

SAFETY DATA SHEET

Product name: FeF Benzalkonium chloride Solution 17% USP/NF Page: 1/11
Revision: 2019-11-05 Print date: 2022-11-03
SDS-ID: GB-EN/14.0

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name: FeF Benzalkonium chloride Solution 17% USP/NF
Container size: 25 kg

1.2. Relevant identified uses of the substance or mixture and uses advised against

Application: Pharmaceutical industry

1.3. Details of the supplier of the safety data sheet

Supplier: Novo Nordisk Pharmatech A/S
Københavnsvej 216
DK-4600 Køge
Tel: +45 56 67 10 00
www.novonordiskpharmatech.com

Supplier: Azelis UK Limited
Axis House, Tudor Rd, Runcorn
WA7 1BD Cheshire
United Kingdom

Responsible for safety data sheet authoring: nnprinfo@novonordiskpharmatech.com

1.4. Emergency telephone number

Emergency telephone: NHS: 111
+ 45 56 67 10 00
(Only during office hours)

SAFETY DATA SHEET

Product name: FeF Benzalkonium chloride Solution 17% USP/NF Page: 2/11
Revision: 2019-11-05 Print date: 2022-11-03
SDS-ID: GB-EN/14.0

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

CLP: Skin Corr. 1B;H314 - Eye Dam. 1;H318 - Aquatic Acute 1;H400 - Aquatic Chronic 2;H411

2.2. Label elements



Danger

Contains: Quaternary ammonium compounds, benzyl C12-16 (even numbered)-alkyldimethyl chlorides

H314 Causes severe skin burns and eye damage.

H400 Very toxic to aquatic life.

H411 Toxic to aquatic life with long lasting effects.

P262 Do not get in eyes, on skin, or on clothing.

P273 Avoid release to the environment.

P280 Wear protective clothing, gloves, eye and face protection.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

2.3. Other hazards

PBT/vPvB: This product does not contain any PBT or vPvB substances.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

The product contains: Aqueous solution of quaternary ammonium compounds.
This product is a UVCB substance and its composition will be variable, so reported properties may vary or require a range of values to describe them.

CLP:

<u>%:</u>	<u>CAS-No.:</u>	<u>EC No.:</u>	<u>REACH Reg. No:</u>	<u>Chemical name:</u>	<u>Hazard classification:</u>	<u>Notes:</u>
17	68424-85-1	939-253-5	01-2119965180-41-0009	Quaternary ammonium compounds, benzyl C12-16 (even numbered)-alkyldimethyl chlorides	Acute Tox. 4;H302 Skin Corr. 1B;H314 Eye Dam. 1;H318 Aquatic Acute 1;H400 Aquatic Chronic 1;H410	

SAFETY DATA SHEET

Product name: FeF Benzalkonium chloride Solution 17% USP/NF Page: 3/11
Revision: 2019-11-05 Print date: 2022-11-03
SDS-ID: GB-EN/14.0

Chemical name: SCL M (ac) M (chr) ATE(o) ATE(d) ATE(i)
(mg/kg) (mg/kg) (vapour,
bw) bw) mg/L)

Quaternary ammonium compounds, benzyl
C12-16 (even numbered)-alkyldimethyl
chlorides 10 1 - - -

References: The full text for all hazard statements is displayed in section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation: Move into fresh air and keep at rest.
Inhalation of aerosols: Move injured person into fresh air and keep person calm under observation. If uncomfortable: Seek hospital and bring these instructions.

Skin contact: Remove contaminated clothes and rinse skin thoroughly with water. In case of eczema or other skin disorders: Seek medical attention and bring these instructions.

Eye contact: Immediately flush with plenty of water. Remove any contact lenses and open eyes wide apart. Call an ambulance and continue flushing during transportation to hospital. Bring these instructions.

Ingestion: Immediately rinse mouth and drink plenty of water. Call an ambulance. Bring along these instructions. Do not induce vomiting.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects: See section 11 for more detailed information on health effects and symptoms.

4.3. Indication of any immediate medical attention and special treatment needed

Medical attention/treatments: Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Extinguishing media: Use fire-extinguishing media appropriate for surrounding materials.

5.2. Special hazards arising from the substance or mixture

Specific hazards: During fire, gases hazardous to health may be formed.
Water used for fire extinguishing, which has been in contact with the product, may be corrosive.

5.3. Advice for firefighters

Protective equipment for fire-fighters: Use air-supplied respirator during fire fighting. Severe corrosive hazard. Wear chemical protection suit.

SAFETY DATA SHEET

Product name: FeF Benzalkonium chloride Solution 17% USP/NF Page: 4/11
Revision: 2019-11-05 Print date: 2022-11-03
SDS-ID: GB-EN/14.0

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Avoid inhalation of spray mist and contact with skin and eyes. Follow precautions for safe handling described in this safety data sheet.

6.2. Environmental precautions

Environmental precautions: Do not discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Absorb spillage with suitable absorbent material. Flush contaminated area with plenty of water.

6.4. Reference to other sections

References: For personal protection, see section 8.
For waste disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Safe handling advice: Observe good chemical hygiene practices. Avoid inhalation of spray mists and contact with skin and eyes. Immediately change drenched clothing.

Technical measures: Keep the workplace clean. Use work methods which minimise aerosol production.

Technical precautions: Provide easy access to water supply and eye wash facilities.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures for safe storage: No special precautions.

Storage conditions: Store in closed original container. Do not store near heat sources or expose to excessive temperatures.

7.3. Specific end use(s)

Specific use(s): Not relevant.

SAFETY DATA SHEET

Product name: FeF Benzalkonium chloride Solution 17% USP/NF Page: 5/11
Revision: 2019-11-05 Print date: 2022-11-03
SDS-ID: GB-EN/14.0

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No occupational exposure limit assigned.

8.2. Exposure controls

Engineering measures: Provide adequate ventilation. Minimise the risk of formation of aerosols. An eye wash bottle must be available at the work site.

Personal protection: Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Respiratory equipment: Risk of inhalation of spray mist: Use respiratory equipment with particle filter, type P2. The use of filtering respirators should be limited to max. 3 hours per day.

Hand protection: Wear protective gloves. Nitrile gloves are recommended. The most suitable glove must be chosen in consultation with the gloves supplier, who can inform about the breakthrough time of the glove material.

Eye protection: Wear goggles/face shield.

Skin protection: Wear apron or protective clothing in case of splashes.

Hygiene measures: Wash hands after contact.

Environmental Exposure Controls: Not available.

SAFETY DATA SHEET

Product name: FeF Benzalkonium chloride Solution 17% USP/NF Page: 6/11
Revision: 2019-11-05 Print date: 2022-11-03
SDS-ID: GB-EN/14.0

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state: Liquid.
Colour: Colourless. / Yellowish.
Odour: Not available.
pH: 6-8
Melting point / freezing point: Not available.
Boiling point: Not available.
Flash point: Not available.
Explosive limits Not relevant.
Vapour pressure: Not available.
Relative density: ~ 0.99
Solubility: Miscible with: Water and lower alcohols.
Viscosity: Not available.

9.2. Other information

Other data: Not relevant.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity: None known.

10.2. Chemical stability

Stability: Stable under normal temperature conditions.

10.3. Possibility of hazardous reactions

Hazardous Reactions: None known.

10.4. Conditions to avoid

Conditions/materials to avoid: Heating.

10.5. Incompatible materials

Incompatible materials: Strong oxidising substances.

10.6. Hazardous decomposition products

Hazardous decomposition products: If heated to more than 150°C, the following substance(s) will be released: Benzyl chloride and Methyl chloride.

SAFETY DATA SHEET

Product name: FeF Benzalkonium chloride Solution 17% USP/NF Page: 7/11
Revision: 2019-11-05 Print date: 2022-11-03
SDS-ID: GB-EN/14.0

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute Toxicity (Oral): Based on available data, the classification criteria are not met.

Acute Toxicity (Dermal): Based on available data, the classification criteria are not met.

Acute Toxicity (Inhalation): Based on available data, the classification criteria are not met.

Skin Corrosion/Irritation: Causes severe skin burns and eye damage.

Serious eye damage/irritation: Causes serious eye damage.

Respiratory or skin sensitisation: Based on available data, the classification criteria are not met.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive Toxicity: Based on available data, the classification criteria are not met.

STOT - Single exposure: Based on available data, the classification criteria are not met.

STOT - Repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

Inhalation: Inhalation of aerosols: Burning pain. Increased flow of saliva (froth at the mouth) and vomiting, sometimes with bloody vomit. Restlessness, confusion and weakness, laboured breathing, bluish colouring of skin and mucous membranes, shock and unconsciousness.

Skin contact: Causes burns.

Eye contact: Corrosive. Immediate first aid is necessary. Risk of serious damage to eyes.

Ingestion: Causes burns. Burning pain. Increased flow of saliva (froth at the mouth) and vomiting, sometimes with bloody vomit. Restlessness, confusion and weakness, laboured breathing, bluish colouring of skin and mucous membranes, shock and unconsciousness.

Specific effects: None known.

Toxicological data: Quaternary ammonium compounds, benzyl C12-16 (even numbered)-alkyldimethyl chlorides:
LD50 (oral, rat): 795 mg/kg

11.2. Information on other hazards

Endocrine disrupting properties: The product does not contain any substance identified as having endocrine disrupting properties.

SAFETY DATA SHEET

Product name: FeF Benzalkonium chloride Solution 17% USP/NF Page: 8/11
Revision: 2019-11-05 Print date: 2022-11-03
SDS-ID: GB-EN/14.0

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity: Very toxic to aquatic life.
Toxic to aquatic life with long lasting effects.

Quaternary ammonium compounds, benzyl C12-16 (even numbered)-
alkyldimethyl chlorides:
M-factor (acute): 10
M-factor (chronic): 1
LC50 (Fish): $0.1 < LC50 \leq 1$ mg/l (96 hours)
EC50 (Daphnia): $0.01 < EC50 \leq 0.1$ mg/l (48 hours)
 $0.001 < NOEC \leq 0.01$ mg/l

12.2. Persistence and degradability

Degradability: The product is readily biodegradable.

12.3. Bioaccumulative potential

Bioaccumulative potential: Bioaccumulation: Is not expected to be bioaccumulable.

12.4. Mobility in soil

Mobility: No data available.

12.5. Results of PBT and vPvB assessment

PBT/vPvB: This product does not contain any PBT or vPvB substances.

12.6. Endocrine disrupting properties

Endocrine disrupting properties: The product does not contain any substance identified as having endocrine disrupting properties.

12.7. Other adverse effects

Other adverse effects: None known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste and residues in accordance with local authority requirements. Waste is classified as hazardous waste.

Waste from residues: EWC-code:
07 05 07

SAFETY DATA SHEET

Product name: FeF Benzalkonium chloride Solution 17% USP/NF Page: 9/11
Revision: 2019-11-05 Print date: 2022-11-03
SDS-ID: GB-EN/14.0

SECTION 14: TRANSPORT INFORMATION

14.1. UN number

UN-No: 3265

14.2. UN proper shipping name

Proper Shipping Name: CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S.
(Benzalkonium chloride)

14.3. Transport hazard class(es)

Class: 8

14.4. Packing group

PG: III

14.5. Environmental hazards

Marine pollutant: Yes.

Environmentally Hazardous substance: Yes.

14.6. Special precautions for user

Special precautions: None known.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Transport in bulk: Not relevant.

SAFETY DATA SHEET

Product name: FeF Benzalkonium chloride Solution 17% USP/NF Page: 10/11
Revision: 2019-11-05 Print date: 2022-11-03
SDS-ID: GB-EN/14.0

SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Special provisions: As a general rule, persons under 18 years of age are not allowed to work with this product. Users must be carefully instructed in the proper work procedure, the dangerous properties of the product and the necessary safety instructions.

National regulation: UK Statutory Instruments, 2021 No. 904, CONSUMER PROTECTION ENVIRONMENTAL PROTECTION HEALTH AND SAFETY. The REACH etc. (Amendment) Regulations 2021.
Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 with amendments.
The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019 No. 720), as amended.
European Union (Withdrawal) Act 2018, as amended.
The Control of Substances Hazardous to Health Regulations 2002 (S.I 2002 No. 2677) with amendments.
The Management of Health and Safety at Work Regulations 1999 (SI 1999 No. 3242), with amendments.
The List of Wastes (England) (Amendment) Regulations 2005. (SI 2005 No. 895).

15.2. Chemical Safety Assessment

CSA status: No chemical safety assessment has been carried out.

SAFETY DATA SHEET

Product name: FeF Benzalkonium chloride Solution 17% USP/NF Page: 11/11
Revision: 2019-11-05 Print date: 2022-11-03
SDS-ID: GB-EN/14.0

SECTION 16: OTHER INFORMATION

For restrictions on use see section 15.

The following sections contain revisions or new statements: 1, 3, 9, 11, 12, 16.

Abbreviations and acronyms used in the safety data sheet: ATE(d) = Acute Toxicity Estimate, dermal.
ATE(o) = Acute Toxicity Estimate, oral.
ATE(i) = Acute Toxicity Estimate, inhalation.
bw = body weight.
CSA= Chemical Safety Assessment.
EC50 = Effective Concentration 50%.
LC50 = Lethal Concentration 50%.
LD50 = Lethal Dose 50%.
M(ac) = M-factor acute toxicity.
M(chr) = M-factor chronic toxicity.
NOEC = No Observed Effect Concentration.
PBT = Persistent, Bioaccumulative and Toxic.
vPvB = very Persistent and very Bioaccumulative.

Additional information: Classification according to Regulation (EC) No. 1272/2008:
Calculation method.

Wording of H-statements:

H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H318 Causes serious eye damage.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H411 Toxic to aquatic life with long lasting effects.

The information on this data sheet represents our current data and is reliable provided that the product is used under the prescribed conditions and in accordance with the application specified on the packaging and/or in the technical guidance literature. Any other use of the product which involves using the product in combination with any other product or any other process is the responsibility of the user.

Made by DHI - Environment and Toxicology, Agern Allé 5, DK-2970 Hørsholm, Denmark.
www.dhigroup.com.
