

# FeF<sup>®</sup> Quats in medical devices

## Description

Quats are well-known antiseptics and have a long history of use in topical products such as antiseptic liquids, creams and gels. They act on a wide range of microorganisms, from gram+ to gram- bacteria, moulds, yeasts and enveloped vira such as HIV, herpes and corona. Our FeF<sup>®</sup> Quats are odourless and colourless, and their effectiveness in all pH ranges combined with their ability to mix well in both aqueous and oily phases, make them an ideal antimicrobial ingredient.

## Applications

Regardless of the classification, for medical devices coming into contact with either healthy or damaged organic tissue, it is necessary to utilize only the purest and safest ingredients. Gauzes/wipes/plasters/patches: FeF<sup>®</sup> Benzalkonium Chloride is often found in solution impregnated gauzes, wipes and plasters for skin and/or wound disinfection at typical concentrations of 0.01 to 0.1%.

Skin and wound cleansing: Solutions of 0.01 to 0.1% FeF<sup>®</sup> Benzalkonium Chloride (BKC) are typically used for cleansing skin, mucous membranes, and wounds. More dilute solutions are suitable for irrigation of deep wounds.

Catheters: FeF<sup>®</sup> Benzalkonium Chloride (BKC) can be coated or impregnated to reduce catheter-induced sepsis by preventing microbial colonization, e.g. in central venous catheters coated or impregnated with BKC. Irrigation solutions: Aqueous solutions of 0.005 to 0.02% FeF<sup>®</sup> Benzalkonium Chloride can be used for irrigation of the bladder and urethra and 0.0025 to 0.005% solutions for retention lavage of the bladder. Surgical glues (tissue adhesive) are other examples of devices containing FeF<sup>®</sup> Benzalkonium Chloride as an auxiliary.

## Safety and efficacy

Since Quats act on the surface and not on the content of the cells, they do not trigger antibiotic resistance. Quats should not be classified as skin sensitizers but as skin irritants. Bromides are less irritating to the skin than chlorides. Quats are relatively non-toxic in use concentrations and only considered harmful in concentrated forms.

Tertiary amines are used in the manufacture of Quats; free amine is a possible impurity and can be responsible for skin irritation. FeF<sup>®</sup> Quats are carefully manufactured with synthetic raw materials from qualified suppliers, and our validated processes are fully controlled to obtain the lowest possible levels of impurities.

## Product characteristics

Solubility: Quats are miscible with water or lower alcohols, such as methanol, ethanol and propanol in all ratios. Quats are not miscible with benzene or ether. Indicative solubility of Quats in %w/w at 20°C in water:

Tertiary Amine Carbon Chain Length (Alkyl Chain Length)	Methyl bromides	Benzyl chloride – Mix to form BKC
C12		70
C14	Cetrimide: 38	10
C16	CTAB: 6	1.5
C18		0.5

Solubility decreases as the alkyl chain length increases.



**Compatibility:** Quats can be combined with e.g. alcohol and chlorhexidine. Mixing Quats with ordinary soaps and/or with anionic detergents may decrease the activity. As Quats are cationic compounds, they should not be mixed with anionic compounds which would neutralize them. Quats can be inhibited by Tween® and by lecithin. Avoid mixing Benzalkonium Chloride (BKC) with citrates, iodides, nitrates, permanganates, salicylates, silver salts and tartrates. Incompatibilities have also been reported with other substances including aluminium, fluorescein sodium, hydrogen peroxide, kaolin and some sulfonamides. Because of their strong adsorption to organic substances, it is also important that surfaces are kept as free as possible from organic material and soap traces in order to obtain the best disinfection.

**Stability:** 5 years shelf life.

**Other:** Odourless, Colourless, Easy to formulate, Surface active / adhesive, Non-volatile and very stable.

### Antimicrobial effect

FeF® Quats are effective at all pH levels. However their effectiveness increases when the pH increases. The higher the pH, the lower the concentration needed to obtain an antimicrobial effect. As opposed to bacteriostatic/fungistatic compounds which only prevent micro-organisms from dividing (growing), Quats are bactericidal/fungicidal, meaning they will kill micro-organisms, whether they are in a growth phase or not. Some antibiotics under given conditions are more effective than antimicrobials. However, in general, they only work if the micro-organism is in a growth phase, and so cannot be used as an antimicrobial. FeF® Quats have been tested against several relevant microbial strains, and shown to be effective against a wide range of microorganisms at low concentrations. FeF® Quats are compared here with ethanol and with a positive control containing Meropenem (a broad-spectrum antibiotic). See Table 1.

**Table 1:** Minimal Inhibitory Concentrations. Mean results in % or µg/ml.

Species	ATCC no.	BKC %	CTAB %	Cetrimide %	Ethanol %	Meropenem µg/ml	Control strain/ Meropenem µg/ml	Range of control µg/ml
Candida albicans	2091	< 0.001	< 0.001	0.002	>1	>16	-	-
Corynebacteria amycolatum	CCUG 33685	0.002	0.004	0.004	>1	0.006	0.006	0.06-0.25
Streptococcus dysgalactiae	12394	< 0.001	< 0.001	0.002	>1	< 0.015	0.06	0.06-0.25
Enterococcus faecalis	29212	< 0.001	< 0.001	< 0.001	>1	0.125-8	0.125-8	2-8
Staphylococcus aureus MRSA	33591	< 0.001	< 0.001	< 0.001	>1	16	-	-
Staphylococcus aureus	29213	< 0.001	< 0.001	< 0.001	>1	0.06	0.06	0.03-0.12
Pseudomonas aeruginosa	27853	0.008	0.063	0.016	>1	0.5	0.5	0.25-1
Mycobacterium abscessus NFM32	-	< 0.001	< 0.001	< 0.001	>1	< 0.001	-	-
Acinetobacter baumannii	19606	0.002	0.002	0.008	>1	1	-	-
Staphylococcus epidermidis	12228	< 0.001	< 0.001	< 0.001	>1	0.06	-	-
Staphylococcus lugdunensis	70328	< 0.001	< 0.001	< 0.001	>1	0.25	-	-

Statens Serum Institute, Denmark (2016)