

Pharmaceutical grade quaternary ammonium compounds





By delivering excellence at every step, we help you do the same



Excellence. Multiplied

Best and safest ingredients

If uniform high quality is the key to your products, you should begin with ours. As the world's leading supplier of quaternary ammonium compounds (Quats), we provide only the best and safest ingredients for the pharmaceutical and personal care industries. Our ingredients are produced according to the highest cGMP standards and backed by complete regulatory documentation. This combination of high-purity products and regulatory services has made us an approved supplier to many of the world's leading pharmaceutical companies.

We are highly specialised in pharmaceutical grade Quats. The uniform quality of our finished products – and of yours – is ensured by our efficient quality control systems, fully validated processes and rigorous laboratory quality control. In-process samples, as well as finished products, are carefully analysed in our modern, well-equipped laboratory.

Quality.Proven

Novo Nordisk Pharmatech manufactures its pharmaceutical quats in accordance with the cGMP Guide ICH Q7 for Active Pharmaceutical Ingredients (APIs), the highest available quality standard in the industry. They are inspected by the FDA and the Danish Medicine Agency (DMA). The high levels of purity make them particularly suited for many pharmaceutical applications.

FeF® Benzalkonium Chloride (BKC), FeF® Cetrimonium Bromide (CTAB), FeF® Cetrimide and FeF® Strong Cetrimide Solution, act either as preservatives or active ingredients in a diverse range of applications, including ophthalmic, nasal, oral, dental or topical treatments, vaccine production and medical devices, such as wound care. Whether FeF® Quats are used as excipients or APIs, you can rely on our product's documented purity.



Product attributes

- Proven record of efficacy against a broad spectrum of microorganisms
- Effective through a wide pH range
- Odourless and colourless in your formulation
- Surface active / adhesive cationic agent
- Very stable, proven under ICH Q1 conditions
- Five-year shelf life

Highest quality standards

Our quality system meets DS/EN ISO 9001 and the ICH Guide Q7 for Active Pharmaceutical Ingredients (ICH Q7). We offer complete QA/QC documentation for our cGMP manufactured Quats.

Our products	Cas number	Packaging size	Item number
FeF® Benzalkonium Chloride Ph.Eur., USP/NF	8001-54-5	1 kg 5 kg	7800014 7800015
FeF® Benzalkonium Chloride Ph.Eur., USP/NF, JP	8001-54-5	1 kg 5 kg	7800012 7800013
FeF® Benzalkonium Chloride Solution 50% Ph.Eur., USP/NF	8001-54-5	1 kg 5 kg 25 kg 1000 kg	7800004 7800005 7800006 7800027
FeF® Benzalkonium Chloride Solution 50% Ph.Eur., USP/NF, JP	8001-54-5	1 kg 5 kg 25 kg	7800009 7800010 7800011
FeF® Benzalkonium Chloride Solution 50% (45/55) Ph.Eur., USP/NF	8001-54-5	1 kg 25 kg	7800020 7800019
FeF® Benzalkonium Chloride Solution 50% (53/30/15/2) Ph.Eur., USP/NF	8001-54-5	1 kg	7800008
FeF® Benzalkonium Chloride Solution 17% USP/NF	8001-54-5	25 kg	7800003
FeF® Cetrimide Ph.Eur.	1119-97-7	25 kg	7800002
FeF® Strong Cetrimide Solution 40% BP Pharma with ethanol	1119-97-7	200 kg	7800024
FeF® Strong Cetrimide Solution 40% BP Pharma with isopropyl alcohol	1119-97-7	200 kg	7800025
FeF® Cetyl Trimethyl Ammonium Bromide (CTAB) USP/NF (cardboard box) (plastic drum)	57-09-0	25 kg 25 kg	7800022 7800023

Applications overview

Vaccines



CTAB USP/NF for vaccine downstream processing

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CTAB USP/NF for vaccine downstream processing



Are all your vaccine ingredients cGMP manufactured?

Utilizing cGMP manufactured, pharma grade ingredients and processing aids can help you secure your vaccine production and minimize your risks. Whether you are manufacturing bacterial or viral vaccines, you want to minimize risks in your process by only using the purest and safest ingredients and materials.

CTAB stands for “Cetyl Trimethyl Ammonium Bromide” and can also be called Hexadecyl trimethyl ammonium bromide or Cetrimonium Bromide. It is a powerful cationic surfactant for use in vaccine downstream purification steps. It is recommended by the WHO^{1) 2)} for the precipitation of polysaccharide-based bacterial vaccines.

CTAB is also used as a purification agent of viral antigens, whether the vaccine is egg-based, cell-based or recombinant (DNA). FeF CTAB is used by many of the world's leading vaccine producers, as we are the only manufacturer offering CTAB in cGMP pharmaceutical grade for APIs, in full compliance with ICH Q7.

This means:

- Original manufacturer with full traceability
- High product purity
- Full USP/NF compliance
- Audit access
- Full regulatory documentation package
- Manufactured under fully validated processes

1) World Health Organization (WHO) Technical Report, Series No. 924, 2004 Annex 2 “Recommendations for the production and control of meningococcal group C conjugate vaccines”

2) Guidelines on the Quality, Safety and Efficacy of Typhoid Conjugate Vaccines” (WHO, 2013)

FeF[®] Quats in ophthalmics



Description

Multidose pharmaceutical products are prone to contamination, both from environmental and corporeal flora. Microbial contamination can present a threat to the safety, the purity or the efficacy of ophthalmic products, hence the importance of utilizing an effective preservative. For formulations coming into contact with corneal tissue, it is necessary to preserve against contamination by utilizing only the purest and safest ingredients. In both human and veterinary ophthalmics, one of the most common and effective preservatives is Benzalkonium Chloride (BKC / BAK).

Our FeF[®] Benzalkonium Chloride is widely used as an excipient in ophthalmic solutions, gels and ointments, where its concentration typically varies from 0.001% up to 0.01%.

Properties

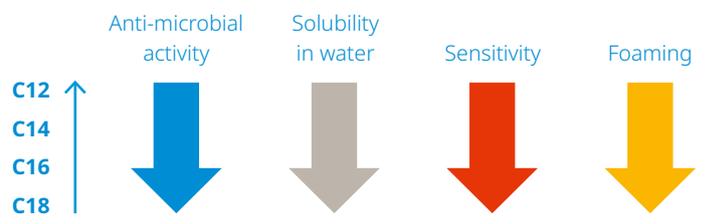
The different alkyl (fatty) chain lengths give Quats different properties. For example, antimicrobial activity is greater for shorter chain lengths, however skin sensitivity decreases as the chain length increases. Shorter chain lengths are more soluble, and they also foam more.

The alkyl chain length distribution often plays a major role for ophthalmic formulators. Our production and process know-how allows us to offer Quats with a completely well-defined alkyl chain length distribution,

whether it is with our standard chain length or with customized chain length distributions.

Our standard chain length distribution in Benzalkonium Chloride is approx. 65% C12 and 35% C14, with max. 5% of C16. We also offer other chain length distribution products or can develop your own, customized product.

Alkyl chain length



Product characteristics

Solubility: FeF[®] Quats are miscible with water or lower alcohols, such as methanol, ethanol and propanol in all ratios. They 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)	Benzyl chloride – Mix to form BKC
C12	70
C14	10
C16	1.5
C18	0.5

Solubility decreases as the alkyl chain length increases.

Compatibility: Mixing BKC 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 have a neutralizing effect. 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. Hyaluronic acid can minimize BKC's irritating effect.

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.

FeF® BKC has been tested against several relevant microbial strains, and shown to be effective against a wide range of microorganisms at low concentrations. FeF® BKC is compared here with ethanol and with a positive control containing Meropenem (a broad-spectrum antibiotic).

Minimal Inhibitory Concentrations. Mean results in % or µg/ml.

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

Statens Serum Institute, Denmark (2016)

FeF® Quats in nasal sprays



Description

Multidose pharmaceutical products are prone to contamination, both from environmental and corporeal flora. Microbial contamination can present a threat to the safety, the purity or the efficacy of nasal products, hence the importance of utilizing an effective preservative.

For formulations coming into contact with mucosal tissue, it is necessary to preserve against contamination by utilizing only the purest and safest ingredients. In both human and veterinary nasal formulations, one of the most common and effective preservatives is Benzalkonium Chloride (BKC / BAK). Our FeF® Benzalkonium Chloride is widely used as an excipient in nasal sprays, drops and ointments, where its concentration typically varies from 0.005% up to 0.2%.

Properties

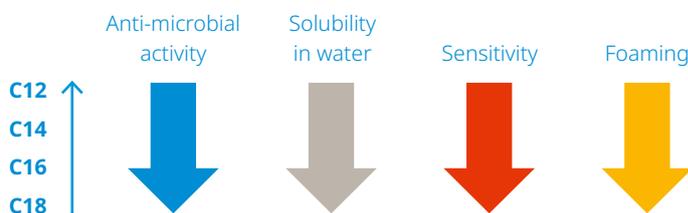
The different alkyl (fatty) chain lengths give Quats different properties. For example, antimicrobial activity is greater for shorter chain lengths, however skin sensitivity decreases as the chain length increases. Shorter chain lengths are more soluble, and they also foam more.

Our production and process know-how allows us to offer Quats with a completely well-defined alkyl chain length distribution, whether it is with our standard chain length or with customized chain length

distributions. Our standard chain length distribution in Benzalkonium Chloride is approx. 65% C12 and 35% C14, with max. 5% of C16.

We also offer other chain length distribution products or can develop your own, customized product.

Alkyl chain length



Product characteristics

Solubility: FeF® Quats are miscible with water or lower alcohols, such as methanol, ethanol and propanol in all ratios. They 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)	Benzyl chloride – Mix to form BKC
C12	70
C14	10
C16	1.5
C18	0.5

Solubility decreases as the alkyl chain length increases.

Compatibility: Mixing BKC 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 have a neutralizing effect. 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.

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.

FeF® BKC has been tested against several relevant microbial strains, and shown to be effective against a wide range of microorganisms at low concentrations. FeF® BKC is compared here with ethanol and with a positive control containing Meropenem (a broad-spectrum antibiotic).

Minimal Inhibitory Concentrations. Mean results in % or µg/ml.

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

Statens Serum Institute, Denmark (2016)

FeF[®] Quats in topical products



Applications

No matter the application, for formulations coming into contact with either healthy or damaged epithelial tissue, it is necessary to utilize only the purest and safest ingredients.

All our FeF[®] Quats products are widely used in both human and veterinary topicals. Skin cleansing solutions: FeF[®] Benzalkonium Chloride (BKC) are used for cleansing skin, mucous membranes, and wounds with a concentration of 0.01 to 0.1%.

Hand sanitizers: Typically the concentration of FeF[®] Benzalkonium Chloride (BKC) in hand sanitizers is maximum 2% w/w. Standard concentrations in finished products normally vary between 0.5% and 1.5% w/w, and more dilute solutions are suitable for irrigation of deep wounds.

Antiseptic creams: FeF[®] Benzalkonium Chloride (BKC), FeF[®] Cetrimide and FeF[®] CTAB are often found in antiseptic creams used in the treatment of nappy rash, eczema, psoriasis, acne and other dermatoses at concentrations varying from 0.1 to 1%.

Hair products: FeF[®] Quats are also used in hair products, for example to treat seborrheic dermatitis. Spermicide: FeF[®] Benzalkonium Chloride (BKC) is widely used in spermicides in foams, creams and ampoules.

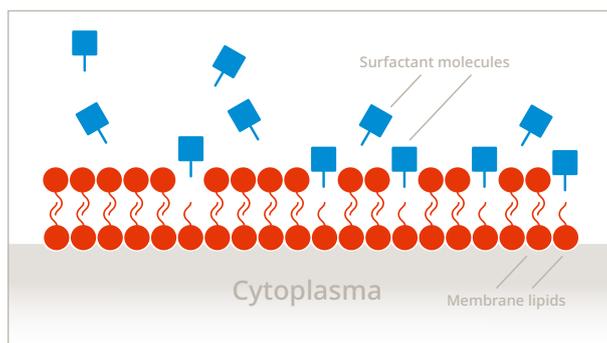
Safety and efficacy

Since Quats act on the surface and not on the content of 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.

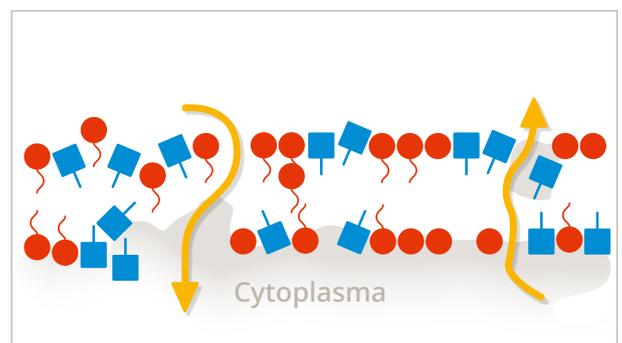
Tertiary amines are used in the manufacture of Quats; free amine is a possible impurity and can be responsible for skin irritation. FeF[®] Quats are carefully manufactured with synthetic raw materials from qualified suppliers, and our validated processes are fully controlled to obtain the lowest possible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

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[®] 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.



Mode of action: The Quats alkyl (fatty) chains have a good affinity for bacterial membranes. Quats disrupt the membrane's structure and provoke leaking of the cytoplasm.





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.

Compatibility: Quats can be combined with e.g. alcohol and chlorhexidine and with the most commonly used compounds in topical formulations. 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 have a neutralizing effect. 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.

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 micro-organisms at low concentrations. FeF® Quats are compared here with ethanol and with a positive control containing Meropenem (a broad-spectrum antibiotic).

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)

FeF[®] Quats in oral products



Description

Quats are well-known antiseptics and have a long history of use in a wide range of both human and veterinary products. 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[®] Quats are odourless and colourless, and their effectiveness in all pH ranges combined with their ability to mix well in most formulations, make them an ideal antimicrobial ingredient.

Applications

No matter the application, for formulations coming into contact with either healthy or damaged buccal tissue, it is necessary to utilize only the purest and safest ingredients.

FeF[®] Quats can be used either as excipients or active pharmaceutical ingredients (APIs) for oral and dental formulations.

Lozenges: FeF[®] Benzalkonium Chloride (BKC) is used as an API in lozenges to treat superficial infections in the mouth and throat. Our crystalline product FeF[®] CTAB is found as an API in lozenges to treat throat infections at typically 1.0 mg/lozenge.

Gels and creams: FeF[®] Benzalkonium Chloride (BKC) is also often found in gels and creams at typical concentrations of 0,01 to 0,1%, to treat herpes and cold sores infections, or as an excipient in pain-relieving gum gels.

Antiseptic mouth sprays with FeF[®] Benzalkonium Chloride (BKC) are also common. Dentistry products: FeF[®] Quats are also used either as an active antiseptic or a preservative in for example rinsing fluids and antiseptic fills.

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 and with the most commonly used compounds in oral & dental formulations. 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 as this would have a neutralizing effect. 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.

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.

FeF® Quats have been tested against several relevant microbial strains, and shown to be effective against a wide range of micro-organisms at low concentrations. FeF® Quats are compared here with ethanol and with a positive control containing Meropenem (a broad-spectrum antibiotic).

Minimal Inhibitory Concentrations. Mean results in % or µg/ml.

Species	ATTC 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)

FeF[®] 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[®] 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[®] 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[®] 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[®] 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[®] 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[®] 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[®] 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).

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)



The Apis bull logo is a registered trademark of Novo Nordisk A/S. June 2021

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