

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT - 3 2003

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

Subject: FMB 504-5 Quat
EPA Registration No. 47371-70
Amendment Date: July 3, 2003
EPA Receipt Date: July 7, 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, Precautionary Statements and Storage and Disposal Statements as required by the applicable PR Notices and the EPA Label Review Manuel

Conditions

Revise the label as follows:

1. The Agency has completed risk assessments to characterize the chemical, Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) and Didecyl Dimethyl Amonium Chloride(DDAC). During this process, the acute toxicology profile was determined for Manufacturing Use Products (MUP) with an active ingredient concentration ranging from 40% to 80%. 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 II
Dermal Sensitization	Positive Sensitizer

CONCURRENCES

YMBOL							
URNAME							

Thus, the precautionary statements must state:

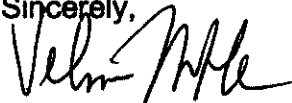
"Corrosive, Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield, protective clothing, and rubber gloves. Maybe fatal if swallowed or inhaled. Do not breather spray mist (or vapor). Wear a dust mist filtering respirator (MSHA/NIOSH approval #Prefix TC-21C) harmful if absorbed through 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 tabasco. 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."** In addition, delete the statement: "Concentrated Germicide" as this is an end use claim and not appropriate for an MUP label.

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 Velma Noble at (703) 308-6233.

Sincerely,



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

Lonza

H&S CHEMICALS DIVISION C/O LONZA INC
17-17 ROUTE 208
FAIR LAWN, NEW JERSEY 07410 USA
EMERGENCY TEL. NO. 309-697-5400

HEALTH	3
FLAMMABILITY	2
REACTIVITY	0
PERSONAL PROTECTION	

FMB 504-5 QUAT

CONCENTRATED GERMICIDE

For Formulation into Antimicrobial Products

Active Ingredients:	Alkyl (C ₁₄ -50%, C ₁₂ -40%, C ₁₆ -10%) Dimethyl Benzyl Ammonium Chloride	20.0%
	Octyl Decyl Dimethyl Ammonium Chloride	15.0%
	Dioctyl Dimethyl Ammonium Chloride	7.5%
	Didecyl Dimethyl Ammonium Chloride	7.5%
Other Ingredients:	50.0%
		100.0%

KEEP OUT OF REACH OF CHILDREN

CAS NO: MIXTURE
EPA Reg. No. 47371-70
EPA EST. No. 6836-IL-1

UN1903
DISINFECTANTS, CORROSIVE LIQUID,
N.O.S. (ALKYL DIMETHYL BENZYL
AMMONIUM CHLORIDE, DIALKYL
DIMETHYL AMMONIUM CHLORIDE)

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

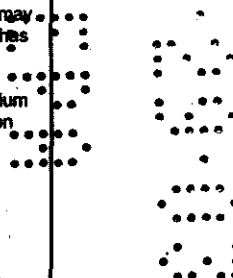
Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mix, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or 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
WARRANTY COMMENTS
Initials and Date:
OCT 3 - 2003
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 47371-70

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

CONSHOHOCKEN, PA

FAIR LAWN, NJ

MAPLETON, IL

PASADENA, TX

WILLIAMSPORT, PA

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