

6836-53

8/28/2003

Page 183

AUG 28 2003

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

Subject: Bardac ® 2280  
EPA Registration No. 6836-53  
Amendment Date: May 30, 2003  
EPA Receipt Date: June 2, 2003

Dear Mr. Robert Sloan,

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

- Update First Aid Statements, Precautionary Statements and Storage and Disposal Statements as required by the applicable PR Notices and the EPA Label Review Manual

**Conditions**

Revise the label as follows:

1. The Agency has completed an risk assessment to characterize Didecyl Dimethyl Ammonium chloride (DDAC) During this process, the acute toxicology profile determined for Manufacturing use Products (MUP) with an active ingredient concentration ranging from 40% to 80% and End-use products (EP) that a formulated repackages of MUPs in the aforementioned concentration range. According to this data, this product is classified as follows:

Primary Eye	Tox I
Primary Skin	Tox I
Acute Inhalation	Tox II
Acute Oral	Tox II
Acute Dermal	Tox III
Dermal Sensitizer	Positive

**CONCURRENCES**

If you feel this information is not accurate please submit or cite data to the agency.						
YMBOL						
JRNAME						
ATE						

Thus revise the Precautionary Statements to read exactly as follows:

**Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield, protective clothing, and rubber gloves. May be fatal if swallowed or inhaled. Do not breathe spray mist (or vapor). Wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C). Harmful if absorbed through the skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. 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. Under "First Aid," bold the subheadings, **If swallowed/If in eyes/If on skin or clothing**, so the statements stand out on the label.
4. Under the "Directions for Use," delete the use sites, "aquatic areas" and "public access premise." Your label needs to be more specific in terms of the sites which will be treated. In addition, delete the following sites which are not supported for this active ingredient: "materials and preservatives" and "antifouling coatings."
5. The statement which follows the product name at the top of the right column is too broad. The Agency is moving toward revising MUP labels to list the specific sites at which a product may be formulated for use, not the pesticidal claims associated with those uses. Revise the statement: "For Formulation into Antimicrobial Products" to read: *"For use by manufacturers only in formulating antimicrobial products for the uses indicated on the label."*

### General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies 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 Velma Noble at (703) 308-6233.

Sincerely,



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

# Lonza

17-17 ROUTE 208  
FAIR LAWN, NEW JERSEY 07410 USA  
EMERGENCY TEL. NO. 309-697-5400

HEALTH 3

FLAMMABILITY 2

REACTIVITY 0

PERSONAL PROTECTION

## BARDAC<sup>®</sup> 2280

For Formulation Into Antimicrobial Products

Active Ingredients: Didecyl Dimethyl Ammonium Chloride ..... 80.0%  
Other Ingredients: ..... 20.0%  
100.0%

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

UN1903

DISINFECTANTS,  
CORROSIVE LIQUID, N.O.S.  
(DIALKYL DIMETHYL AMMONIUM  
CHLORIDE)

CAS NO: MIXTURE  
EPA Reg. No. 6836-53  
EPA EST. No. 6836-IL-1

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER! CORROSIVE.** Causes irreversible eye damage and skin burns. May be fatal if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear protective eyewear, protective clothing and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. 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.

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

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.

#### PHYSICAL OR CHEMICAL HAZARDS

**DO NOT USE OR STORE NEAR HEAT OR FLAME!**

### DIRECTIONS FOR USE

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

This product is a concentrate for formulating purposes only. This product for formulation into antimicrobial products for use in/on Agricultural premises and equipment, Food Handling/Storage establishment premises and equipment, Commercial, institutional and industrial premises and equipment, Residential and public access premises, Materials and Preservatives, Medical Premises and equipment, Industrial processes and water systems, Antifouling Coatings, Wood preservatives, Swimming Pools and Aquatic Areas. Formulators using this product are responsible for providing data for the EPA registration of their formulated products. This product may be used to formulate products for specific use(s) not listed on this label if the formulator or primary registrant has complied with U.S. EPA data requirements regarding the support of such use(s).

**NOTE:** This product should not be used or compounded with any reducing or oxidizing agents (such as calcium hypochlorite, solid perchlorate, or nitric acid) since such mixtures may be explosive. Do not use in conjunction with soap or any anionic wetting agent.

#### 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 empty container 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

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.

FOR HELP IN A CHEMICAL  
EMERGENCY CALL  
CHEMTREC 1-800-424-9300.

BEFORE USING  
CONSULT MATERIAL  
SAFETY DATA SHEET.

**ACCEPTED**  
with COMMENTS  
in EPA Letter Dated:  
AUG 28 2003

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
Bardac, registered under EPA Reg. No. 6836-53

CODE NO. (P)
LOT NO. (S)
WEIGHT. (Q)
lb. kg.
NUMBER:

CONSHOHOCKEN, PA

FAIR LAWN, NJ

MAPLETON, IL

PASADENA, TX

WILLIAMSPORT, PA

373