



Product name: FeF Benzalkonium Chloride Sol. 50% (53/30/15/2) Page: 1/11

Ph. Eur., USP/NF

Revision: 2022-12-05 Print date: 2023-06-28

SDS-ID: EU-EN/1.1

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

1.1. Product identifier

Product name: FeF Benzalkonium Chloride Sol. 50% (53/30/15/2) Ph. Eur., USP/NF

Container size: 1 kg

5 kg 25 kg

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

<u>Application:</u> Preservative and active ingredient in the cosmetic and pharmaceutical industries.

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

Responsible for safety data

sheet authoring:

nnprinfo@novonordiskpharmatech.com

1.4. Emergency telephone number

<u>Emergency telephone:</u> National Poison Control Centres are available in Member Countries.

Product name: FeF Benzalkonium Chloride Sol. 50% (53/30/15/2) Page: 2/11

Ph. Eur., USP/NF

Revision: 2022-12-05 Print date: 2023-06-28

SDS-ID: EU-EN/1.1

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

CLP: 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 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

<u>PBT/vPvB:</u> 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>	CAS-No.:	EC No.:	REACH Reg. No:	<u>Chemical name:</u>	Hazard classification:	Notes:
50	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	

Product name: FeF Benzalkonium Chloride Sol. 50% (53/30/15/2) Page: 3/11

Ph. Eur., USP/NF

Revision: 2022-12-05 Print date: 2023-06-28

> SDS-ID: EU-EN/1.1

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

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

10

1

hospital and bring along 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 along these

instructions.

Eye contact: Immediately flush with plenty of water. Remove any contact lenses and open

eyelids widely. Call an ambulance. Continue flushing during transport to hospital.

Bring along these instructions.

Ingestion: Immediately call a Poison Center/doctor. Rinse mouth. Do not induce vomiting.

Do not drink anything without first consulting a doctor. Have these instructions at

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

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

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

fighters:

Protective equipment for fire- Use air-supplied respirator during fire fighting. Severe corrosive hazard. Wear

chemical protection suits.

Product name: FeF Benzalkonium Chloride Sol. 50% (53/30/15/2) Page: 4/11

Ph. Eur., USP/NF

Revision: 2022-12-05 Print date: 2023-06-28

SDS-ID: EU-EN/1.1

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

<u>Personal precautions:</u> 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

<u>Environmental</u> Do not discharge into drains, water courses or onto the ground.

precautions:

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Absorb spillage with suitable absorbing 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.

<u>Technical measures:</u> Keep the workplace clean. Use work methods which minimise aerosol production.

<u>Technical precautions:</u> Provide easy access to water supply and eye wash facilities.

7.2. Conditions for safe storage, including any incompatibilities

<u>Technical measures for safe</u> No special precautions.

storage:

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.

Product name: FeF Benzalkonium Chloride Sol. 50% (53/30/15/2) Page: 5/11

Ph. Eur., USP/NF

Revision: 2022-12-05 Print date: 2023-06-28

SDS-ID: EU-EN/1.1

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No occupational exposure limit assigned.

Please note that there may be national occupational exposure limits.

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.

<u>Personal protection:</u> 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.

<u>Hand protection:</u> Wear protective gloves. Nitrile gloves are recommended. The most suitable

glove must be chosen in collaboration with the supplier of gloves, who can

inform about the breakthrough time of the glove material.

<u>Eye protection:</u> Wear goggles/face shield.

<u>Skin protection:</u> Wear apron or protective clothing in case of splashes.

<u>Hygiene measures:</u> Wash hands after contact.

Environmental Exposure

Controls:

Not available.

Product name: FeF Benzalkonium Chloride Sol. 50% (53/30/15/2) Page: 6/11

Ph. Eur., USP/NF

Revision: 2022-12-05 Print date: 2023-06-28

SDS-ID: EU-EN/1.1

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state: Viscous liquid. Colour: Colourless. Odour: Not available. pH: 5-6 (10-20 g/l) **Boiling point:** Not available. Flash point: Not available. **Explosion limits:** Not relevant. Vapour pressure: Not available.

Relative density: ~ 0,98

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

<u>Stability:</u> 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

<u>Incompatible materials:</u> Strong oxidizing substances.

10.6. Hazardous decomposition products

<u>Hazardous decomposition</u> If heated to more than 150°C, the following substance(s) will be released: Benzyl

products: chloride and Methyl chloride.

Product name: FeF Benzalkonium Chloride Sol. 50% (53/30/15/2) Page: 7/11

Ph. Eur., USP/NF

Revision: 2022-12-05 Print date: 2023-06-28

> SDS-ID: EU-EN/1.1

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Harmful if swallowed. Acute Toxicity (Oral):

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

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

sensitisation:

Carcinogenicity:

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

Germ cell mutagenicity:

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: Harmful if swallowed. 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.

Quaternary ammonium compounds, benzyl C12-16 (even numbered)-Toxicological data:

alkyldimethyl chlorides:

LD50 (oral, rat):795 mg/kg

11.2. Information on other hazards

Endocrine disrupting

The product does not contain any substance identified as having endocrine

properties:

disrupting properties.

Product name: FeF Benzalkonium Chloride Sol. 50% (53/30/15/2) Page: 8/11

Ph. Eur., USP/NF

Revision: 2022-12-05 Print date: 2023-06-28

SDS-ID: EU-EN/1.1

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

<u>Ecotoxicity:</u> Very 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): $0.1 < LC50 \le 1 \text{ mg/l}$ (96 hours)

EC50 (Daphnia): 0,01 < EC50 ≤ 0,1 mg/l (48 hours)

0,001 < NOEC ≤ 0,01 mg/l

12.2. Persistence and degradability

Degradability: The product is readily biodegradable.

12.3. Bioaccumulative potential

<u>Bioaccumulative potential:</u> Bioaccumulation: Is not expected to be bioaccumulable.

12.4. Mobility in soil

Mobility: No data available.

12.5. Results of PBT and vPvB assessment

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

12.6. Endocrine disrupting properties

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

<u>properties:</u> 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 / 07 06 07

Product name: FeF Benzalkonium Chloride Sol. 50% (53/30/15/2) Page: 9/11

Ph. Eur., USP/NF

Revision: 2022-12-05 Print date: 2023-06-28

SDS-ID: EU-EN/1.1

SECTION 14: TRANSPORT INFORMATION

14.1. UN number

<u>UN-No:</u> 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:

14.5. Environmental hazards

Marine pollutant: Yes. Environmentally Hazardous Yes.

substance:

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

<u>Transport in bulk:</u> Not relevant.

Product name: FeF Benzalkonium Chloride Sol. 50% (53/30/15/2) Page: 10/11

Ph. Eur., USP/NF

Revision: 2022-12-05 Print date: 2023-06-28

SDS-ID: EU-EN/1.1

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: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of

18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and

2000/21/EC, with amendments.

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.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work, with

amendments.

Council Directive 94/33/EC of 22 June 1994 on the protection of young people at

work, with amendments.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, with amendments. 2014/955/EC: Commission Decision of 18 December 2014 amending Decision

2000/532/EC as regards the list of wastes.

15.2. Chemical Safety Assessment

<u>CSA status:</u> No chemical safety assessment has been carried out.

Product name: FeF Benzalkonium Chloride Sol. 50% (53/30/15/2) Page: 11/11

Ph. Eur., USP/NF

Revision: 2022-12-05 Print date: 2023-06-28

SDS-ID: EU-EN/1.1

SECTION 16: OTHER INFORMATION

For restrictions on use see section 15.

<u>Abbreviations and acronyms</u> ATE(d) = Acute Toxicity Estimate, dermal.

<u>used in the safety data sheet:</u> ATE(i) = Acute Toxicity Estimate, inhalation.

ATE(o) = Acute Toxicity Estimate, oral.

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.

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.