SAFETY DATA SHEET

Safety Data Sheet according to OSHA Hazard Communication Standard (HCS) (29 CFR 1910.1200(g)).

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

Product identifier:
FeF Benzalkonium Chloride Solution 50% (53/30/15/2) Ph.Eur., USP/NF
Relevant identified uses of the substance or mixture and uses advised against:
Preservative and active ingredient in the cosmetics and pharmaceutical industries.
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 :
Novo Nordisk Pharmaceuticals Industries Inc.
Building EJ, GMP Warehouse, 646 GLP OneWay
25727 Clayton, North Carolina
USA
Responsible person for the safety data sheet (e-mail): nnprinfo@novonordiskpharmatech.com
Emergency telephone number:
Poison Emergency call 1-800-222-1222 (anywhere in the US)

SECTION 2: Hazards identification

The product is controlled under OSHA Hazard Communication Standard, 29 CFR 1910.1200 and GHS.
Classification of the chemical:
Acute Oral Toxicity Category 4
Skin Corrosive Category 1B
Serious Eye Damage Category 1

Signal word
DANGER

Pictogram(s)/Symbol(s)

Hazard statement(s)
H302: Harmful if swallowed
H314: Causes severe skin burns and eye damage.

SECTION 2: Hazards identification (continued)

Precautionary statement(s)

P260:	Do not breathe vapours/spray.
P264:	Wash skin thoroughly after handling.
P270:	Do not eat, drink or smoke when using this product.
P280:	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330 +P331:	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361 +P353:	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
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.
P363:	Wash contaminated clothing before reuse.
P304+P340:	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P321:	Specific treatment (see section 4 of the SDS).
P405:	Store locked up.
P501:	Dispose of contents/container in accordance with local regulations.

Other hazards not otherwise classified:

The product contains a substance which is very toxic to aquatic life with long-lasting effects.

Ingredients with unknown acute toxicity:

Not relevant.

SECTION 3: Composition/information on ingredients

Substances

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.	REACH reg.no.	Classification	Note
50	Quaternary ammonium compounds, benzyl C12-C16 (even numbered)-alkyldimethyl chlorides	68424-85-1	939-253-5	-	Acute Oral Toxicity Category 4 Skin Corrosive Category 1B Serious Eye Damage Category 1	-

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

SECTION 4: First aid measures

Description of necessary 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.

Most important symptoms and effects, both acute and delayed:

Corrosive to skin, eyes and gastrointestinal tract.

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

Suitable (and unsuitable) extinguishing media:
Not combustible. Use an extinguishing agent suitable for the surrounding fire.
Specific hazards arising from the chemical:
Water used for extinguishing the fire, which has been in contact with the product, may be corrosive.
Special protective equipment and precautions for fire-fighters:
When extinguishing surrounding fires use breathing apparatus with an independent source of air.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:
Use personal protective equipment - see section 8. Ventilate area of leak or spill.
Environmental precautions:
Do not empty into drains – see section 12. Inform appropriate authorities in accordance with local regulations.
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.
Reference to other sections:
See references above.

SECTION 7: Handling and storage

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.
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.

SECTION 8: Exposure controls/personal protection

OSHA Permissible Exposure Limits (PEL): None
Appropriate engineering controls:
Ensure adequate ventilation.

Individual protection measures, such as personal protective equipment (PPE):
PPE must follow OSHA regulations found in 29 CFR 1910.132 and should be chosen in collaboration with the supplier of such equipment. The recommended PPE and the specified standards are only suggestions, as a risk assessment of the relevant current work/operation may lead to other control measures.

Respiratory protection
In case of inadequate ventilation: Use an approved mask with gas filter class A2. The filter has a limited lifetime and must be changed. Read the manufacturer's instructions. Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149.

Skin/hand protection
Wear protective gloves of nitrile rubber It has not been possible to find data for breakthrough time. In case of spill on the glove, it is recommended to change it.

Eye/face protection
Wear tight fitting safety goggles (as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or EN ISO 16321-1) when there is a risk of splashes.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties:

Physical state:	Viscous Liquid
Colour:	Colorless
Odour:	No available data
Melting point/freezing point (°F):	No available data
Boiling point or initial boiling point and boiling range (°F):	No available data
Flammability (solid, gas):	No available data
Lower and upper explosion limit (vol-%):	No available data
Flash point (°F):	No available data
Auto-ignition temperature (°F):	No available data
Decomposition temperature (°F):	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
Density and/or relative density:	~0.98 g/cm^3
Relative vapour density:	No available data
Particle characteristics:	No available data
Other information:	None relevant

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

Information on toxicological (health) effects:
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 Contact:
Has a corrosive effect with redness and pain. May cause wounds and tissue damage.
Eye Contact:
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.

SECTION 11: Toxicological information (continued)

Delayed (chronic) effects:
None known.
Acute Toxicity

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
Not a skin sensitizer.
Mutagenic toxicity
No mutagenic effects
Reproductive toxicity
No reproductive effects.
Carcinogenic toxicity
No carcinogenic effects.
NTP's Report on Carcinogens (RoC), latest ed.: No data
IARC Monographs, or by OSHA.: No data
Specific Target Organ Toxicity
No available data.

SECTION 12: Ecological information

Ecotoxicity:

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

Persistence and degradability:
Benzalkonium Chloride is rapidly biodegradable (OECD 301 test).
Bioaccumulative potential:
BCF (Benzalkonium Chloride) = 79 (no significant bioaccumulative effect).
Mobility in soil:
No available or applicable data.
Endocrine disrupting properties:
None known.
Other adverse effects:
No available information.

SECTION 13: Disposal considerations

Waste treatment methods:
Dispose of contents/container in accordance with applicable local/regional/national/international regulations. See Section 8 for guidance on PPE.

Incinerate and dispose of waste product in a permitted waste incineration facility/industrial waste facility.

Chemical waste generators must determine whether a discarded chemical is classified as hazardous waste. US EPA guidelines for the classification determination are listed in 40 CFR Parts 261.3. Additionally, waste generators must consult state and local hazardous waste regulations to ensure complete and accurate classification.

SECTION 14: Transport information

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

SECTION 15: Regulatory information

US Federal Regulations

NATIONAL INVENTORY STATUS - U.S. Inventory (TSCA):
All components are listed or exempted.
TSCA section 12b:
Not listed.
SARA Title III (Superfund Amendments and Reauthorization Act):
Not listed.
SARA Title III Sect. 302 Extremely Hazardous Substances (40 CFR 355):
Not listed.
SARA Title III Sect. 311/312 Extremely Hazardous Categories (40 CFR 370.21):
Immediate Hazard: Not listed.
Clean Air Act:
Not listed.
Clean Water Act:
Not listed.
STATE REGULATIONS:
Proposition 65: Not regulated.

This SDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.

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.
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

SECTION 16: Other information (continued)

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.
The above information, which is accurate to the best of our knowledge and belief, describes the safety aspects of our product but does not warrant any product properties.

Changes since the previous edition:
1-16

Prepared by: Altox a/s – Tonsbakken 16-18 - 2740 Skovlunde - Phone +45 38 34 77 98 / HA - Quality control: PH