

SAFETY DATA SHEET

Product name: FeF Strong Cetrime Solution 40% BP Pharma with isopropyl alcohol Page: 1/11
 Revision Date: 2016-12-16 Print date: 2016-12-16
 SDS-ID: GB-EN/15.0

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

1.1. Product identifier

Product name: FeF Strong Cetrime Solution 40% BP Pharma with isopropyl alcohol
Container size: 200 kg
 1000 kg

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

Application: Preservative and active ingredient in the personal care and pharmaceutical industries.

Identified use(s): Formulation & (re)packing of substances and mixtures
 Use in personal care products.
 Use of articles with personal care products, pharmaceuticals.
 Formulation of articles with personal care products, pharmaceuticals.

Uses advised against: None.

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

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

SAFETY DATA SHEET

Product name: FeF Strong Cetrimide Solution 40% BP Pharma with isopropyl alcohol Page: 2/11
Revision Date: 2016-12-16 Print date: 2016-12-16
SDS-ID: GB-EN/15.0

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS/CLP: Acute Tox. 4;H302 - Skin Irrit. 2;H315 - Eye Dam. 1;H318 - STOT SE 3;H335 - STOT RE 2;H373 - Aquatic Acute 1;H400

2.2. Label elements



Danger

Contains: Trimethyltetradecylammonium bromide

H302 Harmful if swallowed.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H335 May cause respiratory irritation.

H373c May cause damage to organs through prolonged or repeated exposure if swallowed.

H400 Very toxic to aquatic life.

P260h Do not breathe vapour/spray.

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

P280g Wear eye and face protection.

P305/351/338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P273 Avoid release to the environment.

2.3. Other hazards

This product is not flammable.
Please note that although this material has a flash-point below 55°C, it does not maintain combustion.

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

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

The product contains: quaternary ammonium compounds, organic solvent and water.

SAFETY DATA SHEET

Product name: FeF Strong Cetrime Solution 40% BP Pharma with isopropyl alcohol Page: 3/11
Revision Date: 2016-12-16 Print date: 2016-12-16
SDS-ID: GB-EN/15.0

GHS/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>
32	1119-97-7	214-291-9	-	Trimethyltetradecylammonium bromide	Acute Tox. 4;H332 Skin Irrit. 2;H315 Eye Dam. 1;H318 STOT SE 3;H335 STOT RE 2;H373 Aquatic Acute 1;H400	M = 100
8	1119-94-4	214-290-3	-	Dodecyltrimethylammonium bromide	Acute Tox. 4;H302 Skin Irrit. 2;H315 Eye Irrit. 2;H319 STOT SE 3;H335 Aquatic Acute 1;H400	M = 100
8	67-63-0	200-661-7	-	Propan-2-ol	Flam. Liq. 2;H225 Eye Irrit. 2;H319 STOT SE 3;H336	

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 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 for up to 15 minutes. Remove any contact lenses and open eyelids widely. If irritation persists: Continue flushing during transport to hospital. Bring these instructions.

Ingestion: Immediately rinse mouth and drink plenty of water. Keep person under observation. If person becomes uncomfortable seek hospital and bring these instructions.

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.

SAFETY DATA SHEET

Product name: FeF Strong Cetrimide Solution 40% BP Pharma with isopropyl alcohol Page: 4/11
Revision Date: 2016-12-16 Print date: 2016-12-16
SDS-ID: GB-EN/15.0

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.(HBr, NOx)

5.3. Advice for firefighters

Protective equipment for fire-fighters: Selection of respiratory protection for fire fighting: follow the general fire precautions indicated in the workplace.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Avoid inhalation of vapours and 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: Small spillages: Absorb spillage with suitable absorbent material.
Large spillages: Dam and absorb spillages with sand, earth or other non-combustible 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 vapours and spray mist and contact with skin and eyes. Change contaminated 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: Follow rules for flammable liquids.

Storage conditions: Store in tightly closed original container in a well-ventilated place. 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 Strong Cetrimide Solution 40% BP Pharma with isopropyl alcohol Page: 5/11
Revision Date: 2016-12-16 Print date: 2016-12-16
SDS-ID: GB-EN/15.0

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Occupational exposure limits:

<u>CAS-No.:</u>	<u>Chemical name:</u>	<u>As:</u>	<u>Exposure limits:</u>	<u>Type:</u>	<u>Notes:</u>	<u>References:</u>	
67-63-0	Propan-2-ol	-	400 ppm	999 mg/m ³	TWA	-	EH40
		-	500 ppm	1250 mg/m ³	STEL	15min	

DNEL/PNEC:

Trimethyltetradecylammonium bromide:

DNEL:

Acute Toxicity (Inhalation): - Local Effects: 0,05 mg/m³

Acute Toxicity (Dermal): - Local Effects: 250 µg/cm²

Long term systemic effect - (Inhalation.): 0,05 mg/m³

Long term systemic effect - (Dermal): 0,4 mg/kg/day

Long Term - Local Effects - (Dermal): 50 µg/cm²

PNEC:

Freshwater: 0,026 µg/l

Marinewater: 0,0026 µg/l

Intermittent release: 0,54 µg/l

STP: 0,19 mg/l

Soil: 0,21 mg/kg

8.2. Exposure controls

Engineering measures:

Provide adequate ventilation. Observe Occupational Exposure Limits and minimise the risk of inhalation of vapours and spray mist. 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:

In case of inadequate ventilation use suitable respirator. It is recommended to use respiratory equipment with combination filter, type A2/P3. The use of filtering respirators should be limited to max. 3 hours per day.

Hand protection:

Wear protective gloves. Nitrile gloves are recommended, but be aware that the liquid may penetrate the gloves. Frequent change is advisable. 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 suitable protective clothing.

Hygiene measures:

Wash hands after contact.

Environmental Exposure Controls:

Not available.

SAFETY DATA SHEET

Product name: FeF Strong Cetrimide Solution 40% BP Pharma with isopropyl alcohol Page: 6/11
Revision Date: 2016-12-16 Print date: 2016-12-16
SDS-ID: GB-EN/15.0

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance: Clear and colourless to slightly yellow viscous solution.
Odour: Odour of alcohol.
pH: 5-7.5 (100 g/l)
Boiling point: Not available.
Flash point: 48°C
Explosive limits Not relevant.
Relative density: ~ 1.0
Solubility: Miscible with: Water and lower alcohols.
Decomposition temperature (°C): Not available.

9.2. Other information

Other data: Please note that although this material has a flash-point below 55°C, it does not maintain combustion.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity: None known.

10.2. Chemical stability

Stability: Stable under the prescribed storage 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 200°C, the following substance(s) will be released: Alkyl bromides. Amines.

SAFETY DATA SHEET

Product name: FeF Strong Cetrimide Solution 40% BP Pharma with isopropyl alcohol Page: 7/11
Revision Date: 2016-12-16 Print date: 2016-12-16
SDS-ID: GB-EN/15.0

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute Toxicity (Oral): Harmful if swallowed.

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 skin irritation.

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: May cause respiratory irritation.

STOT - Repeated exposure: May cause damage to organs through prolonged or repeated exposure if swallowed.

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

Inhalation: Irritating to respiratory system. In high concentrations, vapours are narcotic and may cause headache, fatigue, dizziness and nausea.

Skin contact: Irritating to skin.

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

Ingestion: Harmful if swallowed. Causes stomach pain, vomiting, diarrhoea and convulsions.

Specific effects: Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Toxicological data: Trimethyltetradecylammonium bromide:
Acute Toxicity (Oral LD50): 333-460 mg/kg (Rat)
Acute Toxicity (Dermal LD50): 4,3 ml/kg (~2150 mg/kg) (Rabbit)
Acute Toxicity (Inhalation): Adverse Effects: 1,8 mg/m³ (Mouse)
Long Term (Oral) Adverse Effects: 75 mg/kg/day - 21days (Rat)

SAFETY DATA SHEET

Product name: FeF Strong Cetrime Solution 40% BP Pharma with isopropyl alcohol Page: 8/11
Revision Date: 2016-12-16 Print date: 2016-12-16
SDS-ID: GB-EN/15.0

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity: Very toxic to aquatic organisms.

Trimethyltetradecylammonium bromide ($0.001 < EC_{50} \leq 0.01$ mg/l):
LC₅₀ (Danio rerio, 96 hours): 1,81 mg/l (OECD Test Guideline 203)
EC₅₀ (Daphnia magna, 48 hours): 0,022 mg/l (OECD Test Guideline 202)
IC₅₀ (Pseudokirchneriella subcapitata, 72 hours): 0,0054 mg/l (OECD Test Guideline 201)

12.2. Persistence and degradability

Degradability: The product is expected to be biodegradable.
(quaternary ammonium compounds, FeF Chemicals A/S, 1993)

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. Other adverse effects

Other adverse effects: The product contains a substance which has a photochemical ozone creation potential.

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

SAFETY DATA SHEET

Product name: FeF Strong Cetrimide Solution 40% BP Pharma with isopropyl alcohol Page: 9/11
Revision Date: 2016-12-16 Print date: 2016-12-16
SDS-ID: GB-EN/15.0

SECTION 14: TRANSPORT INFORMATION

14.1. UN number

UN-No: 3082

14.2. UN proper shipping name

Proper Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Trimethyltetradecylammonium bromide)

14.3. Transport hazard class(es)

Class: 9

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 Strong Cetrimide Solution 40% BP Pharma with isopropyl alcohol	Page:	10/11
Revision Date:	2016-12-16	Print date:	2016-12-16
		SDS-ID:	GB-EN/15.0

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: 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.

-

The Control of Substances Hazardous to Health Regulations 2002 (S.I 2002 No. 2677) with amendments.

EH40/2005, Workplace exposure limits 2005, 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 Strong Cetrimide Solution 40% BP Pharma with isopropyl alcohol Page: 11/11
Revision Date: 2016-12-16 Print date: 2016-12-16
SDS-ID: GB-EN/15.0

SECTION 16: OTHER INFORMATION

For restrictions on use see section 15.

The following sections contain revisions or new statements: 1, 11.

Abbreviations and acronyms used in the safety data sheet: PBT = Persistent, Bioaccumulative and Toxic.
vPvB = very Persistent and very Bioaccumulative.
DNEL = Derived No Effect Level.
PNEC = Predicted No Effect Concentration.
STP = Sewage Treatment Plant.

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

Wording of H-statements:

H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.

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.
