

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1/5

1-25-2005

6836-232

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JAN 25 2005

Robert J. Sloan
Sr. Regulatory Service Associate
Lonza, Inc.
17-17 Route 208
Fair Lawn, NJ 07410

Subject: Bardac 22 - 50
EPA Registration No. 6836-232
Amendment Dated: Oct 26, 2004
EPA Received Date: Oct 27, 2004

Dear Robert J. Sloan

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, is acceptable with comments.

Proposed Amendment

- Revised Label

Label Comments

1. Revise the "Precautionary Statements" to read exactly as follows:
 - In the directions for use as a sanitizer of food processing equipment revised to state: "Prepare Fresh solution daily or more often when use solution becomes diluted or visibility soiled."
 - In the "Storage and Disposal" section under the subheading "Pesticide Storage" place the following statement since this product will be used in areas occupied by children: "Store in locked area inaccessible to children."

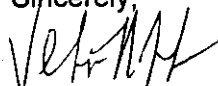
General Comments

A stamped copy of the accepted labels are enclosed for your records. Submit (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

CONCURRENCES							
S:	-						
SURNAME	J. Sloan						
DATE	1-25-05						

Submit revised labeling for review by the agency. 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 Branch1
Antimicrobial Division (7510c)

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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 (safety glasses, goggles or face shield), protective clothing, and protective gloves (rubber or chemical resistant). May be fatal if swallowed. Harmful if absorbed through the skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

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. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferable by mouth-to-mouth if possible. 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.

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.

PHYSICAL OR CHEMICAL HAZARDS

-Do not use or store near heat or flame.

BARDAC 22-50

DISINFECTANT - SANITIZER - DEODORIZER

for Hospital, Institutional, Industrial, School, Food Processing, Dairy and Poultry and Swine Premise Use

Active Ingredient:

Didecyl dimethyl ammonium chloride.....50.00%
Other Ingredients50.00%
Total:100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

See [back] [side] [right] [left] panel for Precautionary Statements and First Aid

EPA Registration No. 6836-232
EPA Establishment No. (as indicated on container)
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:**

JAN 25 2005

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. **6836-232**

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.

At 0.375 oz. /10 gallons of water, Bardac 22-50 fulfills the criteria of Appendix F of the Grade "A" Pasteurized Milk Ordinances 1978 Recommendations of the U.S. Public Health Service in waters up to 1000 ppm of hardness calculated as CaCO₃ when evaluated by the AOAC Germicidal and Detergent Sanitizer Method against Escherichia coli and Staphylococcus aureus.

Use Bardac 22-50 to disinfect floors, walls, bedframes, countertops, tables, chairs, garbage pails, cabinets, stovetops, refrigerated storage and display equipment cabinets, doorknobs, telephones, drain pans of air-conditioning and refrigeration equipment and heat pumps, woodwork, plastic upholstery, lavatories, sinks, bathing areas, bathtubs, shower stalls, bathroom fixtures, urinals, glazed porcelain tiling and vinyl.

DIRECTIONS FOR USE

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

TO DISINFECT: Apply Bardac 22-50 with a cloth, mop, sponge, sprayer or by immersion. For sprayer applications, use a coarse spray device. Spray 6 - 8 inches from surface, rub with brush, sponge or cloth. NOTE: With sprayer applications, cover or remove all food products.

Prepare a fresh solution daily or more often if the solution becomes visibly diluted or soiled. All food-contact surfaces must be rinsed with potable water after disinfection.

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

Add 1.25 oz. of Bardac 22-50 to 10 gallons of water (500 ppm active quaternary compound). Apply this use-solution to previously cleaned, nonporous hard-surfaces. Treated surfaces must remain wet for 10 minutes. At this use-level, Bardac 22-50 is effective against Pseudomonas aeruginosa, Staphylococcus aureus and Salmonella choleraesuis.

DISINFECTION IN INSTITUTIONS, INDUSTRY AND SCHOOLS

Add 0.75 oz. of Bardac 22-50 to 10 gallons of water (300 ppm active quaternary compound). Apply this use-solution to previously cleaned, nonporous hard surfaces. Treated surfaces must remain wet for 10 minutes. At this use-level, Bardac 22-50 is effective against Staphylococcus aureus and Salmonella choleraesuis.

(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.

Poultry and Swine Premise Disinfection

Remove all animals and feeds from premises, trucks, coops and crates. Remove all litter, droppings and manure from floors, walls and surfaces of facilities 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 a fresh dilution of Bardac 22-50 in water (1.25 oz./10 gallons of water, 500 ppm active quaternary compound). Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes. Ventilate buildings, coops, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated food racks, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

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

Prior to application, remove gross food particles and soil by a pre-flush, or pre-scrape and, when necessary, pre-soak. Then thoroughly wash surfaces or objects with a good detergent or compatible cleaner, followed by a potable water rinse before application of the sanitizing solution. Apply a solution of 0.375 oz. of Bardac 22-50 per 10 gallons of water (150 ppm active quaternary compound). Surfaces should remain wet for at least one minute followed by adequate draining [and air-drying]. Fresh solution should be prepared daily or more often when use solution becomes diluted or visibly soiled. For mechanical application, use solution may not be reused for sanitizing applications. **Do not rinse.**

Dairy Cows

The udders, flanks, and teats of dairy cows can be sanitized by washing with a solution of 0.375 oz. of Bardac 22-50 per 10 gallons of warm water (150 ppm active quaternary compound). **Do not rinse.**

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.

5/15
(Note to reviewer: If the 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. Discard in trash or recycle.

(Note to reviewer: If the container size is greater than 1 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.

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

(Plastic containers): Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out 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.