

# FMB 4500 QUAT

FMB 4500 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 4500 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 4500-5</u>	<u>FMB 4500-8</u>	<u>FMB 4500-28</u>
EPA Registration Number	47371-16	47371-12	47371-22

**Active Ingredients:**

n-Alkyl (C<sub>14</sub> 60%, C<sub>16</sub> 30%, C<sub>12</sub> 5%,  
C<sub>18</sub> 5%) dimethyl benzyl ammonium  
chloride  
ethanol

50%  
10%

80%  
12.5%

80%  
20%

**Inert Ingredients:**

Water

40%

7.5%

X

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

The FMB 4500 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 4500 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 4500 Quats are effective in disinfecting precleaned hard, non-porous surfaces in 10 minutes with a recommended use solution of 550 ppm active quat for hospital use areas and with a recommended use solution of 400 ppm active quat for general use areas.

NOT REVIEWED  
In Accordance with PR Notice 82-20  
Based on Draft Labeling Dated  
AUG 05 1983

<u>Organism</u>	<u>FMB Quat</u>	<u>No. of Positives</u>	<u>No. of Carriers Tested</u>
Psudomonas aeruginosa	550 ppm	0	180
Staphylococcus aureus	400 ppm	0	180
Salmonella choleraesuis	400 ppm	0	180

HOSPITAL DISINFECTION . . . . . 550 ppm quat  
GENERAL OR HOUSEHOLD DISINFECTION . . . . . 400 ppm quat  
SANITIZATION. . . . . 200 ppm quat

FMB 4500 Quats are effective against Staphylococcus aureus and E. coli as a sanitizer in 550 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 4500 Quats may be used on food-contact surfaces in public eating places.

FMB 4500 Quats sanitize precleaned food contact surfaces in one minute with the recommended use solution diluted in water up to 550 ppm water hardness (calculated as CaCO<sub>3</sub>) at 200 ppm active quat. FMB 4500 Quats are in compliance with 21 CFR §178.1010 (b)(9) and (c)(6).

FMB 4500 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 4500 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.

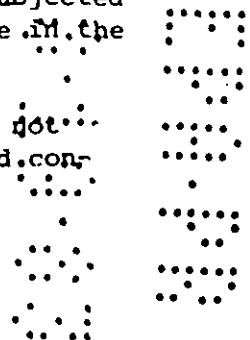
For use in sanitizing dishes, silverware, glasses, and other food utensils at 200 ppm active quat. FMB 4500 Quats may be used on food contact surfaces in public eating places. Do not rinse with potable water.

Food eggs that have been sanitized with FMB 4500 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 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.

NOT REVIEWED  
In Accordance with PR Notice 82-2,  
based on Draft Labeling Dated

AUG 05 1983



FMB 4500 Quats have been tested for ten different nitrosamines including n-nitrosodiethanolamine (NDEL). It was determined that the FMB 4500 Quats contained less than 20 parts per billion (ppb) and for the other nine nitrosamines FMB 4500 Quats contained less than 100 ppb.

Formulators using this product are responsible for EPA registration for their formulated products. For technical service and registration assistance, contact the 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 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 4500 Quats.

FMB 4500-5 Quat	EPA Reg. No. 47371-16
FMB 4500-8 Quat	EPA Reg. No. 47371-12
FMB 4500-28 Quat	EPA Reg. No. 47371-22

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

NOT REVIEWED  
 In Accordance with PR Notice 82-2.  
 Based on Draft Labeling Dated

AUG 0 1 1983

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177.31  
47371-12  
427  
M & S Chemicals Division  
Div. of Huntington Laboratories, Inc.  
976 E. Tipton St.  
Huntington, IN 46750

05 AUG 1983

Attention: Mr. Richard D. Sheets

Gentlemen:

Subject: FME 4500-6 Quat  
EPA Registration No. 47371-12 ✓  
FME 4500-5 Quat  
EPA Registration No. 47371-16  
FME 4500-26 Quat  
EPA Registration No. 47371-22  
Submission Dated June 6, 1983

The Technical Bulletin (FME 4500 Quat) submitted in connection with registration under FIFRA is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:
  - a. In paragraph 7, page 2, replace the words "Sanitize" and "Sanitizing" with the word "wash."
2. 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. 4(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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

Sincerely yours,



John E. Lee  
Product Manager (31)  
Disinfectants Branch  
Registration Division (TL-767C)

Enclosure

BIS:J Lee:DCR-18390:VANC-0059C:LM:kaven:479-2013:7/22/83

CONCURRENCES

SYMBOL	SURNAME	DATE						

# FMB 4500 QUAT

FMB 4500 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 4500 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 4500-5</u>	<u>FMB 4500-8</u>	<u>FMB 4500-28</u>
EPA Registration Number	47371-16	47371-12	47371-22

**Active Ingredients:**

n-Alkyl (C <sub>14</sub> 60%, C <sub>16</sub> 30%, C <sub>12</sub> 5%, C <sub>18</sub> 5%) dimethyl benzyl ammonium chloride	50%	80%	80%
ethanol	10%	12.5%	20%

**Inert Ingredients:**

Water	40%	7.5%	X
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It is a violation of federal law to use this product in a manner inconsistent with its labeling.

The FMB 4500 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 4500 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 4500 Quats are effective in disinfecting precleaned hard, non-porous surfaces in 10 minutes with a recommended use solution of 550 ppm active quat for hospital use areas and with a recommended use solution of 400 ppm active quat for general use areas.

**ACCEPTED**  
with COMMENTS  
in EPA Letter Dated:

**AUG 05 1983**

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

47371-12

<u>Organism</u>	<u>FMB Quat</u>	<u>No. of Positives</u>	<u>No. of Carriers Tested</u>
Pseudomonas aeruginosa	550 ppm	0	180
Staphylococcus aureus	400 ppm	0	180
Salmonella choleraesuis	400 ppm	0	180

HOSPITAL DISINFECTION . . . . . 550 ppm quat  
GENERAL OR HOUSEHOLD DISINFECTION . . . . . 400 ppm quat  
SANITIZATION. . . . . 200 ppm quat

FMB 4500 Quats are effective against Staphylococcus aureus and E. coli as a sanitizer in 550 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 4500 Quats may be used on food-contact surfaces in public eating places.

FMB 4500 Quats sanitize precleaned food contact surfaces in one minute with the recommended use solution diluted in water up to 550 ppm water hardness (calculated as CaCO<sub>3</sub>) at 200 ppm active quat. FMB 4500 Quats are in compliance with 21 CFR §178.1010 (b) (9) and (c) (6).

FMB 4500 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 4500 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 in sanitizing dishes, silverware, glasses, and other food utensils at 200 ppm active quat. FMB 4500 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 4500 Quat shall be subjected to a thorough potable water rinse only if they are broken for use in the manufacture of egg products.

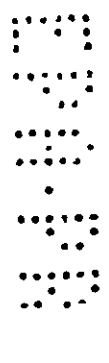
For use to sanitize the udders, flanks, and teats of dairy cows. Do not rinse with potable water. Use a fresh towel for each cow. Avoid contamination of sanitizing solution by dirt and soil. Do not dip towel back into sanitizing solution. When solution becomes visibly dirty, discard and provide fresh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

ACCEPTED  
with COMMENTS  
In EPA Letter Dated

AUG 05 1983

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

47371-12



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FMB 4500 Quats have been tested for ten different nitrosamines including n-nitrosodiethanolamine (NDEL). It was determined that the FMB 4500 Quats contained less than 20 parts per billion (ppb) and for the other nine nitrosamines FMB 4500 Quats contained less than 100 ppb.

Formulators using this product are responsible for EPA registration for their formulated products. For technical service and registration assistance, contact the 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 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 4500 Quats.

FMB 4500-5 Quat	EPA Reg. No. 47371-16
FMB 4500-8 Quat	EPA Reg. No. 47371-12
FMB 4500-28 Quat	EPA Reg. No. 47371-22

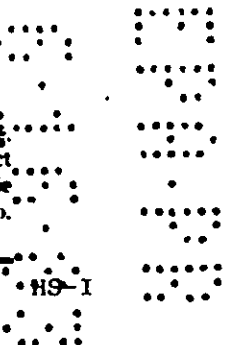
H&S Chemicals Division  
970 East Tipton Street  
Huntington, Indiana 46750  
219/356-8100

**ACCEPTED**  
with **COMMENTS**  
in EPA Letter Dated:

**AUG 05 1983**

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

47371-12



HS-I

our quality control procedures to test every kind and every batch microbially and chemically to assure the customer that every batch meets our high standards.

	FMB 4500-5	FMB 4500-8
Chemical Concentration	4500-5	4500-8
EPA Registration Number	47371-10	47371-12

Active Ingredients:

n-Alkyl (C <sub>12</sub> , 60%, C <sub>14</sub> , 20%, C <sub>12</sub> , 5%, C <sub>18</sub> , 15%) Quaternary Ammonium chloride	50%	80%
ethanol	10%	12.5%

Inert Ingredients:

Water	40%	7.5%
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It is a violation of federal law to use this product in a manner inconsistent with its labeling.

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FMB 4500 Quats are designed for formulation of germicides. For example, infectant cleaners in hospitals and nursing homes, as disinfectant cleaners for use in schools and colleges, hotels and motels, office buildings, holds, medical and dental offices, veterinary clinics, dairy and poultry

FMB 4500 Quats are effective in disinfecting pre-cleaned hard, non-porous surfaces in 10 minutes with a recommended use solution of 550 ppm active for hospital use areas and with a recommended use solution of 400 ppm active quat for general use areas.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

AUG 05 1983

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

47371-10





Product	FMB No.	No. of Registries	No. of Carriers Listed
1. FMB 4500 Quat	4500	1	100
2. FMB 4500 Quat	4500	0	100
3. FMB 4500 Quat	4500	0	10
FMB 4500 Quat			500 per quat
FMB 4500 Quat			400 per quat
FMB 4500 Quat			200 per quat

FMB 4500 Quat is a sanitizer for use on all surfaces and is effective against *Salmonella*, *Shigella*, *Staphylococcus aureus*, and *Escherichia coli* as a sanitizer for use on all surfaces. It is also effective against *Legionella* and other gram-negative bacteria. It is suitable for use on all food processing equipment and surfaces, including food contact surfaces, in public eating places.

FMB 4500 Quat is a sanitizer for use on all surfaces in one minute with the recommended amount of water up to 100 ppm water hardness (calculated as CaCO<sub>3</sub>) at 200 ppm active quat. FMB 4500 Quat is in compliance with 21 CFR 210.110 (a) (1) (i) and (j).

FMB 4500 Quat is a sanitizer for use on all surfaces in one minute with the recommended amount of water up to 100 ppm water hardness (calculated as CaCO<sub>3</sub>) at 200 ppm active quat. FMB 4500 Quat is in compliance with 21 CFR 210.110 (a) (1) (i) and (j).

For use in plants operating under Federally Inspected Poultry, Meat, Rabbit, Shell Egg Grading, and Egg Products Inspection Programs. FMB 4500 Quat is 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.

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Food eggs that have been sanitized with FMB 4500 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.

APR 05 1983

U.S. DEPARTMENT OF AGRICULTURE  
 FEDERAL REGISTER  
 Vol. 48, No. 68  
 Washington, D.C. 20503  
 47371-12

FMB 4500 Quats have been tested for ten different nitrosamines including n-nitrosodiethanolamine (NDEA). It was determined that the FMB 4500 Quats contained less than 20 parts per billion (ppb) and for the other nine nitrosamines FMB 4500 Quats contained less than 100 ppb.

Formulators using this product are responsible for EPA registration for their formulated products. For technical service and registration assistance, contact the 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.

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**STATEMENT OF PRACTICAL TREATMENT**

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**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 4500 Quats.

FMB 4500-5 Quat	EPA Reg. No. 47371-16
FMB 4500-8 Quat	EPA Reg. No. 47371-12
FMB 4500-28 Quat	EPA Reg. No. 47371-22

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

ACCEPTED  
with COMMENTS  
By EPA Area Office

AUG 05 1983

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

47371-12

15-1