

04 FEB 1985

W & S Chemicals, Div.
Div. of Huntington Labs., Inc.
970 E. Tipton St.
Huntington, IN 46750

BEST AVAILABLE COPY

Attention: Mr. Richard D. Sheets

Gentlemen:

Subject: FMS 451-5 Gant
EPA Registration No. 47371-11
FMS 451-8 Gant
EPA Registration No. 47371-10
FMS 451-15 Gant
EPA Registration No. 47371-17
FMS 451-20 Gant
EPA Registration No. 47371-18✓
Your Application Dated October 18, 1984
EPA Received Dated October 24, 1984

The Brochure referred to above, submitted in connection with registration under FIFRA is acceptable provided that you:

1. Submit five (5) copies of your final printed labeling before you release the product for shipment.

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


At the next printing of the Brochure, in paragraph 1, pg. 2, replace the word "sanitizer" with the word "wash" in the sentence "for use to wash the walls, flanks...."

CONCURRENCES

BY							
DATE							

Submit, for your file, a copy of "Authorizations for these products issued November 26, 1982," referred to in the USDA letter of February 22, 1983, copy attached.

Sincerely yours,


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

Enclosure

JOB-91005:Miller:Kendrick & Co.:898-1270:tar:C.Disk:1/31/85:del.2/11/85

FMB 451 QUAT

concentrated germicide

FMB 451 Quat series are designed for formulation of disinfectants, sanitizers, fungicides, water treatment microbicides, swimming pool algaecides, mildewcides, oil field water flood and salt water disposal products. FMB 451 Quats consist of an effective system of alkyl dimethyl benzyl ammonium chlorides. The multi-purpose quats provide you with an efficient chemical for formulation of disinfectant-sanitizers.

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 451-5</u>	<u>FMB 451-8</u>	<u>FMB 451-15</u>	<u>FMB 451-28</u>
EPA Registration Number	47371-11	47371-13	47371-17	47371-18

Active Ingredients:

n-Alkyl (C₁₄ 50%, C₁₂ 40%, C₁₆ 10%) dimethyl benzyl ammonium chloride

ACCEPTED
with COMMENTS
in EPA Letter Dated:

50% 80%
FEB 04 1985

Inert Ingredients:

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

47371-18

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

The FMB 451 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*.

FMB 451 Quats are designed for formulation of germicides. For example, disinfectant cleaners in hospitals and nursing homes, as disinfectant cleaners for use in schools and colleges, hotels and motels, office buildings, households, medical and dental offices, veterinary clinics, dairy and poultry farms.

FMB 451 Quats are for disinfecting precleaned hard, non-porous surfaces in 10 minutes with a recommended use solution of 800 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>	800 ppm	0	180
<i>Staphylococcus aureus</i>	400 ppm	0	180
<i>Salmonella choleraesuis</i>	400 ppm	0	180

HOSPITAL DISINFECTION	800 ppm quat
GENERAL OR HOUSEHOLD DISINFECTION	400 ppm quat
SANITIZATION.	200 ppm quat

FMB 451 Quats are effective against *Staphylococcus aureus* and *E. coli* as a sanitizer in 750 ppm hard water as tested by the A.O.A.C. Germicidal and Detergent-Sanitizer Method at 200 ppm quat. In addition to use on food processing equipment and utensils, FMB 451 Quats may be used on food-contact surfaces in public eating places.

FMB 451 Quats sanitize precleaned food contact surfaces in one minute with the recommended use solution diluted in water up to 750 ppm water hardness (calculated as CaCO_3) at 200 ppm active quat. FMB 451 Quats are in compliance with 21 CFR §178.1010 (b)(9) and (c)(6).

FMB 451 Quats are designed for formulation of sanitizer-cleaners for use in restaurants and bars, dietary areas, dairy and poultry farms, federally inspected meat and poultry processing plants, and food processing plants such as:

For use in plants operating under federally inspected Poultry, Meat, Rabbit, Shell Egg Grading, and Egg Products Inspection Programs. FMB 451 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 200 ppm active. FMB 451 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 451 Quat shall be subjected to a thorough potable water rinse only if they are broken for use in the manufacture of egg products.

For use to sanitize the udders, flanks, and teats of dairy cows. Do not rinse with potable water. Use a fresh towel for each cow. Avoid contamination of sanitizing solution by dirt and soil. Do not dip towel back into sanitizing solution. When solution becomes visibly dirty, discard and provide fresh solution.

FMB 451 Quats have been tested for ten different nitrosamines including n-nitrosodichloroamine (NDEL). It was determined that the FMB 451 Quats contained less than 20 parts per billion (ppb) NDEL and for the other nine nitrosamines FMB 451 Quats contained less than 200 ppb.

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.

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

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. Harmful or fatal if swallowed. Avoid contamination of food.

STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes with plenty of water for 15 minutes. Call a physician immediately. In case of contact, wash skin thoroughly with soap and water after handling. Call a physician immediately. 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 451 Quats.

TOXICITY TEST RESULTS

Eye Irritation: corrosive irritant
Primary Skin Irritation: severe, corrosive irritant
Acute Dermal LD₅₀ = 0.8 ml./kg.
Acute Oral LD₅₀ = 0.46 ml./kg.

FMB 451-5 Quat	EPA Reg. No. 47371-11
FMB 451-8 Quat	EPA Reg. No. 47371-10
FMB 451-15 Quat	EPA Reg. No. 47371-17
FMB 451-28 Quat	EPA Reg. No. 47371-18

ACCEPTED
with COMMENTS
by EPA Letter Dated:

FEB 04 1985

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

47371-18

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

