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

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

BARQUAT 42Z-10F cleans, shines, deodorizes and disinfects hard nonporous surfaces. Inhibits the growth of mold and mildew, leaving bathrooms & kitchens clean and fresh.

BARQUAT 42Z-10F 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-10F** with a cloth, mop or coarse mechanical spray device. Treated surfaces must remain wet for 10 minutes. Wipe or allow to air dry. Fresh solution must be prepared daily or when the use solution becomes visibly dirty.

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

For disinfecting floors, walls, countertops, bathing areas, lavatories, bedframes, tables, chairs, garbage pails and other hard non-porous surfaces. Add 1 oz. **BARQUAT 42Z-10F** per gallon of water. Apply to previously cleaned hard surface with mop or cloth. At this use-level, **BARQUAT 42Z-10F** is effective against *Pseudomonas aeruginosa*. Treated surfaces must remain wet for 10 minutes. Wipe or allow to air dry.

(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.

DISINFECTION IN INSTITUTIONS, INDUSTRY AND SCHOOLS.

For disinfecting floors, walls, bedframes, countertops, tables, chairs, garbage pails, bathroom fixtures and other hard, non-porous surfaces. Add 0.6 oz. of **BARQUAT 42Z-10F** per gallon of water. Apply to previously cleaned hard surface with mop or cloth. At 0.6 oz. per gallon of water use-level, **BARQUAT 42Z-10F** is effective against *Staphylococcus aureus* and *Salmonella choleraesuis*. Treated surfaces must remain wet for 10 minutes. Wipe or allow to air dry.

Sanitizing of Food Processing Equipment and Other Hard Surfaces in Food Contact Locations.

For sanitizing food processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage and display equipment and other hard non-porous surfaces. Wash and rinse all articles thoroughly, then apply a solution of 1 oz. **BARQUAT 42Z-10F** in 4 gallons of water (200 ppm active). Surfaces must remain wet for at least one minute followed by adequate draining and air drying. Fresh solution must be prepared daily or when use solution becomes visibly dirty. Apply to sink tops, countertops, refrigerated storage and display equipment and other stationary hard surfaces by cloth or brush. Dishes, silverware, glasses, cooking utensils and other similar size food processing equipment can be sanitized by immersion in a 1 oz./4 gallon dilution of **BARQUAT 42Z-10F**. No potable water rinse is required.

Farm Use

The udders, flanks and teats of dairy cows can be sanitized by washing with solution of 1 oz. BARQUAT 42Z-10F in 4 gallons of warm water.

Use a fresh towel for each cow. Avoid contamination of sanitizing solution by dirt and soil. Do not dip used towel back into sanitizing solution. When solution becomes visibly dirty, discard and provide fresh solution.

FOR THE CONTROL OF MOLLUSKS, BACTERIA, FUNGI AND ALGAE

When used as directed, BARQUAT 42Z-10F helps to effectively control algae, bacteria, fungi and macrofouling species such as clams, barnacles, and mussels in commercial and industrial recirculating and once-through cooling water systems, influent water systems, brewery pasteurizers, auxiliary water systems and waste water systems. Product addition must be made with a metering pump. Product may be fed continuously or on an intermittent basis depending on the degree of system fouling and retention time.

BACTERIAL, FUNGAL, AND ALGAE CONTROL IN RECIRCULATING AUXILIARY AND WASTE WATER SYSTEMS, AND PASTEURIZERS

INITIAL DOSE: Add BARQUAT 42Z-10F at an initial dosage of 1-2 gallons per 5,000 gallons of system water (200-400 ppm). Repeat until the desired level of control is achieved. Heavily contaminated systems must be precleaned.

SUBSEQUENT DOSE: Once control is achieved, add maintenance dosages of 1-4 quarts BARQUAT 42Z-10F per 5,000 gallons of system water (50-200 ppm) weekly or as needed to maintain control. Apply BARQUAT 42Z-10F to a point in the system where it will be uniformly mixed and distributed, such as the tower sump.

MACROFOULING CONTROL IN RECIRCULATING AUXILIARY COOLING WATER AND WASTE WATER SYSTEMS

INITIAL DOSE: For the control of macrofouling growth such as clams, barnacles, and mussels, add 0.08-0.80 lbs. of BARQUAT 42Z-10F per 1,000 gallons of water (10-100 ppm). Repeat as necessary to achieve control.

SUBSEQUENT DOSE: When control is evident, add 0.08-0.40 pounds of BARQUAT 42Z-10F per 1,000 gallons of system water (10-50 ppm) as needed to maintain control.

ONCE-THROUGH COOLING WATER SYSTEMS INTERMITTENT FEED

INITIAL DOSE: When the system is noticeably fouled, add BARQUAT 42Z-10F at a dosage of 0.08-0.80 pounds per 1,000 gallons of water (10-100 ppm) based on system flow rates. The minimum treatment period must be 6 to 24 hours. Repeat as necessary to achieve control.

SUBSEQUENT DOSE: When control is evident, add BARQUAT 42Z-10F at a dosage of 0.04-0.40 pounds per 1,000 gallons of water (5-50 ppm) based on system flow rates on an as needed basis to maintain control. Frequency of feed should be tied to an in-plant monitoring program for macrofouling growth.

ONCE-THROUGH COOLING WATER SYSTEMS CONTINUOUS FEED

INITIAL DOSE: When the system is noticeably fouled, add BARQUAT 42Z-10F at a dosage of 0.04-0.40 pounds per 1,000 gallons of water (5-50 ppm) based on system flow rates. Continue to feed until needed control is achieved.

SUBSEQUENT DOSE: Maintenance control can be effective through continuous feed of BARQUAT 42Z-10F at a dosage of 0.016-0.16 pounds per 1,000 gallons of water (2-20 ppm) based on system flow rates.

BARQUAT 42Z-10F IS INTENDED FOR HOSPITAL, INSTITUTIONAL, INDUSTRIAL, SCHOOL, DAIRY AND OTHER FARM USE ONLY

Do not apply to potable or domestic water systems. Do not use water containing residues from use of this product to irrigate crops used for food or feed.

Use of the product in either public/municipal or single or multiple family private/residential potable/drinking water systems is strictly prohibited. Use of the product in any cooling water system that discharges effluent within 1/4 mile of either a public/municipal or single or multiple family private/residential potable/drinking water intake is strictly prohibited.