

SAFETY DATA SHEET

Product name:	FeF Cetrimide Ph.Eur.	Page:	1/12
Revision:	2019-11-05	Print date:	2019-11-05
		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 Cetrimide Ph.Eur.
CAS-No.: 1119-97-7
EC No.: 214-291-9
REACH Reg. No: 01-2119989161-33-0000
Container size: 25 kg

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

Application: Preservative and active ingredient in the cosmetic and pharmaceutical industries.
Identified use(s): Manufacture of substances.
Formulation & (re)packing of substances and mixtures.
Formulation of articles with cosmetics, personal care products, pharmaceuticals.
Use as a processing aid.
Use in cosmetics and personal care products.
Use in laboratories.
Use of articles with cosmetics, 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 Cetrimide Ph.Eur.
Revision: 2019-11-05

Page: 2/12
Print date: 2019-11-05
SDS-ID: GB-EN/14.0

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

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 - Aquatic Chronic 1;H410

References: SCL: Skin Irrit. 2;H315: C ≥ 2,5%

2.2. Label elements



Danger

Contains:

Tetradonium bromide
EC No.: 214-291-9

H302	Harmful if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.
H373	May cause damage to organs through prolonged or repeated exposure if swallowed.
H410	Very toxic to aquatic life with long lasting effects.
P260	Do not breathe dust.
P262	Do not get in eyes, on skin, or on clothing.
P280	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

PBT/vPvB: This substance is not classified as PBT or vPvB.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

SAFETY DATA SHEET

Product name: FeF Cetrimide Ph.Eur. Page: 3/12
Revision: 2019-11-05 Print date: 2019-11-05
SDS-ID: GB-EN/14.0

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>
100	1119-97-7	214-291-9	-	Tetradonium bromide	Acute Tox. 4;H302 Skin Irrit. 2;H315 Eye Dam. 1;H318 STOT SE 3;H335 STOT RE 2;H373 Aquatic Acute 1;H400 Aquatic Chronic 1;H410	

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: Dust 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. If irritation persists: Seek medical attention and bring along these instructions.

Eye contact: Do not rub eye. Immediately flush with plenty of water for at least 15 minutes. Remove any contact lenses and open eyelids widely. If irritation persists: Continue flushing during transport to hospital. Bring along 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.

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.

SAFETY DATA SHEET

Product name: FeF Cetrimide Ph.Eur.

Page: 4/12

Revision: 2019-11-05

Print date: 2019-11-05

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 dust and contact with skin and eyes. Use work methods which minimise dust production. 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: Collect spillage with shovel, broom or the like. 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 dust and contact with skin and eyes. Change contaminated clothing. Avoid eating, drinking and smoking when using the product.

Technical measures: Use work methods which minimise dust production. Avoid spreading dust.

Technical precautions: Mechanical ventilation required. 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 Cetrimide Ph.Eur.

Page: 5/12

Revision: 2019-11-05

Print date: 2019-11-05

SDS-ID: GB-EN/14.0

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>
-	Dusts, respirable dust	-	4 mg/m ³	TWA	-	EH40
-	Dusts, total inhalable dust	-	10 mg/m ³	TWA	-	EH40

Notes: EH40: EH40/2005.

DNEL/PNEC:

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 dust. 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:

During dust-raising work: 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. Other types of gloves can be recommended by the glove supplier.

Eye protection:

Wear goggles/face shield.

Skin protection:

Wear suitable protective clothing.

Hygiene measures:

Wash hands after contact.

Wash contaminated clothing before reuse.

Environmental Exposure Controls:

Not available.

SAFETY DATA SHEET

Product name: FeF Cetrimide Ph.Eur.
Revision: 2019-11-05

Page: 6/12
Print date: 2019-11-05
SDS-ID: GB-EN/14.0

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance: A white or almost white crystalline powder.
Manufacture of substances.: Solution.

Odour: Not available.

Odour threshold: Not available.

pH: Not available.

Melting point / freezing point: 245°C (101,3 kPa)

Boiling point: Not relevant. Decomposes prior to boiling

Flash point: Not relevant. Solid.

Evaporation rate: Negligible.

Flammability (solid, gas): Not flammable.

Explosive limits Not relevant.

Vapour pressure: < 0,001 Pa (25°C) (calculated)

Vapour density: Not relevant.

Relative density: 0,5 g/cm³ (20°C)

Solubility: Soluble in water.
200 g/l (20°C) (calculated)

Partition coefficient (n-octanol/water): log Kow: 2,2 (20°C)

Auto-ignition temperature (°C): 210°C (1013 hPa)

Decomposition temperature (°C): >200°C

Viscosity: Not relevant. Solid.

Explosive properties: None.

Oxidising properties: None.

9.2. Other information

Other data: Surface tension: 42 mN/m (20°C) (in water: 336 mg/l)

SAFETY DATA SHEET

Product name: FeF Cetrimide Ph.Eur.

Page: 7/12

Revision: 2019-11-05

Print date: 2019-11-05

SDS-ID: GB-EN/14.0

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 Cetrimide Ph.Eur.

Page: 8/12

Revision: 2019-11-05

Print date: 2019-11-05

SDS-ID: GB-EN/14.0

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

<u>Acute Toxicity (Oral):</u>	Harmful if swallowed.
<u>Acute Toxicity (Dermal):</u>	Based on available data, the classification criteria are not met.
<u>Acute Toxicity (Inhalation):</u>	Based on available data, the classification criteria are not met.
<u>Skin Corrosion/Irritation:</u>	Causes skin irritation.
<u>Serious eye damage/irritation:</u>	Causes serious eye damage.
<u>Respiratory or skin sensitisation:</u>	Skin sensitisation: Based on available data, the classification criteria are not met. Respiratory sensitisation: Data lacking.
<u>Germ cell mutagenicity:</u>	Based on available data, the classification criteria are not met.
<u>Carcinogenicity:</u>	Based on available data, the classification criteria are not met.
<u>Reproductive Toxicity:</u>	Based on available data, the classification criteria are not met.
<u>STOT - Single exposure:</u>	May cause respiratory irritation.
<u>STOT - Repeated exposure:</u>	May cause damage to organs through prolonged or repeated exposure if swallowed.
<u>Aspiration hazard:</u>	Data lacking.
<u>Inhalation:</u>	Dust irritates the respiratory system, and may cause coughing and difficulties in breathing.
<u>Skin contact:</u>	Causes skin irritation.
<u>Eye contact:</u>	Causes serious eye damage. Immediate first aid is necessary.
<u>Ingestion:</u>	Harmful if swallowed. Causes stomach pain, vomiting, diarrhoea and convulsions.
<u>Specific effects:</u>	May cause damage to organs through prolonged or repeated exposure if swallowed. Target organs: Gastro-intestinal tract.
<u>Toxicological data:</u>	Acute Toxicity (Oral LD50): 390 mg/kg (rat) Acute Toxicity (Dermal LD50): 2150 mg/kg (rabbit) Acute Toxicity (Inhalation): Adverse Effects: 1,8 mg/m ³ (Mouse)

SAFETY DATA SHEET

Product name: FeF Cetrimide Ph.Eur.

Page: 9/12

Revision: 2019-11-05

Print date: 2019-11-05

SDS-ID: GB-EN/14.0

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

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

M-factor (acute): 100

M-factor (chronic): 1

Freshwater fish:

LC50 (Danio rerio, 96 hours): 1,81 mg/l

NOEC (Pimephales sp.): 0.46 mg/l

Freshwater invertebrates:

EC50 (Daphnia magna, 48 hours): 22 µg/l = 0,022 mg/l

NOEC (Daphnia magna, 21 days): 23 µg/l = 0,023 mg/l

Freshwater algae:

EC50 (Pseudokirchneriella subcapitata, 72 hours): 5,38 µg/l = 0,00538 mg/l

NOEC: 1,3 µg/l = 0,0013 mg/l (Pseudokirchnerella subcapitata, 72 hours)

Aquatic Microorganisms:

EC50/LC50: 19 mg/l

Soil Macroorganisms:

NOEC: 620 mg/kg

Toxicity to terrestrial plants:

EC50: 0,2 mg/l

Soil Microorganisms:

EC50/LC50: 2000 mg/kg

NOEC: 21 mg/kg

Toxicity to other terrestrial organisms:

NOEC: 1028 mg/kg (Chironomus riparius)

12.2. Persistence and degradability

Degradability: Water: The product is readily biodegradable.

Soil: Half-life: 58 days (22°C)

12.3. Bioaccumulative potential

Bioaccumulative potential: The product is not bioaccumulating.

BCF 750

12.4. Mobility in soil

Mobility: The product adsorbs to soil particles.

Koc: 31000 (20°C):

log Koc: 4,49 (20°C):

SAFETY DATA SHEET

Product name: FeF Cetrimide Ph.Eur.
Revision: 2019-11-05

Page: 10/12
Print date: 2019-11-05
SDS-ID: GB-EN/14.0

12.5. Results of PBT and vPvB assessment

PBT/vPvB: This substance is not classified as PBT or vPvB.

12.6. 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

SECTION 14: TRANSPORT INFORMATION

14.1. UN number

UN-No: 3077

14.2. UN proper shipping name

Proper Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Tetradonium 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 Cetrimide Ph.Eur.

Page: 11/12

Revision: 2019-11-05

Print date: 2019-11-05

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:

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).

The Management of Health and Safety at Work Regulations 1999 (SI 1999 No. 3242), with amendments.

15.2. Chemical Safety Assessment

CSA status:

A chemical safety assessment has been carried out.

SAFETY DATA SHEET

Product name: FeF Cetrimide Ph.Eur.

Page: 12/12

Revision: 2019-11-05

Print date: 2019-11-05

SDS-ID: GB-EN/14.0

SECTION 16: OTHER INFORMATION

For restrictions on use see section 15.

The user must be instructed in the proper work procedure and be familiar with the contents of these instructions.

The following sections contain revisions or new statements: 2, 3, 8, 9, 11, 16.

Abbreviations and acronyms UVCB substances = Substances of Unknown or Variable composition.

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.

SCL: Specific Concentration Limit

NOEC = No Observed Effect Concentration.

LD50 = Lethal Dose 50%.

EC50 = Effective Concentration 50%.

STP = Sewage Treatment Plant.

Key literature references and sources for data:

CHEMICAL SAFETY REPORT on Tetradonium bromide

Wording of H-statements:

H302	Harmful if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.
H373	May cause damage to organs through prolonged or repeated exposure.
H373c	May cause damage to organs through prolonged or repeated exposure if swallowed.
H373C	May cause damage to organs (blood, thymus) through prolonged or repeated exposure.
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.
