

FEB 10 1997

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

Subject: FMB 1210-8 QUAT
EPA Registration No. 47371-42
Your Application of December 10, 1996

Attn: Joseph R. Robinson, Lonza, Inc.
Director, Regulatory and Technical Affairs

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, subject to the following comment.

1. Revise the ingredient statement so that the active ingredients equal 100%.

The ingredient section should declare:

Active Ingredients:
n-alkyl (C14 50%, C12 40%, C16 10%)dimethylbenzyl
ammonium chloride.....32%
didecyl dimethyl ammonium chloride.....48%
Inert Ingredients.....20%
Total100%

A stamped copy is enclosed for your records. Submit one (1) copy of the finished printed label before this product is released for shipment.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

2/17

If you have any questions about the comments in this letter, you should contact Drusilla Copeland at (703) 305-6244.

Sincerely,

WJ

for

Marion M. Johnson
Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

Enclosure

30/7

Strikethrough = Deleted Text
Highlighted = Added Text



Huntington®

FMB 1210-8 QUAT

concentrated germicide

FOR FORMULATING DISINFECTANTS, SANITIZERS, FUNGICIDES, WATER TREATMENT MICROBICIDES, SWIMMING POOL ALGAEICIDES, OIL FIELD WATER FLOOD, SALT WATER DISPOSAL PRODUCTS, AND MILDEWICIDES.

ACTIVE INGREDIENTS:

n-alkyl (C14 50%, C12 40%, C18 10%) dimethyl benzyl ammonium chloride.....	21.0%
dioctyl dimethyl ammonium chloride.....	48.0%
INERT INGREDIENTS.....	20.0%

DANGER: KEEP OUT OF REACH OF CHILDREN

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.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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. Wash thoroughly with soap and water after handling. Harmful or fatal if swallowed. Avoid contamination of food.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge into lakes, streams, ponds or public waters unless in accordance with an NPDES permit. For guidance, contact your Regional Office of the Environmental Protection Agency. 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 Environmental Protection Agency.

PHYSICAL AND CHEMICAL HAZARDS

FMB 1210-8 is a cationic germicide. Do not mix with soap or anionic materials. Do not use or store near heat or flame.

STORAGE AND DISPOSAL

This pesticide must be kept under locked storage sufficient to make it inaccessible to children or persons unfamiliar with its proper use. Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse 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 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.

INSTRUCTIONS FOR FORMULATION

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 1210-8 QUAT for instructions on formulation and other information.

EPA REG. NO. 47371-42 EPA EST. NO. 47371-1N-01
H&S CHEMICALS DIVISION
970 EAST TIPTON, HUNTINGTON, IN 46750 (219) 356-8100

HL-11891-PS-061693

REC'D
DEC 11 11:12
MUPD1

ACCEPTED
WITH COMMENTS
BY EPA Letter dated

FEB 10 1997

Under the provisions of the
Pesticide and Insecticide
Act, amended by the
FIFRA Act of 1972, the
EPA is hereby notified that
47371-42

ACCEPTED 4087
EPA Reg. No. 47371-42

FMB 1210 QUATS

FEB 10 1997

Concentrated Germicides

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

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

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

Our Quality Control program consists of checking each and every batch made, chemically and microbiologically, to insure the customer that every batch meets our rigid specifications.

<u>Product Name</u>	FMB 1210-5	FMB 1210-8
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%

Products containing quaternary ammonium compounds that are shipped in interstate commerce must be registered with the Environmental Protection Agency. The efficacy of these formulations containing FMB 1210 Quats must be established by the utilization of the appropriate procedures. The Chemicals Division of Huntington Laboratories can assist you with registration of your product.

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

FMB 1210 Quats are for disinfecting precleaned hard, non-porous 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.

The 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,

970 East Tipton, Huntington, Indiana 46750 219/356-8100

BEST AVAILABLE COPY

507

fungicidal against animal pathogens (Aspergillus sp.) and human pathogens (Candida albicans and Trichophyton interdigitale), and virucidal against animal pathogens in the presence of 5% organic serum.

<u>Organism</u>	<u>ppm of Active Quat</u>	<u>No. of Carriers Tested</u>
Pseudomonas aeruginosa	450 ppm	180
Staphylococcus aureus	250 ppm	180
Salmonella choleraesuis	250 ppm	180
Escherichia coli	250 ppm	20
Salmonella typhi	250 ppm	20
Serratia marcescens	250 ppm	20
Klebsiella pneumoniae	250 ppm	20
Streptococcus pyogenes	250 ppm	20
Shigella flexneri	250 ppm	20
Proteus mirabilis	250 ppm	20
Staphylococcus aureus phage 80	250 ppm	20
Staphylococcus aureus phage 81	250 ppm	20
Enterobacter aerogenes	250 ppm	20
Mycoplasma gallisepticum	250 ppm	20

Fungicidal

Aspergillus flavus	250 ppm
Aspergillus fumigatus	250 ppm
Aspergillus glaucus	250 ppm
Candida albicans	250 ppm
Trichophyton interdigitale	250 ppm

Virucidal

*Bovine Rhinotracheitis virus	450 ppm
*Bronchitis virus	450 ppm
*Newcastle virus	450 ppm

Sanitizer

Staphylococcus aureus	150 ppm
Escherichia coli	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.

ACCEPTED
with COMMENTS
in EPA Letter Dated

FEB 10 1997

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

47371-72

BEST AVAILABLE COPY

FMB 1210 Quat formulations are for use in plants operating under the USDA Poultry, Meat, Rabbit, Shell Egg Grading, and Egg Products Inspection Programs. FMB 1210 Quat is for use 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.

Authorization for the use of a formulated product in USDA inspected meat, poultry, and food processing plants must be obtained by the formulators from USDA.

FMB 1210 Quats are for use sanitizing previously cleaned and rinsed dishes, silverware, glasses, and other food utensils at 150 ppm active. FMB 1210 Quats may be used on food contact surfaces in public eating places. For use on food contact surfaces, do not rinse with potable water.

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

FMB 1210 Quats are for use 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 control algae and bacterial slimes, use FMB 1210 as directed. For best results, slug feed. The frequency of addition of microbicide needed depends on many factors. The following are examples of acceptable 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 in 1 or 2 gallons of water, then add to the tower. Should tower be heavily fouled, a precleaning is required.

ACCEPTED
with COMMENTS
in EPA Letter Report

FEB 10 1997

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

49371-92

BEST AVAILABLE COPY

7017

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 (1-1/2 - 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 (1-1/2 - 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.

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

Formulators using this product are responsible for EPA registration and USDA authorization for their formulated products. For technical service and registration assistance, contact H&S Chemicals Division at 219/356-8100. A complete registration package is available upon request.

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.

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.

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

H&S Chemicals Division
970 East Tipton Street
Huntington, Indiana 46750
219/356-8100

ACCEPTED
with CONCERN
to EPA Letter D-116

HS-I

FEB 10 1997

BEST AVAILABLE COPY

This is a true and correct
duplicate and reproduction of the
original as the same was
registered under EPA Reg. No.
47371-42