

17 MAR 1983

Lonza, Inc.
22-10 Route 208
Fairlawn, NJ 07410

Attention: Irving Gottlieb
Manager, Governmental Relations

Gentlemen:

Subject: Bardac 205M
EPA Registration No. 6836-66
Your Application Dated January 10, 1983

The amendment referred to above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A), is acceptable provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:
 - a. Include a statement which clarifies that the attached label (EPA Reg. No. 6836-70) is an example of an end-use product ~~labeling~~ ~~relative and product identity statements~~ which has been registered with EPA (page 4).
3. Submit five (5) copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the Product Information Bulletin is enclosed for your records.

CONCURRENCES

SYMBOL ▶							
SIGNATURE ▶							
DATE ▶							

For reference: The Accession Number is 249381. A copy of the Technical Support Section Efficacy Review-II is enclosed for your records.

Sincerely yours,



John H. Lee
Product Manager (31)
Disinfectants Branch
Registration Division (TS-767C)

Enclosures

RD:John H. Lee:DCR-03071:WANG-2610C:aca:Raven:479-2013:2/17/83
REVISED 2/24/83:DCR-03078:WANG-2696C:gmm

LONZA

PRODUCT INFORMATION

ACCEPTED
with COMMENTS
in EPA Letter Dated:

BARDAC 205M
BARDAC 208M

MAR 17 1983

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
6836-66

Bardac 205M/208M is a radically new development based upon Lonza Inc. patented "Twin Chain" quaternary ammonium compound technology. Bardac 205M/208M, when evaluated by accepted laboratory procedures, provides superior germicidal and fungicidal activity far beyond that achieved with currently available quaternary ammonium compounds. This provides the formulator with unequalled latitude in the design of biocidal systems.

Chemical Composition

<u>Active Ingredients</u>	<u>Bardac 205M</u>	<u>Bardac 208M</u>
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	20.0%	32.0%
Octyl decyl dimethyl ammonium chloride	15.0%	24.0%
Dioctyl dimethyl ammonium chloride	7.5%	12.0%
Didecyl dimethyl ammonium chloride	7.5%	12.0%
<u>Inert Ingredients</u>	50.0%	20.0%

Physical Properties

Average molecular weight	342
pH (10% solution)	6.5-9
Physical state	Liquid
Color	Clear to light amber
Flash point (Seta Flash)	116°F 118°F
Specific gravity (@ 25°C)	0.946 0.912
	(7.89 lbs./gal.) (7.61 lbs./gal.)

EPA Registration No.

6836-66 6836-67

CAS No.

68424-95-5 & 130-08-2

Summary of the superior performance characteristics of Bardac 205M/208M:

- Better disinfectant performance.
- Broad spectrum biocidal activity against both gram positive and gram negative organisms.
- Increased hard water tolerance for sanitizing activity.
- Superior fungicidal performance.
- Substantial organic soil tolerance (in accordance with the latest EPA requirements).

GERMICIDAL ACTIVITY

Important Note: All microbiological evaluations were performed in the presence of an organic soil load represented by 5% blood serum; proposed EPA guidelines – Subpart G, Supplemental Recommendations #4, p 11-112, June 22, 1979. The serum was added to the inoculum prior to the carrier drying step (or other appropriate procedure).

Disinfectant Activity Determined by AOAC Use-Dilution Tests

The minimum concentration of Bardac 205M/208M required for effective disinfection is determined by the AOAC, 13th Edition, paragraph 4.007-4.011 (1980) procedure commonly known as the Use-Dilution Test.

<u>Test Organism</u>	<u>ATCC #</u>	<u>Minimum Effective Concentration</u>
Staphylococcus aureus	6538	250 ppm active quaternary
Salmonella choleraesuis	10708	250 ppm active quaternary
Pseudomonas aeruginosa	10524	450 ppm active quaternary

The broad spectrum germicidal activity of Bardac 205M/208M was confirmed by the AOAC Use-Dilution evaluations against the following organisms:

<u>Test Organism</u>	<u>ATCC #</u>	<u>Minimum Effective Concentration</u>
Escherichia coli	11229	250 ppm active quaternary
Serratia marcescens	8101	250 ppm active quaternary
Brevibacterium ammoniagenes	6871	250 ppm active quaternary
Salmonella typhi	6539	250 ppm active quaternary

**Disinfectant Activity Determined by AOAC Use Dilution Tests
in the Presence of Hard Water and Organic Soil**

<u>Test Organism</u>	<u>ATCC #</u>	<u>Hard Water Concentration</u>	<u>Minimum Effective Concentration</u>
Pseudomonas aeruginosa	10524	0 ppm/CaCO ₃	450 ppm active quaternary
		300 ppm/CaCO ₃	850 ppm active quaternary
		400 ppm/CaCO ₃	850 ppm active quaternary
		500 ppm/CaCO ₃	1000 ppm active quaternary
Salmonella choleraesuis	10708	0 ppm/CaCO ₃	250 ppm active quaternary
		300 ppm/CaCO ₃	600 ppm active quaternary
		400 ppm/CaCO ₃	600 ppm active quaternary
		500 ppm/CaCO ₃	700 ppm active quaternary

VIRUCIDAL ACTIVITY

• The virucidal activity of Bardac 205M/208M was confirmed by current EPA accepted protocol against Influenza A₂ (Hong Kong), Herpes simplex and Vaccinia at 450 ppm active quaternary.

Sanitizing Performance/Hard Water Tolerance

Bardac 205M/208M has been cleared by the FDA as an "Indirect Food Additive" under 21CFR178.1010 "Sanitizing Solutions" at a concentration of 150-400 ppm active, and requires no potable water rinse. This clearance covers the usage of Bardac 205M/208M on food processing equipment and utensils and food contact surfaces in public eating places. In addition, the use of sanitizing solutions based on Bardac 205M/208M fulfills the criteria of the Grade "A" Pasteurized Milk Ordinance 1978 Recommendations of the United States Public Health Service.

The hard water tolerance of Bardac 205M/208M is measured by the AOAC Germicidal and Detergent Sanitizer Method, 13th Edition, paragraph 4.023-4.032 (1980), commonly called the hard water tolerance test. Exposure of 100 million organisms of Escherichia coli (#11229) to 150 ppm of Bardac 205M/208M for 30 seconds at 25°C in 800 ppm of water hardness results in the required reduction of 99.999% of the bacteria.

Calcium and magnesium salts are typical hard water components; however, other electrolytes may be present during actual field applications.

<u>Test Organism</u>	<u>Concentration of Bardac 205M/208M Required for 99.999% Reduction</u>	<u>Hard Water Ceiling</u>
Escherichia coli, #11229	150 ppm	800 ppm hard water
	200 ppm	1100 ppm hard water
Staphylococcus aureus, #6538	150 ppm	800 ppm hard water
	200 ppm	1100 ppm hard water

Non-Food Contact Application

The non-food contact surface sanitizing activity of Bardac 205M/208M was determined by the following test methodology: EPA DIS/ISS-10, February 6, 1979 and the Guidelines for Registering Pesticides in the United States, Subpart G - Product Performance, June 22, 1979 Draft, Recommended Method #8 (Sanitizers-Non-Food Contact Surfaces), p 101-102.

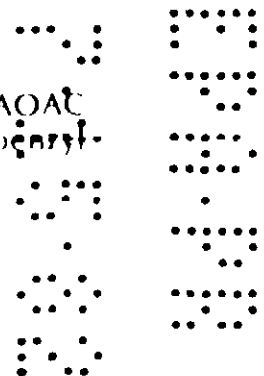
<u>Test Organism</u>	<u>Concentration of Bardac 205M/208M Required for 99.999% Reduction</u>	<u>Hard Water Ceiling</u>	<u>Contact Time</u>
Staphylococcus aureus (ATCC #6538)	150 ppm (active)	800 ppm	2 min.
	200 ppm (active)	1100 ppm	1 min.
Klebsiella pneumoniae (ATCC #4352)	150 ppm (active)	800 ppm	2 min.
	200 ppm (active)	1100 ppm	1 min.

Fungicidal Performance as Determined by the AOAC Fungicidal Test

Possessing superior fungicidal activity, Bardac 205M/208M effectively passes the AOAC Fungicidal test at one-eighth the concentration required for conventional alkyl benzyl quaternaries.

<u>Test Organism</u>	<u>Ten Minute Killing Dilution (100% active)</u>
Trichophyton mentagrophytes	1:8000 125 ppm

ACCEPTED
with COMMENTS
in EPA Letter Dated
MAR 17 1983
Fungicide, Alkylbenzyl Quaternary
as defined in the Fungicide Act
registered under EPA Reg. No.



Summary of Applications and Recommended Use-Levels

Application

Recommended Use-Levels on 100% Active Basis

Hospital Disinfection	450 ppm active quaternary
General Disinfection	250 ppm active quaternary
Sanitizing	150 ppm active quaternary

Product Registration

The Lonza Technical Service Department will assist you with Bardac 205M/208M based formulations and EPA registration.

Prototype formulations based on Bardac 205M/208M, their EPA data base references and sample labels are available upon request. For formulations of your own development, you are responsible to provide data currently required by the EPA to support that registration.

Disinfectant and sanitizer products containing Quaternary Ammonium Compounds must be registered with the U.S. Environmental Protection Agency. Applications for registration must be accompanied by two copies of your proposed label and should be sent to Product Manager No. 31, Office of Pesticide Programs, Registration Division (TS-767), U.S. Environmental Protection Agency, Washington D.C. 20460. Some state agencies also require registration of your product independent of your EPA registration.

Precautionary Statements

Danger: Keep Out of Reach of Children. Corrosive. Causes severe eye and skin damage. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Do not contaminate water, food or feed by storage or disposal.

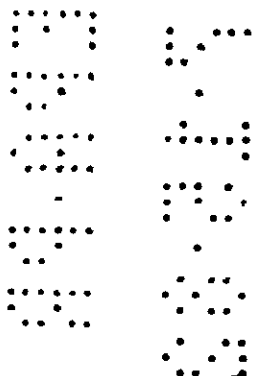
Statement Of Practical Treatment: In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse.

If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution; or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

Note To Physician: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

Container Disposal: Dispose of in an incinerator or landfill approved for pesticide containers.

Disposal: Bury in a safe place or return to drum reconditioner.



SCD 078 682 10

The seller makes no warranty, expressed or implied, concerning the accuracy of any information obtained from the use of any information and no warranty expressed or implied concerning the use of the products other than indicated above. The buyer assumes all risks of use and/or handling. No statement is intended or should be construed as a recommendation to infringe any patent.

8
7
2

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. **No Potable water rinse is required.**

Wash and rinse all articles thoroughly. Then apply a solution of 1 oz. BARDAC-205-7.5 in 4 gallons of water (150ppm active). Surfaces should remain wet for at least one minute followed by adequate draining and air drying. Fresh solution should be prepared daily or when the solution becomes visibly dirty. For mechanical application, use solution may not be reused for sanitizing applications.

Apply to sink tops, countertops, refrigerated storage and display equipment and other stationary hard surfaces by brush or brush or mechanical spray device. **No Potable water rinse is required.**

Dishes, silverware, glasses, cooking utensils and other similar size food processing equipment can be sanitized by immersion in a 1 oz. 4 gallon solution of BARDAC-205-7.5. **No Potable water rinse is required.**

At 1 oz./4 gallons BARDAC-205-7.5 meets the criteria of Appendix F of the Grade "A" Pasteurized Milk Ordinance, 1978 Recommendations of the U.S. Public Health Services in waters up to 800 ppm of hardness calculated as CaCO₃ when evaluated by the AOAC Germicidal and Detergent Sanitizer Method against Escherichia coli and Staphylococcus aureus.

The udders, flanks and teats of dairy cows can be sanitized by washing with a solution of 1 oz. BARDAC-205-7.5 in 4 gallons of warm water. **No Potable water rinse is required.** 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.

Precautionary Statements

Hazards to Humans and domestic animals

DANGER

Keep out of reach of children. Corrosive. Causes eye and skin irritation. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed. Do not breathe spray mist. Avoid contamination of food.

STORAGE AND DISPOSAL

- DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL
- OPEN DUMPING IS PROHIBITED
- DO NOT REUSE EMPTY CONTAINER

PESTICIDE DISPOSAL

PESTICIDE SPRAY MIXTURE OR RINSE WATER THAT CANNOT BE USED ACCORDING TO LABEL INSTRUCTIONS MUST BE DISPOSED OF ACCORDING TO FEDERAL OR APPROVED STATE PROCEDURES UNDER SUBTITLE C OF THE RESOURCE CONSERVATION AND RECOVERY ACT.

CONTAINER DISPOSAL

TRIPLE RINSE (OR EQUIVALENT), THEN OFFER FOR RECYCLING OR RECONDITIONING, OR DISPOSE OF IN A SANITARY LANDFILL, OR BY INCINERATION IF ALLOWED BY STATE AND LOCAL AUTHORITIES.

GENERAL

CONSULT FEDERAL, STATE OR LOCAL DISPOSAL AUTHORITIES FOR APPROVED ALTERNATIVE PROCEDURES.

BARDAC 205M-7.5

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

Active Ingredients

Octyl decyl dimethyl ammonium chloride	2.250%
Didecyl dimethyl ammonium chloride	1.125%
Diocetyl dimethyl ammonium chloride	1.125%
Alkyl (C ₁₄ : 50%; C ₁₂ : 40%; C ₁₆ : 10%) dimethyl benzyl ammonium chloride	3.000%

Inert Ingredients

Water	92.500%
Total	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER

Statement of Practical Treatment

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse.

If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration No. 6836-70

EPA Establishment No. 6836-IL-1

Net Contents

MANUFACTURED BY:

LONZA INC., 22-10 Route 208, Fair Lawn, N.J. 07410

**For Sale For Use And Storage
By Maintenance Personnel Only**

It is a violation in manner incor

Apply BARDAC spray device to surface must surfaces must should be pre visibly dirty

Disinfection h Care Instituti tops bathing garbage pails

Add 3.5 oz. B previously u BARDAC-205 ghosa Staphy aureus in the by the AOAC

*Virucidal Pe Bardac-205M serum and f viruses Herp (Kong) on na

Disinfection oz of BARD

Fungicidal Pe use level BAF Trichophyton when used o dressing roo facilities, util

Disinfection as combs, br by immersing 7.5.

Disinfection Kennels. Po equipment a kennel areas applying a so of water Sm Prior to disinf feeds must b emptying all appliances f walls and oth or other am After disinfe closed spac employ equ or dried All treated water must b

The formula you are manufacturing is EPA registered, thus specifying by law the correct amounts of active ingredients to be present in your finished product. Therefore, the amounts and directions for the proper production of the formula given below must be followed explicitly.

The greatest accuracy in preparing this formulation is achieved when all ingredients are added by weight. If this is not possible, measure the liquids and weigh the solids.

The amounts given are for a production batch of 1,000 lbs. In order to produce larger or smaller batches, merely add multiples or fractions of the amounts listed.

The specific gravity/density of the ingredients required to correctly produce a 7.5% active Bardac 205M/208M dilution have been taken into account in the amounts given below:

**Bardac 205M/208M /7.5% Dilution
1,000 lb. batch**

Ingredients	Density lb./gal.	% wt/wt		If Addition is by Weight, add in lbs.		If Addition is by Volume, add in gallons	
		205M	208M	205M	208M	205M	208M
Bardac 205M	7.89	15.0	—	150.0	—	19.0	—
Bardac 208M	7.61	—	9.38	—	93.8	—	12.3
Water	8.34	85.0	90.62	850.0	906.2	101.92	108.66
Total	—	100.0	100.00	1,000.0	1,000.0	120.92	120.96

205M 208M

- Specific Gravity at room temperature of Bardac 205M/208M - 7.5% active dilution

0.987 0.985

- Density at room temperature of Bardac 205M/208M - 7.5% active dilution

8.23 8.21
lbs./gal lbs./gal.

Production Procedure for Bardac 205M/208M - 7.5% Active Dilution

- In a suitable blending vessel add together the water and Bardac 205M/208M. Mix for 45 minutes, making sure a clear, uniform solution has been achieved. Package

BEST AVAILABLE COPY