

6836-65

11/14/2003

1/6

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

Subject: Bardac 20-10
EPA Registration No. 6836-65
Amendment Date: August 18, 2003
EPA Receipt Date: August 19, 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 "Precautionary Statements" to read :

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, safety glasses, or faceshield), protective clothing, and protective gloves (chemical resistant or rubber gloves). Harmful if swallowed, absorbed through the skin, or inhaled. Do not breathe vapor. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

2. Revise the "First Aid" statements by adding "**If inhaled:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice."
3. Page 2: Revise the 2nd claim's use solution for hospital disinfection to read 3 ½ oz per 4 gallons of water.
4. Revise the heading "Disinfection in institutions, industry, and schools" to read "Disinfection in commercial, industry, and non-medical areas."

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

2/6

5. Under the directions, add the statement "Allow surfaces to air dry or wipe excess liquid with cloth, sponge, or mop."

6. Revise the "Disinfection of Barber Tools" to read :

Preclean hard nonporous instruments and tools. Completely immerse combs, brushes, rollers, manicure, and other salon/barber instruments and tools in use solution of 1/2 oz per gallon of water for 10 minutes. Rinse thoroughly and dry before use. Use a fresh product daily. Do not reuse solutions, and discard solutions if it becomes diluted or soiled.

Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried, and kept in a clean non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

7. Under "Poultry Equipment/ Animal Quarters/Kennels" delete the first paragraph. It is an incomplete version of the directions which appear below it. It would be beneficial to add the statement "For disinfection of poultry brooders, watering fountains, feeding equipment, and other quarters(such as stalls and kennel areas)." It should appear as the first statement of the directions.

Also, delete the last statement in this section, "All treated equipment .. before reuse." It is a redundant statement.

8. Since this product is not a one step cleaner/deodorizer/disinfectant, you must add separate deodorizing directions that state "Deodorization: Apply 3 oz per 5 1/2 gallons of water with mop, cloth, sponge, or mechanical sprayer. Thoroughly wet surfaces and allow to air dry.

9. Since this product is fungicidal, you must add the following claim:

Fungicidal: At 3 1/2 oz per 4 gallons of water this product is effective against *Trichophyton mentagrophytes* (Athletes foot fungus) when used on surfaces in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities. Follow Disinfection Directions.

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.

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Sincerely,



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

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

416

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER Causes eye damage and skin irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. Avoid contamination of food.

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.

Measures against circulatory shock, respiratory depression and convulsion may be needed.

(If the container size is 5 gallons or greater, the following Environmental Hazards will be used:)

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.

BARDAC 20-10

Disinfectant - Sanitizer
Fungicide - Deodorizer
with Organic Tolerance
for Hospital, Institutional, Industrial,
School, Dairy and Other Farm Use

Active Ingredients:

Octyl decyl dimethyl ammonium chloride.....	5.0%
Dioctyl dimethyl ammonium chloride	3.0%
Didecyl dimethyl ammonium chloride	2.0%
Other Ingredients:.....	90.0%
Total:.....	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER (PELIGRO)

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

EPA Reg. No. 6836-65

EPA Est. No. *(insert EPA Establishment number here)*

Net Contents *(insert container size here)*

MANUFACTURED BY:

LONZA INC.
17-17 Route 208
Fair Lawn, N.J. 07410

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 14 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 6836-65

BARDAC 20-10
EPA REG NO. 6836-65
EPA DRAFT LABEL 8/15/03

BARDAC 20-10 is effective against *Staphylococcus aureus* and *Salmonella choleraesuis* when used at 3 oz. per 5½ gallons.

BARDAC 20-10 is effective against *Staphylococcus aureus* and *Salmonella choleraesuis* and *Pseudomonas aeruginosa* when used at 3 oz. per 4 gallons.

Use for disinfecting floors, walls, bathing areas, bedframes, lavatories, countertops, tables, chairs, garbage pails, bathroom fixtures and other hard nonporous surfaces.

At 3/4 oz. per 4 gallons, **BARDAC 20-10** fulfills the criteria of Appendix F of the Grade "A" Pasteurized Milk Ordinances 1978 Recommendations of the U.S. Public Health Services in waters up to 400 ppm of hardness calculated as CaCO_3 when evaluated by the AOAC Germicidal and Detergent Sanitizer Method against *Escherichia coli* and *Staphylococcus aureus*.

PELIGRO: SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.

DIRECTIONS FOR USE

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

DISINFECTION IN INSTITUTIONS, INDUSTRY AND SCHOOLS

Use 3 oz. of **BARDAC 20-10** to 5½ gallons of water.

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

Use 3½ oz. of **BARDAC 20-10** to 4 gallons water.

Preclean surfaces prior to disinfection. Apply appropriate amount of **BARDAC 20-10** with a cloth, mop, sponge or coarse (mechanical) spray device until thoroughly wetted. Treated surfaces must remain wet for 10 minutes. 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.

(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.

DISINFECTION OF BARBER TOOLS

Precleaned barber tools (such as combs, brushes, razors, and scissors) can be disinfected by immersing in a 1/2 oz. / gallon solution of **BARDAC 20-10** for 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 3 1/2 oz. **BARDAC 20-10** to 4 gallons 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 enclosure 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. Use 3½ oz. of **BARDAC 20-10** to 4 gallons 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 buildings, 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.

All treated equipment that will contact feed or drinking water must be rinsed with potable water before reuse.

SANITIZING OF FOOD PROCESSING EQUIPMENT AND OTHER HARD SURFACES IN FOOD CONTACT LOCATIONS

Use for sanitizing food processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage and display equipment and other hard surfaces.

Prior to application, remove gross food particles and soil by a pre-flush, or pre-scrape and, when necessary, pre-soak. Then thoroughly wash objects with a good detergent or compatible cleaner followed by a potable water rinse before application of the sanitizing solution.

Apply a solution of $\frac{3}{4}$ oz. Bardac 20-10 in 4 gallons of water. (150 ppm active) to pre-cleaned hard surfaces thoroughly wetting surfaces with a cloth, mop, sponge, coarse sprayer or by immersion. Surfaces must remain wet for at least one minute (60 seconds) followed by adequate draining (and air drying). Do not rinse.

Fresh solution should be prepared daily or more often if use solution becomes visibly dirty.

For mechanical application, use solution may not be reused for sanitizing applications but may be used for other purposes cleaning.

Apply to sink tops, countertops, refrigerated storage and display equipment and other stationary hard surfaces by cloth, sponge or brush.

Sanitize dishes, silverware, glasses, cooking utensils and other similar size food processing equipment by immersion.

DAIRY COW APPLICATION DIRECTIONS:

The udders, flanks, and teats of dairy cows can be sanitized by washing with a solution of $\frac{3}{4}$ oz. BARDAC 20-10 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.

(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. 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.