

SAFETY DATA SHEET

Electrode Cream

The safety data sheet is in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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

Date issued 15.06.2016

1.1. Product identifier

Product name Electrode Cream

Article no. 217 083 01, 217 083 05, 217 083 14, 217 083 18, 2046978-001

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

Use categories nordic (UCN). 55 Others

Use of the substance/preparation The Electrode Cream is intended use to support the quality of electrical connection between devices and the human body for ECG acquisition with reusable electrodes and for Electrical Cardioversion (Defibrillation) with hard paddles.
The Electrode Cream is intended for use on adult and pediatric patients.
The Electride Cream is intended for use by qualified medical personnel under the direct supervision of a licensed health-care practitioner.

1.3. Details of the supplier of the safety data sheet

Importer

Company name CareFusion Finland 320 Oy

Postal address Kuortaneenkatu 2

Postcode 00510

City Helsinki

Country Finland

Tel +358 (0)20 7871 090

Fax +358 (0)20 7871 099

E-mail asiakaspalvelu@carefusion.com

Website <http://www.carefusion.fi>

Enterprise no. 2353074-1

1.4. Emergency telephone number

Emergency telephone Emergency telephone number:112
Poison Information Centre (in Finland), open 24 h daily:(09) 471977 or (09) 4711

Identification comments Please contact the Emergency Centre in your own country, e.g. 112 in European Union countries.

SECTION 2: Hazards identification

2.1. Classification of substance or mixture

Classification notes CLP In accordance with current regulations, this product has not been classified as hazardous.

2.2. Label elements

Other Label Information (CLP) No labeling. In accordance with current regulations, this product has not been classified as hazardous.

No labeling: Product is in compliance with the Medical Device Directive

93/42/EEC.

2.3. Other hazards

Other hazards Not known.

SECTION 3: Composition/information on ingredients**3.2. Mixtures**

Substance	Identification	Classification	Contents
Octadecan-1-ol, ethoxylated, < 2.5 EO	CAS no.: 9005-00-9 EC no.: 500-017-8	Aquatic Acute 1;H400; Aquatic Chronic 2;H411; M-factor:1	0 - 2 %
Alcohols, C16-18, ethoxylated	CAS no.: 68439-49-6 EC no.: 500-212-8	Acute tox. 4; H302 Eye Irrit. 2; H319 Aquatic Acute 1; H400 Aquatic Chronic 3; H412	0 - 1,5 %

Description of the mixture

Water based viscous cream.

Substance comments

The product does not contain other ingredients classified as hazardous to health or the environment at concentrations exceeding the concentration limits for listing such ingredients.

The product contains (according to INCI): Aqua, Sorbitol, Sodium Chloride, Cetearyl Alcohol, Steareth-2, Cetareth-12, Phenoxyethanol, Potassium Sorbate, Sodium Hydroxide, Carbomer, Edta, Sorbic Acid, Perfume

The full text for all hazard statements is displayed in section 16.

SECTION 4: First aid measures**4.1. Description of first aid measures**

General	Get medical advice/attention if you feel unwell.
Inhalation	If symptoms occur, move exposed person to fresh air. Get medical attention if symptoms persist or are severe.
Skin contact	Wash contaminated skin thoroughly with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.
Eye contact	Immediately flush eyes with plenty of water for several minutes, holding eyelids open. Remove contact lenses, if present and easy to do, and continue rinsing. If eye irritation persists: Get medical advice/attention.
Ingestion	Do NOT induce vomiting. Rinse mouth with water and then drink plenty of water. Seek medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Acute symptoms and effects None known.

Delayed symptoms and effects None known.

4.3. Indication of any immediate medical attention and special treatment needed

Other Information Treat symptomatically.

SECTION 5: Firefighting measures**5.1. Extinguishing media**

Suitable extinguishing media Use an extinguishing agent suitable for the surrounding fire.

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products None known.

5.3. Advice for firefighters

Personal protective equipment Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	Stop leak if safe to do so.
Personal protection measures	Avoid contact with skin or eyes. Wear appropriate personal protective equipment.

6.2. Environmental precautions

Environmental precautionary measures	Not relevant.
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6.3. Methods and material for containment and cleaning up

Cleaning method	Wash in clear warm water. After cream has dried clean with brush and wash with clear warm water.
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6.4. Reference to other sections

Other instructions	Safe handling: see point 7. Personal protective equipment: see point 8. Waste disposal: see point 13.
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling	Handling: No precautions required.
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Protective Safety Measures

Advice on general occupational hygiene	Handle in accordance with good industrial hygiene and safety practices. Wash hands before breaks and at the end of workday. Wash contaminated clothes before reuse.
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7.2. Conditions for safe storage, including any incompatibilities

Storage	Storage: Keep in a cool and dry place. Do not expose to ultraviolet rays for a long time.
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7.3. Specific end use(s)

Specific use(s)	None reported.
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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Other Information about threshold limit values	No applicable exposure limit values. DNEL/PNEC: Chemical safety assessment has not been performed for the product, no information available about ingredients.
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8.2. Exposure controls

Precautionary measures to prevent exposure

Technical measures to prevent exposure	No protective measures required.
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Respiratory protection

Respiratory protection	No protective measures required.
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Hand protection

Hand protection	No protective measures required.
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Eye / face protection

Eye protection	No protective measures required.
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Skin protection

Skin protection (except hands)	No protective measures required.
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Appropriate environmental exposure control

Environmental exposure controls	Prevent entry into drains, sewers, waterways or soil.
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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Viscous liquid.
Colour	White.
Odour	Perfume.
Comments, Odour limit	Not relevant.
pH (as supplied)	Value: 5,0-6,0
Comments, Melting point / melting range	Not determined.
Comments, Boiling point / boiling range	Not determined.
Comments, Flash point	Not determined.
Comments, Evaporation rate	Not determined.
Flammability (solid, gas)	Not relevant.
Comments, Explosion limit	Not determined.
Comments, Vapour pressure	Not determined.
Comments, Vapour density	Not determined.
Density	Value: 1,00 - 1,10 g/cm ³
Solubility in water	Unknown.
Comments, Partition coefficient: n-octanol / water	Not determined.
Comments, Spontaneous combustability	Not determined.
Comments, Decomposition temperature	Not determined.
Viscosity	Value: > 60 Poise
Explosive properties	Not classified as explosive.
Oxidising properties	Not classified as oxidising.

9.2. Other information

Other physical and chemical properties

Physical and chemical properties	Consistency: 5.5 – 7.5 cm Electrical Conductivity: >4.5 mS/cm
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SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity	Not reactive under normal use and storage conditions.
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10.2. Chemical stability

Stability	Stable under normal storage and handling conditions.
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10.3. Possibility of hazardous reactions

Possibility of hazardous reactions	None known.
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10.4. Conditions to avoid

Conditions to avoid	None known.
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10.5. Incompatible materials

Materials to avoid	No incompatible groups noted.
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10.6. Hazardous decomposition products

Hazardous decomposition products	None known.
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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicological Information:

Other toxicological data	The product is not classified as acutely toxic. There is no toxicological data available about the product as such.
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Toxicological data for substances

Substance Octadecan-1-ol, ethoxylated, < 2.5 EO

LD50 oral **Value:** > 21000 mg/kg

Animal test species: rat

LD50 dermal **Value:** > 2000 mg/kg

Comments: OECD 402

Substance Alcohols, C16-18, ethoxylated

LD50 oral **Value:** > 300 - 2000 mg/kg

Animal test species: rat

Potential acute effects

Skin contact The product is not classified as irritant or corrosive to skin.

Eye contact The product is not classified as damaging or irritating to eyes.

Aspiration hazard The product is not classified as an aspiration hazard.

Delayed effects / repeated exposure

Sensitisation The product is not classified as a respiratory or skin sensitiser.

STOT-single exposure The product is not classified as toxic to specific target organs at a single exposure.

STOT-repeated exposure The product is not classified as toxic to specific target organs at repeated exposure.

Carcinogenic, Mutagenic or Reprotoxic

Carcinogenicity The product is not classified as a carcinogen.

Mutagenicity The product is not classified as a mutagen.

Reproductive toxicity The product is not classified as toxic to reproduction.

Symptoms of Exposure

Other Information No other health effects reported.

SECTION 12: Ecological information

12.1. Toxicity

Aquatic, comments There is no ecotoxicological data available about the product as such.

Toxicological data for substances

Substance Octadecan-1-ol, ethoxylated, < 2.5 EO

Acute aquatic, fish **Value:** > 5,6 mg/l

Method of testing: LC50

Species: Oncorhynchus mykiss

Duration: 96 h

Acute aquatic, Daphnia **Value:** 0,32 mg/l

Method of testing: EC50 (OECD 202)

Species: Daphnia magna

Duration: 48 h

Substance Alcohols, C16-18, ethoxylated

Acute aquatic, fish **Value:** > 1-10 mg/l

Method of testing: LC50 (DIN EN ISO 7346-2)

Species: Leuciscus idus

Acute aquatic, algae **Value:** 0,1-1 mg/l

Method of testing: EC50

Species: Scenedesmus subspicatus

Remarks: NOEC > 0,1 - 1 mg/l, Scenedesmus subspicatus

Component substances' impact on sewage treatment plants EC0 > 100 mg/l, Pseudomonas putida

12.2. Persistence and degradability

Persistence and degradability No data available.

12.3. Bioaccumulative potential

Bioaccumulative potential	No data available.
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12.4. Mobility in soil

Mobility	No information.
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12.5. Results of PBT and vPvB assessment

PBT assessment results	Chemical safety assessment has not been performed for the product, no information available about ingredients.
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12.6. Other adverse effects

Environmental details, summation	There is no environmental data available about the product as such. The product is not classified as hazardous to the environment. Prevent entry into drains, sewers, waterways or soil.
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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product classified as hazardous waste	No
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Other Information	Dispose of in compliance with local and national regulations. Avoid release to the environment.
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SECTION 14: Transport information

14.1. UN number

Comments	The product is not classified for transportation.
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14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazards

Comments	The product is not classified as hazardous to the environment.
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14.6. Special precautions for user

Special safety precautions for user	No special safety precautions.
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14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Additional information.

Additional information.	Not applicable.
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SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Legislation and regulations	Product is in compliance with the Medical Device Directive 93/42/EEC. Product meets requirements for biocompatibility according ISO 10993.
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15.2. Chemical safety assessment

Chemical safety assessment performed	No
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SECTION 16: Other information

Supplier's notes	Details given in this document are believed to be correct on our present state of knowledge. Whilst proper care has been taken in the preparation of this document, no liability for injury or damage resulting from its use is accepted.
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List of relevant H-phrases (Section 2 and 3).	H302 Harmful if swallowed. H412 Harmful to aquatic life with long lasting effects. H400 Very toxic to aquatic life. H411 Toxic to aquatic life with long lasting effects.
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Training advice	H319 Causes serious eye irritation. Read safety data sheet.
Abbreviations and acronyms used	EC50: Effective concentration: concentration which kills or immobilises 50 % of exposed organisms LC50: Lethal concentration 50 % (median lethal concentration): concentration which kills 50 % of exposed organisms LD50: Lethal dose 50 % (median lethal dose): dose which kills 50 % of exposed organisms
Important data sources used to construct the safety data sheet	SDS by product manufacturer SDSs for product components
Version	1
Responsible for safety data sheet	CareFusion Finland 320 Oy