



# FeF Benzalkonium Chloride

## Ph.Eur., USP/NF, JP

### Application

FeF Benzalkonium Chloride Ph.Eur., USP/NF, JP (BKC Multicompendial) is a viscous liquid made of quaternary ammonium compounds. FeF BKC Multicompendial is a very efficient germicide which is active against most common micro-organisms, such as bacteria, fungi and algae. FeF BKC Multicompendial is widely used in pharmaceuticals as the active ingredient (API) due to its anti-microbial effect and as an excipient because of its preserving properties.

Item No. 7800012 (1 kg)

Item No. 7800013 (5 kg)

### Specifications

Identification:	Complies to Ph.Eur., USP/NF, JP
Appearance of solution:	Max. as ref. susp. I Max. as ref. solution Y6.
Purity 1:	Clear and colourless to light yellow
Purity 2:	Max. 1.0 % w/w
Acidity or alkalinity:	Max. 0.1 ml 0.1M HCl or NaOH
Ratio of alkyl components:	C12: 60 - 70%w/w, C14: 30 - 40%w/w, C16: Max. 5%w/w
Benzyl alcohol (A):	Max. 0.5% w/w
Benzaldehyde (B):	Max. 0.15% w/w
(Chloromethyl)benzene (C):	Max. 0.05% w/w
Any other detectable impurity:	Max. 0.10% w/w
Amines and amine salts:	Max. 1.0 ml/g
Water:	Max.10.0% w/w
Sulphated ash (Ph.Eur.) / Residue on ignition ( USP/NF, JP):	Max. 0.1% w/w
Water-insoluble matter:	No turbidity and insoluble matter
Assay (anhydrous basis):	Ph.Eur.: 95.0 - 104.0% w/w USP/NF: 97.0 - 103.0% w/w JP: 95.0 – 105.0% w/w
Total Aerobic Microbial Count:	Max. 1 CFU/g
Total comb. Yeast/Mould Count:	Max. 1 CFU/g
Staphylococcus aureus:	Absent in 1 g
Pseudomonas aeruginosa:	Absent in 1 g
Salmonella spp.:	Absent in 10 g
Escherichia coli:	Absent in 1 g
Bile-tol. gram-neg. bact.:	Absent in 1 g

## Description

Composition:	FeF BKC Multicompendial consists of Benzyl (dodecyl) dimethyl ammonium chloride (approx. 65%) and Benzyl (tetradecyl) dimethyl ammonium chloride (approx. 35%). FeF BKC Multicompendial contains approx. 95% active ingredients.
CAS No.:	8001-54-5
EINECS No.:	264-151-6
Names:	Benzalkonium Chloride (BKC). Alkyl dimethyl benzyl ammonium chloride.
Appearance of product:	Clear, or white to yellowish-white solid or viscous liquid. May contain yellowish-white fragments.
Chain length:	60-70% w/w C <sub>12</sub> , 30-40% w/w C <sub>14</sub> and Max. 5% w/w C <sub>16</sub> .

## Technical information

Standards:	The quality system meets DS/EN ISO 9001. The environmental system meets DS/EN ISO 14001.
Grade:	Pharmaceutical grade.
Quality:	The product is manufactured in accordance with the cGMP Guide for Active Pharmaceutical Ingredients (API) ICH Q7.
Documentation:	Certificate of Suitability (CEP)
TSE:	FeF BKC Multicompendial does not contain materials of animal origin.
Solubility:	FeF BKC Multicompendial is miscible with water or lower alcohols, such as methanol, ethanol and propanol in all ratios. FeF BKC Multicompendial is neither miscible with benzene nor ether.
Compatibility:	Mixing FeF BKC Multicompendial with ordinary soaps and/or with anionic detergents may decrease the activity.
Density:	Approx. 0.98 g/ml.
Packaging:	FeF BKC Multicompendial 1 kg is packaged in rectangular HDPE plastic containers with tamper proof LDPE Caps. FeF BKC Multicompendial 5 kg is packaged in round PP plastic containers with tamper proof PP lids.
Shelf life:	5 years.
Storage:	Store at temperatures above 15°C. Store protected from excessive heat. FeF BKC Multicompendial may be a liquid, paste or solid depending on the storage conditions.

## Safety and handling

See the Material Safety Data Sheet on [novonordiskpharmatech.com](http://novonordiskpharmatech.com)

### Please note

*The information contained herein is to our best knowledge true and accurate, but all recommendations or suggestions are made without guarantee since the conditions of use are beyond our control. Novo Nordisk Pharmatech A/S disclaims any liability incurred with the use of these data or suggestions.*