

JUN 20 2000

H & S Chemicals Division
 Lonza Inc.
 17-17 Route 208
 Fair Lawn, NJ 07410

ATTENTION: Wendy A. McCombie
 Agent for Lonza

SUBJECT: FMB 1210-5 QUAT
 EPA Registration Number 47371-27
 Amendment to Revise Label
 Your Amendment Dated: March 15, 2000
 EPA Received Date: March 23, 2000

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. The term "Germicide" is an end use claim and requires data to be submitted to the Agency for review. This claim would be supported by the end user or formulator and is not acceptable for the label of a Manufacturing Use Product. Replace "Germicide" with "Antimicrobial" as it appears on the label and the technical bulletin.

B. You have used the "cite-all" method to support the data requirements for this product. Based on this method of support, the following information from the Agency database is being used to determine the toxicity profile for this product. Most of this data is based on toxicity testing of Didecyl dimethyl ammonium chloride at 2500.

CONCURRENCES

SYMBOL	7510C						
SURNAME	W. J. ...						
DATE	6/20/00						

Acute Oral	III
Acute Dermal	III
Acute Inhalation	II
Primary Eye	I
Primary Skin	I
Dermal Sensitization	non-sensitizer

Based on this toxicity profile, revise your "Statement of Practical Treatment" to read exactly as follows:

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol."

Revise you "Precautionary Statements" exactly as follows:

"Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through the skin. Do not breath vapor or spray mist. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield, protective clothing and rubber gloves. Wear a respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P or HE prefilter. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse."

You may retain your "Note to Physician."

If you know of other data which can be used to support this product please resubmit and cite that data by MRID and we will re-evaluate this toxicity profile.

C. Add the following statement to the "Directions For Use" section of the label:
 "For Manufacturing Use Only."

3. Submit two (2) copies of your final printed labeling before you release the product for shipment.

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

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

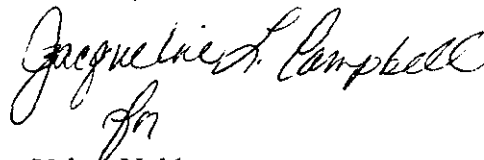
3/9

Currently, the Agency is developing a Manufacturing Use Product (MUP) labeling policy for end use sites. This label policy will require all MUP labels to list specific end-use sites for which end use materials/products may be reformulated. The Agency's position is that stating, as an example, "For use by manufacturers only in formulating microbiocides, disinfectants, sanitizers, fungicides, and water treatment microbicides", on an MUP label is too broad. The label should indicate what use patterns the active ingredient(s) are approved for formulation into end-use products. Also, the above example implies that the product is already approved for certain levels of antimicrobial activity (i.e disinfectant, sanitizer). However, it is the end-users responsibility to generate the appropriate data to prove that the end-use product is efficacious as a disinfectant, sanitizer, and/or fungicide. Once this policy is approved, you will be required to revise all of your MUP labels according to the policy.

When you begin to revise your MUP labels, you should change the formulation statement commonly found under the product name by stating "For Formulation into Antimicrobial Products." You will need to incorporate the use sites under the "Directions For Use" heading by revising the first part of the statement to state: "For Formulation into Antimicrobial Products for use In", then you should use Draft 40 CFR Part 158, Appendix B-Antimicrobial Product Use Sites and Categories as a referenced guide for examples of possible use sites. You should not be limited to the use sites listed in Appendix B. The Agency also recommends looking at your end-use product labels's use sites for assistance.

A stamped copy of the labeling is enclosed for your records. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



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

7510C:T.Lantz:6/20/00:47371-27a		CONCURRENCES					
SYMBOL							
SURNAME							
DATE							

4/9

CONTAINER LABEL

FMB 1210-5 QUAT

CONCENTRATED GERMICIDE
FOR FORMULATING DISINFECTANTS SANITIZERS, FUNGICIDES, WATER TREATMENT MICROBIOCIDES, SWIMMING POOL ALGAECIDES, OIL FIELD WATER FLOOD, SALT WATER DISPOSAL PRODUCTS, MILDEWCIDES AND WOOD PRESERVATIVES.

ACTIVE INGREDIENTS:	
n-alkyl (C ₁₄ -50%, C ₁₂ -40%, C ₁₆ -10%) dimethyl benzyl ammonium chloride	20.0%
didecyl dimethyl ammonium chloride	30.0%
INERT INGREDIENTS:	50.0%
TOTAL ACCEPTED	100.0%

with COMMENTS
in EPA Letter Dated:

**KEEP OUT OF REACH OF CHILDREN
DANGER**

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 20 2000

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

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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

Corrosive. Causes severe eye and skin damage. Do not get in eyes or on skin. Wash clothing before reuse. Wear goggles or face shield and rubber gloves when handling. Wash with soap and water after handling. Harmful or fatal if swallowed. Avoid contamination of food.

47371-27

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. 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.

ENVIRONMENTAL HAZARDS

This product 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 AND CHEMICAL HAZARDS

FMB 1210-5 QUAT is a cationic antimicrobial. Do not mix with soap or anionic materials. Do not use or store near heat or flame.

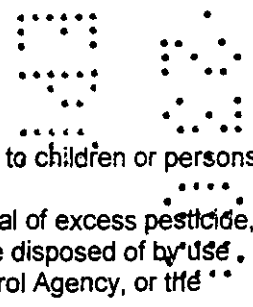
STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE:

This pesticide must be kept under locked storage sufficient to make it inaccessible to children or persons unfamiliar with its proper use. Do not re-use empty container.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these pesticides 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:

FIBER DRUMS WITH LINERS:

Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused dispose of in the same manner.

METAL CONTAINERS

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other approved state and local procedures.

DIRECTIONS FOR USE

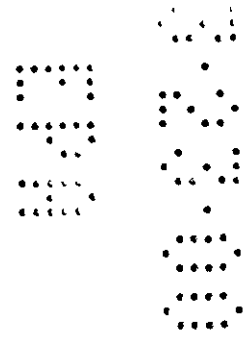
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Formulators using this product are responsible for providing data to EPA to support the registration of their formulated products. Refer to Technical Bulletin on FMB 1210 QUATs for information on formulation and other information.

EPA Reg.No.47371-27

EPA Est. No. 6836-IL-1

H&S Chemicals Division
c/o Lonza, Inc.
17-17 Route 208, Fair Lawn, NJ 07401



6/9

Technical Bulletin

FMB 1210 QUATs

CONCENTRATED GERMICIDES

For formulation of disinfectants, sanitizers, fungicides, water treatment microbicides, swimming pool algaecides, oil field water flood, salt water disposal products, mildewcides and wood preservatives.

FMB 1210 QUATs consist of an effective quaternary system of didecyl dimethyl ammonium chloride and n-alkyl (C₁₄-50%, C₁₂-40%, C₁₆-10%) dimethyl benzyl ammonium chloride. These multi-purpose quats provide you with an efficient disinfectant-sanitizer system.

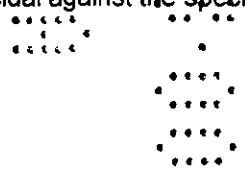
<u>Product Name</u>	FMB 1210-5 QUAT	FMB 1210-8 QUAT
EPA Registration Number	47371-27	47371-42
<u>Chemical Composition</u>		
Active Ingredients:		
Didecyl dimethyl ammonium chloride	30%	48%
n-Alkyl (C ₁₄ -50%, C ₁₂ -40%, C ₁₆ -10%) dimethyl benzyl ammonium chloride	20%	32%
Inert Ingredients:	50%	20%

The efficacy of these formulations containing FMB 1210 QUATs must be established by the utilization of appropriate procedures.

FMB 1210 QUATs are technical chemicals designed for formulation of germicides. For example, as disinfectant cleaners for use in hospitals and nursing homes; in schools, colleges and other public institutions; households; and poultry, dairy and swine farms.

FMB 1210 QUATs can be used for disinfecting hard, nonporous surfaces in 10 minutes with a recommended use solution of 450 ppm active quat for hospital use areas and with a recommended use solution of 250 ppm active quat for general use areas.

FMB 1210 QUATs are effective against the representative gram-positive pathogen *Staphylococcus aureus*, the representative gram-negative pathogen *Salmonella choleraesuis*, the representative hospital pathogen *Pseudomonas aeruginosa*, bactericidal against several gram-negative and gram-positive hospital pathogens, fungicidal against the following animal pathogens (*Aspergillus sp.*) and the following human pathogens (*Candida albicans* and *Trichophyton mentagrophytes*), and virucidal against the specific animal pathogens listed below in the presence of 5% organic serum.



Organism	ppm of Active Quat	No. of Carriers Tested
<i>Pseudomonas aeruginosa</i>	450 ppm	180
<i>Staphylococcus aureus</i>	250 ppm	180
<i>Salmonella choleraesuis</i>	250 ppm	180
<i>Escherichia coli</i>	250 ppm	20
<i>Salmonella typhi</i>	150 ppm	20
<i>Serratia marcescens</i>	250 ppm	20
<i>Klebsiella pneumoniae</i>	250 ppm	20
<i>Streptococcus pyogenes</i>	250 ppm	20
<i>Shigella flexneri</i>	250 ppm	20
<i>Proteus mirabilis</i>	150 ppm	20
<i>Staphylococcus aureus</i> phage 80	250 ppm	20
<i>Staphylococcus aureus</i> phage 81	250 ppm	20
<i>Enterobacter aerogenes</i>	250 ppm	20
<i>Mycoplasma gallisepticum</i>	250 ppm	20
<u>Fungicidal</u>		
<i>Aspergillus flavus</i>	250 ppm	
<i>Aspergillus fumigatus</i>	250 ppm	
<i>Aspergillus glaucus</i>	250 ppm	
<i>Candida albicans</i>	250 ppm	
<i>Trichophyton mentagrophytes</i>	250 ppm	
<u>Virucidal</u>		
Bovine Rhinotracheitis virus	450 ppm	
Bronchitis virus	450 ppm	
Newcastle virus	450 ppm	
<u>Sanitizer</u>		
<i>Staphylococcus aureus</i>	150 ppm	
<i>Escherichia coli</i>	150 ppm	

HOSPITAL DISINFECTION	450 ppm quat
GENERAL OR HOUSEHOLD DISINFECTION	250 ppm quat
SANITIZATION	150 ppm quat

FMB 1210 QUATs are effective against *Staphylococcus aureus* and *E. coli* as a sanitizer in 800 ppm hard water as tested by the A.O.A.C Germicidal and Detergent - Sanitizer Method at 150 ppm quat. FMB 1210 QUATs fulfill the criteria of Appendix F of the Grade A Pasteurized Milk Ordinance 1978 Recommendation of the U.S. Public Health Service.

FMB 1210 QUAT formulations are recommended for use in plants operating under the USDA Poultry, Meat, Rabbit, Shell Egg Grading, and Egg Products Inspection Programs. FMB 1210 QUATs can be used as a sanitizer on all surfaces not always requiring a rinse. Before using this compound, food products and packaging materials must be removed from the room or carefully protected. For use on food contact surfaces, do not rinse with potable water.

FMB 1210 QUATs can be used to sanitize previously cleaned and rinsed dishes, silverware, glasses, and other food utensils at 150 ppm active. FMB 1210 QUATs can be used on food contact surfaces in public eating places. When used on food contact surfaces, do not rinse with potable water.

Food eggs that have been sanitized with FMB 1210 QUATs shall be subjected to a thorough potable water rinse only if they are broken when used in the manufacture of egg products.

FMB 1210 QUATs can be used to wash the udders, flanks, and teats of dairy cows. Do not rinse with potable water. Use a fresh towel for each cow. Avoid contamination of wash solution by dirt and soil. Do not dip towel back into wash solution. When solution becomes visibly dirty, discard and provide fresh solution.

FMB 1210 QUATs can be used to control algae and bacterial slimes. For best results, slug feed. The frequency of addition of microbicide needed depends on many factors. The following are examples of Directions for Use:

RECIRCULATING COOLING TOWERS

1. Initially use 6 fluid ounces per 1,000 gallons of water to be treated (20 ppm active quaternary) Should the above dosage not give satisfactory results, use 9 fluid ounces per 1,000 gallons of water Repeat the initial dose every seven days or increase the frequency if needed.
2. When the above treatment level is successful, use 2 to 3 fluid ounces per 1,000 gallons of water to maximize efficiency. Repeat weekly as needed. Should slime develop again, go back to initial dosage.

Cooling tower waters that are inherently low in algae growth and bacteria count may be adequately controlled by the lower range of these dosages, slug fed every seven days. Dilute the appropriate amount of FMB 1210 QUAT in 1 or 2 gallons of water, then add to the tower. Should tower be heavily fouled, a precleaning is required

OIL FIELD WATER FLOOD OR SALT WATER DISPOSAL SYSTEMS:

(Do not apply in Marine and Estuarine Oil Fields.)

1. For the control of slime forming and sulfate reducing bacteria in oilfield water flood or salt water disposal systems, add 5-10 ppm active) FMB 1210 QUAT (1½ - 3 gallons per 3,000 barrels of water) continuously. Levels for effective control will vary depending on conditions at the site.
2. For intermittent use, dose at a rate of 5-20 ppm (active) FMB 1210 QUAT (1½ - 6 gallons per 3,000 barrels of water) for 4-8 hours per day, one to four times a week as needed to maintain control

WOOD PRESERVATIVES:

FMB 1210 QUATs are concentrated biocides for use as a wood preservative. When used as directed FMB 1210 QUATs will protect treated wood articles from the destructive attack of fungi, mold and mildew. Treatment can be done by pressure or double vacuum. Wood articles that will be protected by these treatments would include millwork, construction timbers, decking, wood shingles, posts and other articles to be used in above ground applications.

Dilute FMB 1210 QUAT in either water or mineral spirits to produce a 0.5% to 3.0% active quaternary ammonium compound (DDAC/ADBAC) solution. This formulation can be used for both pressure and double vacuum treatment.

Pressure Treatment: Place the wood article to be treated into the pressure cylinder and seal unit. Treat the wooden articles using the pressure treatment procedures consistent with the equipment being used and standard treatment practices. Treatment conditions should be as such as to produce a 0.1 to 0.6 lb./ft³ retention in the treated article. Such treated wood is to be used for above ground uses only.

Double Vacuum: Stack the wooden articles to be treated in the treatment vessels so that the preservative solution will have access to all sides of the articles. Seal the vessel. Reduce the pressure within the vessel to -10 inches for five (5) minutes. Cover all the articles with preservative solution. Allow the pressure to return to atmospheric conditions and discharge the preservative solution. Reduce the

9/9

pressure to -20 inches and maintain for 20 minutes. Allow pressure to return to atmospheric and remove treated wooden articles. Treatment conditions should be as such as to produce a 0.1 to 0.6 lb./ft³ retention of DDAC/ADBAC in the treated article. Wood treated to this retention is suitable for above-ground use only.

Sap Stain Control: For control of mold and fungus on green or freshly cut lumber. May be used in dip or spray application. Before use, dilute at a rate of 1 gallon of FMB 1210 QUAT per 25 -100 gallons of water. Seasonal variation in storage and shipping conditions, species and condition of wood should be considered in selection of end-use concentration. For effective inhibition of mold and fungus, lumber and logs must be dipped or sprayed in a manner that ensures that all surfaces are uniformly treated. For best results, green wood should be treated immediately, at least within 24 hours after cutting or sawing. Mold and fungus growth begins immediately after cutting so delayed treatment is much less effective and requires increased chemical concentration. Green untreated lumber should not be used for stickers. Freshly treated lumber should not be allowed to remain unprotected in heavy rains. Dip tanks and dip aprons must be roofed, paved and drained to prevent dilution and loss of anti-stain solution.

Add FMB 1210 QUATs directly from the drum with the proper type of metering equipment.

Formulators using this product are responsible for EPA registration for their formulated products. For technical service and registration assistance, contact Lonza Inc. at 201-794-2400.

DANGER: CORROSIVE: Causes severe eye and skin damage. Do not get in eyes or on skin. Wash contaminated clothing before reuse. Wear goggles or face shield and rubber gloves when handling this product. Harmful or fatal if swallowed. Avoid contamination of food.

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. 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

Consult the label for other instructions and precautionary statements before use of FMB 1210 QUATs

FMB 1210-5 QUAT	EPA Reg. No. 47371-27
FMB 1210-8 QUAT	EPA Reg. No. 47371-42

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