SAFETY DATA SHEET

Safety Data Sheet according to (EC) No. 1907/2006, Annex II, as amended by Regulation (EU) 2020/878.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier:

FeF Benzalkonium Chloride Solution 50%

FeF Benzalkonium Chloride 50% Ph.Eur., USP/NF

FeF Benzalkonium Chloride 50% Ph.Eur., USP/NF, JP

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

Preservative and active ingredient in the cosmetics and pharmaceutical industries.

1.3. Details of the supplier of the safety data sheet:

Novo Nordisk Pharmatech A/S

Københavnsvej 216 Tel: +45 56 67 10 00

DK-4600 Køge

Supplier:

Azelis UK Limited

Axis House, Tudor Rd, Runcorn

WA7 1BD Cheshire

United Kingdom

Responsible person for the safety data sheet (e-mail): nnprinfo@novonordiskpharmatech.com

1.4. Emergency telephone number:

NHS (England or Wales): Dial 111 or 0845 4647 NHS 24 (Scotland): 08454 24 24 24.

National Poisons Information Centre (Ireland): +353 (1) 809 2166 (8.00 a.m. to 10.00 p.m. 7 days a week).

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture:

Corrosive and environmentally hazardous liquid.

CLP (1272/2008): Acute Tox. 4; H302 Skin Corr. 1B; H314 Eye Dam. 1; H318 Aquatic Acute 1; H400 Aquatic Chronic 1; H410

2.2. Label elements:

DANGER

Contains:	Quaternary ammonium compounds, benzyl C12-16 (even numbered)-alkyldimethyl chlorides
H302:	Harmful if swallowed
H314:	Causes severe skin burns and eye damage.
H410:	Very 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 gloves/protective clothing/eye protection/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:	Call a POISON INFORMATION/doctor immediately.

2.3. Other hazards:

PBT/vPvB: The ingredients are not considered PBT/vPvB according to criteria in Regulation 2023/707.

Endocrine disrupting properties: The substances are not identified as having endocrine disrupting properties in accordance with the criteria set out in Regulation 2023/707.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

The product contains: Aqueous solution of quaternary ammonium compounds.

The substance is a UVCB substance, and its composition will be variable, so reported properties may vary or require a range of values to describe them.

% w/w	Substance name	CAS-no.	EC-no.	Index-no.	REACH reg.no.	Classification	Note
50	Quaternary ammonium compounds, benzyl C12-C16 (even numbered)-alkyldimethyl chlorides	68424-85-1	939-253-5	-	01-2119965180-41	Acute Tox. 4;H302 Skin Corr. 1B;H314 Eye Dam. 1;H318 Aquatic Acute 1;H400 (M=10) Aquatic Chronic 1;H410 (M=1)	-

Wording of hazard statement(s) – see Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures:

Inhalation: Move the affected person to fresh air. Keep at rest. In case of discomfort: Seek medical advice.

Skin contact: Remove contaminated clothing immediately. Flush skin with plenty of water. In case of rash, wound, or other skin irritation: Seek medical advice.

Eye contact: Immediately flush with water or physiological salt water for at least 15 minutes, holding eye lids open, remember to remove contact lenses, if any. Seek medical advice. Continue rinsing during transport to the doctor/hospital.

Ingestion: Call an ambulance immediately. Rinse mouth thoroughly. Do not induce vomiting.

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

Corrosive to skin, eyes and gastrointestinal tract.

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

Show this safety data sheet to a physician or emergency ward.

SECTION 5: Firefighting measures

5.1. Extinguishing media:

Not combustible.

5.2. Special hazards arising from the substance or mixture:

Water used for extinguishing the fire, which has been in contact with the product, may be corrosive.

5.3. Advice for firefighters:

When extinguishing surrounding fires use breathing apparatus with an independent source of air.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment - see section 8. Ventilate area of leak or spill.

6.2. Environmental precautions:

Do not empty into drains – see section 12. Inform appropriate authorities in accordance with local regulations.

6.3. Methods and material for containment and cleaning up:

Spills are collected with a broom, shovel or similar. Flush area of spill with water. Further handling of spillage - see section 13.

6.4. Reference to other sections:

See references above.

SECTION 7: Handling and storage

7.1. Precautions for safe handling:
Avoid contact with skin, eyes and clothing. Change contaminated clothes immediately. After use, wash with plenty of soap and water. There must be access to plenty of water and an eyewash bottle. Do not eat, drink or smoke during use.

7.2. Conditions for safe storage, including any incompatibilities:
Store in tightly closed original container in a dry and well-ventilated place and protected from direct sunlight and heat.

7.3. Specific end use(s):
See section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters:
Occupational exposure limits (EH40/ed.2020): None.
Occupational exposure limit values, Ireland (2024): None
DNEL: No data

PNEC (Benzalkonium Chloride):

Medium	Value
Freshwater	0.42 µg/l
Marine water	0.096 µg/l
Freshwater sediment	68 mg/kg
Sea water sediment	115.75 mg/kg
Soil	1.66 mg/kg
STP	160 µg/l

8.2. Exposure controls:
Appropriate engineering controls: Ensure adequate ventilation.
Personal protective equipment:
Inhalation: In case of inadequate ventilation: Use an approved mask with gas filter class A2 (Brown - for organic vapours) (EN 140). The filter has a limited lifetime and must be changed. Read the manufacturer's instructions.
Skin: Wear protective gloves of nitrile rubber (EN 374). It has not been possible to find data for breakthrough time. In case of spill on the glove it is recommended to change it.
Eyes: Wear safety goggles (EN ISO 16321-1) when there is a risk of splashes.
Environmental exposure controls: None particular.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties:

Physical state:	Viscous liquid.
Colour:	Colourless.
Odour:	No available data
Melting point/freezing point (°C):	No available data
Boiling point or initial boiling point and boiling range (°C):	No available data
Flammability (solid, gas):	No available data
Lower and upper explosion limit (vol-%):	No available data
Flash point (°C):	No available data
Auto-ignition temperature (°C):	No available data
Decomposition temperature (°C):	No available data
pH:	5-6 (10-20 g/l)
Kinematic viscosity:	No available data
Solubility:	Miscible with water and lower alcohols
Partition coefficient n-octanol/water (log value):	No available data
Vapour pressure:	No available data

SECTION 9: Physical and chemical properties (continued)

Density and/or relative density:	~0.98 g/cm^3
Relative vapour density:	No available data
Particle characteristics:	No available data
9.2. Other information:	None relevant

SECTION 10: Stability and reactivity

10.1. Reactivity:
No available data.
10.2. Chemical stability:
Stable under the recommended storage conditions - see section 7.
10.3. Possibility of hazardous reactions:
None known.
10.4. Conditions to avoid:
Avoid heating.
10.5. Incompatible materials:
Strong oxidizing agents.
10.6. Hazardous decomposition products:
When heated to high temperatures (decomposition) highly toxic gases are emitted: (carbon oxides, benzyl chloride, methyl chloride).

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008:

Acute toxicity:	Acute Tox. 4;H302 Harmful if swallowed.
Skin corrosion/irritation:	Skin Corr. 1B;H314 Causes severe skin burns and eye damage.
Serious eye damage/irritation:	Eye Dam. 1;H318 Causes serious eye damage.
Respiratory or skin sensitization:	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.

Hazard class	Data (Benzalkonium Chloride)	Test	Data source
Acute toxicity:			
Inhalation	LC50 (rat, 4h) = 0.22 mg/l	OECD 403	ECHA
Dermal	LD50 (rabbit) = 2,848 mg/kg	EPA OPPTS 870.1200	ECHA
Oral	LD50 (rat) = 350 mg/kg	OECD 401	ECHA
Corrosion/irritation:	Corrosive to skin, rabbit	No data	ECHA
	Serious eye damage, rabbit	No data	ECHA
Sensitization:	No skin sensitization, guinea pigs	Draize	ECHA
CMR:	No CMR effects	Miscellaneous	ECHA

Information on likely routes of exposure: Skin, eyes and gastrointestinal tract.
Symptoms:

Inhalation:	Not relevant at normal working temperatures. If heated, hazardous vapours may be formed.
Skin:	Has a corrosive effect with redness and pain. May cause wounds and tissue damage.
Eyes:	Has a corrosive effect with the risk of serious eye damage.
Ingestion:	Has a corrosive effect with pain in the mouth, throat, oesophagus and gastrointestinal tract. Risk of tissue damage and perforation of the oesophagus/stomach.
Chronic effects:	None known.

11.2. Information on other hazards: None known.

SECTION 12: Ecological information

12.1. Toxicity:

Aquatic	Data (Benzalkonium Chloride)	Test (Media)	Data source
Fish	LC50 (Oncorhynchus mykiss, 96h) = 1.7 mg/l	OECD 203 (FW)	ECHA
Daphnia	EC50 (Daphnia magna, 48h) = 0.016 mg/l	OECD 202 (FW)	ECHA
Algae	EC50 (Raphidocelis subcapitata, 72h) = 49 µg/l	OECD 201(FW)	ECHA

12.2. Persistence and degradability:
Benzalkonium Chloride is rapidly biodegradable (OECD 301 test).
12.3. Bioaccumulative potential:
BCF (Benzalkonium Chloride) = 79 (no significant bioaccumulative effect).
12.4. Mobility in soil:
No available or applicable data.
12.5. Results of PBT and vPvB assessment:
The ingredients are not considered PBT/vPvB according to criteria in Regulation 2023/707.
12.6. Endocrine disrupting properties:
None known.
12.7. Other adverse effects:
No available information.

SECTION 13: Disposal considerations

13.1. Waste treatment methods:
Disposal should be according to local, state or national legislation. Dispose of through authority facilities or pass to chemical disposal company.
EWC-code:
07 05 07 (Waste from pharmaceutical production)
07 06 07 (Waste from the manufacture and use of preservatives)
15 02 02 (absorbents contaminated with the product)

SECTION 14: Transport information

14.1. UN number or ID number: 3265
14.2. UN proper shipping name: CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (Benzalkonium Chloride)
14.3. Transport hazard class(es): 8
14.4. Packing group: II
14.5. Environmental hazards: Yes
14.6. Special precautions for user: None.
14.7. Maritime transport in bulk according to IMO instruments: Not relevant.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:
Should not be used by persons under 18 years of age.
15.2. Chemical safety assessment:
No CSR

SECTION 16: Other information

Hazard statements mentioned in section 3:
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.
Abbreviations:
CMR = Carcinogenicity, mutagenicity and reproductive toxicity.
CSR = Chemical Safety Report
DNEL = Derived No-Effect Level
EC_{50} = Effect Concentration 50%
FW = Fresh Water
LC_{50} = Lethal Concentration 50%
LD_{50} = Lethal Dose 50%
PBT = Persistent, Bioaccumulative, Toxic
PNEC = Predicted No-Effect Concentration
vPvB = very Persistent, very Bioaccumulative
Literature:
ECHA
Training advice:
No special training is required. However, the user should be well instructed in the execution of his/her task, be familiar with this Safety Data Sheet and have normal training in the use of personal protective equipment.
Changes since the previous edition:
1-16

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