

# SAFETY DATA SHEET

Product name:	FeF Cetrimide Ph.Eur.	Page:	1/12
Revision:		Print date:	2022-12-06
		SDS-ID:	EU-EN/1.0

## 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: National Poison Control Centres are available in Member Countries.  
 + 45 56 67 10 00  
 (Only during office hours)

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## 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

### 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 + P351 + P338	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

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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	

<u>Chemical name:</u>	<u>SCL</u>	<u>M (ac)</u>	<u>M (chr)</u>
Tetradonium bromide	Skin Irrit. 2;H315: C ≥ 2.5%	100	1

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

<u>Inhalation:</u>	Dust inhalation: Move injured person into fresh air and keep person calm under observation. If uncomfortable: Seek hospital and bring along these instructions.
<u>Skin contact:</u>	Remove contaminated clothes and rinse skin thoroughly with water. If irritation persists: Seek medical attention and bring along these instructions.
<u>Eye contact:</u>	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.
<u>Ingestion:</u>	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.

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## 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.

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## 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.

DNEL/PNEC:

DNEL:

Acute Toxicity (Inhalation): - Local Effects: 0,05 mg/m<sup>3</sup>

Acute Toxicity (Dermal): - Local Effects: 250 µg/cm<sup>2</sup>

Long term systemic effect - (Inhalation): 0,05 mg/m<sup>3</sup>

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

Long Term - Local Effects - (Dermal): 50 µg/cm<sup>2</sup>

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.

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## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

Physical state: 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.

Explosion limits: Not relevant.

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

Vapour density: Not relevant.

Relative density: 0,5 g/cm<sup>3</sup> (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)

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## 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 oxidizing 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.

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## 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 <sup>3</sup> (Mouse)

### 11.2. Information on other hazards

Endocrine disrupting properties: The substance is not identified as having endocrine disrupting properties.

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## 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):

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## **12.5. Results of PBT and vPvB assessment**

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

## **12.6. Endocrine disrupting properties**

Endocrine disrupting properties: The substance is not identified as having endocrine 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

## **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.

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## 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.

Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, with amendments.

Commission Directive 91/322/EEC of 29 May 1991 on establishing indicative limit values by implementing Council Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work, with amendments.

Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, with amendments.

Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos 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.

Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work, with amendments.

### **15.2. Chemical Safety Assessment**

**CSA status:**

A chemical safety assessment has been carried out.

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## 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.

Abbreviations and acronyms used in the safety data sheet: CSA = Chemical Safety Assessment.  
DNEL = Derived No Effect Level.  
EC50 = Effective Concentration 50%.  
LD50 = Lethal Dose 50%.  
NOEC = No Observed Effect Concentration.  
PBT = Persistent, Bioaccumulative and Toxic.  
PNEC = Predicted No Effect Concentration.  
SCL = Specific Concentration Limit.  
STOT = Specific Target Organ Toxicity.  
STP = Sewage Treatment Plant.  
UVCB substances = Substances of Unknown or Variable composition.  
vPvB = very Persistent and very Bioaccumulative.

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.

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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](http://www.dhigroup.com).

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