

SAFETY DATA SHEET

EPICONT

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 EPICONT

Article no. 217 083 12, 217 083 13, 2034741-001, 2034741-002

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 EPICONT is intended to support the quality of electrical connection between devices and the human body for ECG acquisition with reusable electrodes. EPICONT is intended for use on adult and pediatric patients. EPICONT 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 according to EUH 208

Regulation (EC) No 1272/2008

[CLP/GHS]

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

2.2. Label elements

Special supplemental label info EUH208 Contains N,N"-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioximidazolidin-4-yl)urea]. May produce an allergic reaction.

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.
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2.3. Other hazards

Other hazards	Not known.
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SECTION 3: Composition/information on ingredients

3.2. Mixtures

Substance	Identification	Classification	Contents
N,N"-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)]urea]	CAS no.: 39236-46-9 EC no.: 254-372-6 Registration number: 01-2119983788-11	Skin Sens. 1; H317	0 - 0,2 %
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, Silicium Carbide, Sorbitol, Sodium Chloride, Cetearyl Alcohol, Prunus Armeniaca, , Glycerin, Steareth-2, Cetareth-12, Triethanolamine, Imidazolidinyl Urea, Carbomer, Edta, Perfume, Cetylpyridinium Chloride. 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 or rash 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	May produce an allergic skin reaction.
Delayed symptoms and effects	None known.

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

Other Information	Treat symptomatically.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	Use an extinguishing agent suitable for the surrounding fire.
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5.2. Special hazards arising from the substance or mixture

Hazardous combustion products	None known.
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5.3. Advice for firefighters

Personal protective equipment	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA).
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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	Grey.
Odour	Perfume.
Comments, Odour limit	Not relevant.
pH (as supplied)	Value: 5,5-6,5
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: 1,05 - 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: > 70 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 – 7.0 cm Electrical Conductivity: >4,0 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	N,N"-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]
LD50 oral	Value: 5200 mg/kg Animal test species: rat
LD50 dermal	Value: > 5000 mg/kg Animal test species: rabbit
LC50 inhalation	Value: > 5,5 mg/l Animal test species: rat Duration: 1 h

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. However, the product contains a small amount of a component that may produce an allergic reaction.
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.
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SECTION 12: Ecological information

12.1. Toxicity

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

Substance	N,N"-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]
Acute aquatic, fish	Value: 220 mg/l Method of testing: LC50 Duration: 96 h
Acute aquatic, algae	Value: 5,78 mg/l Method of testing: ErC50 Species: Green algae Duration: 72 h
Acute aquatic, Daphnia	Value: 58 mg/l Method of testing: EC50 (immobilisation test) Species: Daphnia magna Duration: 48 h
Ecotoxicity, other effects	Bacteria: EC50: 567 mg/l (3 h; OECD 209) EC0: 200 mg/l (3 h; OECD 209)

12.2. Persistence and degradability

Persistence and degradability	No data available.
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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.

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.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product classified as hazardous waste No

Other Information Dispose of in compliance with local and national regulations. Avoid release to the environment.

SECTION 14: Transport information

14.1. UN number

Comments The product is not classified for transportation.

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.

14.6. Special precautions for user

Special safety precautions for user No special safety precautions.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Additional information.

Additional information. Not applicable.

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.

15.2. Chemical safety assessment

Chemical safety assessment performed No

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.

Classification according to Regulation (EC) No 1272/2008 [CLP/GHS] ; EUH 208;

List of relevant H-phrases (Section 2 and 3). H317 May cause an allergic skin reaction. EUH 208 Contains May produce an allergic reaction.

Training advice Read safety data sheet.

Abbreviations and acronyms used EC50: Effective concentration: concentration which kills or immobilises 50 % of exposed organisms

	ErC50: Effective concentration (growth rate): concentration at which a 50% inhibition of growth rate is observed
	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
Version	SDSs for product components
Responsible for safety data sheet	1
	CareFusion Finland 320 Oy