

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 28 1992

Mr. Richard D. Sheets
H & S Chemicals Division
970 East Tipton Street
Huntington, IN 46750

Dear Mr. Sheets:

Subject: Application for Amended Registration - Add Wood Uses
FMB 210-15 Quat Concentrated Germicide
EPA Registration No. 47371-23
Amendment dated October 23, 1990

The amendment referred to above, submitted in connection with registration under the Federal insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable provided that you:

1. Make the following changes listed below to technical bulletin referenced on the product label before you release the product for shipment bearing the amended labeling:

a. Under chemical composition in the bulletin, delete the reference to isopropanol since neither product contains this chemical.

b. The directions for use relating to sapstain control and wood preservatives are confusing in that directions appear to be for end-use of the product rather than formulating use. To clarify, the labeling/bulletin should be revised as follows:

i) For sapstain, revise the first two sentences to: "Formulation of Sapstain Control Products: Product formulated for the control of mold and fungus on green or freshly cut lumber may be used as a dip or spray application as directed on the product labels. Labeling should address the following factors."

ii) For wood preservatives, revise the first sentence to: "Formulation of Wood Preservative Products: Products to be formulated for protection against rot and decay of soft woods and exterior woods such as fence rails, porch rails, siding and all

CONCURRENCES

SYMBOL	H7505C						
SURNAME	Shelton						
DATE	9/15/92						

above ground wood and lumber must be used at appropriate concentrations." (Note that fence posts must be deleted since this is considered a ground contact use.) Revise the third sentence to "Formulated products are not-----."

2. Submit one (1) copy of your final printed labeling before you release the product for shipment.

A stamped copy of the label is enclosed for your records.

Sincerely yours,

Cynthia Giles-Parker
Product Manager (22)
Fungicide-Herbicide Branch
Registration Division (H7505C)

Enclosure

with GENE...
In EPA Reg. No. 47371-23

SEP 10 1984

Under the Federal Insecticide
Fungicide and Fertilizer Act
Registration No. 47371-23

47371-23

Huntington

FMB 210-15 QUAT concentrated germicide

FOR FORMULATION OF DISINFECTANTS, SANITIZERS, FUNGICIDES, WATER TREATMENT MICROBICIDES,
SWIMMING POOL ALGACIDES AND MILDICIDES, WOOD PRESERVATIVES & SAPSTAIN CONTROLS

ACTIVE INGREDIENTS:	
Didcyl Dimethyl Ammonium Chloride	80.0%
INERT INGREDIENTS	80.0%
Total	100.0%

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

HAZARDOUS 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 the concentrate. Harmful or fatal if swallowed. Avoid contamination of food.

ENVIRONMENTAL HAZARDS

This product 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.

PHYSICAL AND CHEMICAL HAZARDS

FMB 210-15 is a caustic germicide. Do not mix with soap or acidic materials. Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

This product must be kept under locked storage sufficient to make it impossible 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 residue 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

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 procedures approved by state and local authorities.

INSTRUCTIONS FOR FORMULATION

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 obtaining EPA registration for their formulated products. Refer to technical bulletin for FMB 210 Quats for instructions for formulations and other information.

EPA REG. NO. 47371-23

EPA EST. NO. 47371-01-01

HS-4

870 EAST TIPTON

HLS CHEMICALS DIVISION
HUNTINGTON, IN 46766

219/296-8100

TEST COPY

FMB 210 QUAT

FMB 210 Quat series are designed for formulation of disinfectants, sanitizers, fungicides, water treatment microbicides, mildewcides, and swimming pool algaecides. FMB 210 Quats consist of a powerful quaternary system of didecyl dimethyl ammonium chlorides. This multi-purpose quat provides 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>Chemical Composition</u>	<u>FMB 210-15</u>	<u>FMB 210-25</u>	<u>FMB 210-8</u>
EPA Registration Number	47371-23	47371-24	47371-47
Active Ingredients:			
didecyl dimethyl ammonium chloride	50%	50%	80%
Inert Ingredients:			
isopropanol	X	20%	X
ethanol	10%	X	12.5%
Water	40%	30%	7.5%

The FMB 210 Quats are effective against the representative gram-positive pathogen *Staphylococcus aureus*, the representative gram-negative pathogen *Salmonella choleraesuis*, and the representative hospital pathogen *Pseudomonas aeruginosa* in the presence of 5% organic serum.

FMB 210 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 and households.

FMB 210 Quats are for disinfecting pre-cleaned hard, non-porous surfaces in 10 minutes with a recommended use solution of 500 ppm active quat for hospital use areas and with a recommended use solution of 400 ppm active quat for general use areas.

<u>Organism</u>	<u>FMB Quat</u>	<u>No. of Positives</u>	<u>No. of Carriers Tested</u>
<i>Pseudomonas aeruginosa</i>	500 ppm	0	180
<i>Staphylococcus aureus</i>	400 ppm	0	180
<i>Salmonella choleraesuis</i>	300 ppm	0	180

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HOSPITAL DISINFECTION	500 ppm quat
GENERAL OR HOUSEHOLD DISINFECTION	400 ppm quat
SANITIZATION.	150 ppm quat

FMB 210 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. In addition to use on food processing equipment and utensils, FMB 210 Quats may be used on food-contact surfaces in public eating places.

FMB 210 Quats are designed for formulation of sanitizer-cleaners for use in restaurants and bars, dietary areas, farms, federally inspected meat and poultry processing plants, and food processing plants such as:

FMB 210 Quats sanitize precleaned food contact surfaces in one minute with the recommended use solution diluted in water up to 800 ppm water hardness (calculated as CaCO₃) at 150 ppm active quat. FMB 210 Quats are in compliance with 21 CFR §178.1010 (b)(17) and (c)(12).

For use in plants operating under the federally inspected Poultry, Meat, Rabbit, Shell Egg Grading, and Egg Products Inspection Programs. FMB 210 Quats are for use as a sanitizer on all surfaces not always requiring a rinse. Before using these compounds, food products and packaging materials must be removed from the room or carefully protected. A potable water rinse is not required following use of these compounds on previously cleaned hard surfaces provided that the surfaces are adequately drained before contact with food so that little or no residue remains which can adulterate or have deleterious effect on edible products. A potable water rinse is required following use of these compounds under conditions other than those stated above.

For use sanitizing dishes, silverware, glasses, and other food utensils at 150 ppm active. FMB 210 Quats may be used on food contact surfaces in public eating places. Do not rinse with potable water.

Food eggs that have been sanitized with FMB 210 Quat shall be subjected to a thorough potable water rinse only if they are to be immediately broken for use in the manufacture of egg products.

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 210 Quats have been tested for ten different nitrosamines including n-nitrosodiethanolamine (NDEL). It was determined that the FMB 210 Quats contained less than 100 parts per billion (ppb) for nine nitrosamines and 20 ppb for nitrosodimethylamine (NDMA).

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Formulators using this product are responsible for EPA registration, FDA, 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 210 Quats.

TOXICITY TEST RESULTS

Eye Irritation Test: corrosive irritant
Primary Skin Irritation: severe, corrosive irritant
Acute Dermal LD₅₀ = 1.8 ml./kg.
Acute Oral LD₅₀ = 0.065 ml./kg.
Acute Inhalation = 7.5 mcl./li./hr.

FMB 210-15 Quat	EPA Reg. No. 47371-23
FMB 210-25 Quat	EPA Reg. No. 47371-24
FMB 210-8 Quat	EPA Reg. No. 47371-47

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219/356-8100

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