SAFETY DATA SHEET
Electrode Gel


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

<table>
<thead>
<tr>
<th>Date issued</th>
<th>15.06.2016</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.1. Product identifier</strong></td>
<td></td>
</tr>
<tr>
<td>Product name</td>
<td>Electrode Gel</td>
</tr>
<tr>
<td>Article no.</td>
<td>217 083 03, 217 083 06, 2034731-001, 2034731-002</td>
</tr>
<tr>
<td><strong>1.2. Relevant identified uses of the substance or mixture and uses advised against</strong></td>
<td></td>
</tr>
<tr>
<td>Use categories nordic (UCN).</td>
<td>55 Others</td>
</tr>
<tr>
<td>Use of the substance/preparation</td>
<td>The Electrode Gel 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 Gel is intended for use on adult and pediatric patients. The Electride Gel is intended for use by qualified medical personnel under the direct supervision of a licensed health-care practitioner.</td>
</tr>
</tbody>
</table>

**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: Poison Information Centre (in Finland), open 24 h daily: (09) 471977 or (09) 4711 Emergency telephone number: 112
- 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 Regulation (EC) No 1272/2008 [CLP/GHS]
- Classification notes CLP: In accordance with current regulations, this product has not been classified as hazardous.
- EUH 208

**2.2. Label elements**
2.3. Other hazards

Other hazards

Not known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

<table>
<thead>
<tr>
<th>Substance</th>
<th>Identification</th>
<th>Classification</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>CAS no.: 1310-73-2 EC no.: 215-185-5 Index no.: 011-002-00-6 Registration number: 01-211947892-27</td>
<td>Met. Corr. 1; H290 Skin Corr 1A; H314</td>
<td>0 - 2 %</td>
</tr>
<tr>
<td>N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]</td>
<td>CAS no.: 39236-46-9 EC no.: 254-372-6 Registration number: 01-2119983788-11</td>
<td>Skin Sens. 1; H317</td>
<td>0 - 0.5 %</td>
</tr>
</tbody>
</table>

Description of the mixture

Water based viscous gel.

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, Sodium Chloride, Carbomer, Sodium Hydroxide, Imidazolidinyl Urea, Edta, Perfume, CL 42051

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.

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

<table>
<thead>
<tr>
<th>General measures</th>
<th>Stop leak if safe to do so.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal protection measures</td>
<td>Avoid contact with skin or eyes. Wear appropriate personal protective equipment.</td>
</tr>
</tbody>
</table>

6.2. Environmental precautions

Environmental precautionary measures

Not relevant.

6.3. Methods and material for containment and cleaning up

Cleaning method

Wash in clear warm water. After gel has dried clean with brush and wash with clear warm water.

6.4. Reference to other sections

Other instructions

Safe handling: see point 7.
Personal protective equipment: see point 8.
Waste disposal: see point 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling

Handling: No precautions required.

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.

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.

7.3. Specific end use(s)

Specific use(s)

None reported.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational Exposure limit values

<table>
<thead>
<tr>
<th>Substance</th>
<th>Identification</th>
<th>Value</th>
<th>TWA Year</th>
</tr>
</thead>
</table>
| Sodium hydroxide   | CAS no.: 1310-73-2  
                    | EC no.: 215-185-5  
                    | Index no.: 011-002-00-6  
                    | Registration number: 01-2119457892-27 | 15 min.: 2 mg/m3  
                    |                                      | Ceiling value |

DNEL / PNEC from substances

| Substance          | Group: Worker  
                   | Exposure route: Inhalation  
                   | Exposure frequency: Long term (repeated)  
                   | Type of effect: Local effect  
                   | Value: 1,0 mg/m3 |
|--------------------|--------------|
| Sodium hydroxide   | Group: Consumer  
                   | Exposure route: Inhalation  
                   |
8.2. Exposure controls

**Precautionary measures to prevent exposure**

<table>
<thead>
<tr>
<th>Technical measures to prevent exposure</th>
<th>No protective measures required.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Respiratory protection</strong></td>
<td></td>
</tr>
<tr>
<td>Respiratory protection</td>
<td>No protective measures required.</td>
</tr>
<tr>
<td><strong>Hand protection</strong></td>
<td></td>
</tr>
<tr>
<td>Hand protection</td>
<td>No protective measures required.</td>
</tr>
<tr>
<td><strong>Eye / face protection</strong></td>
<td></td>
</tr>
<tr>
<td>Eye protection</td>
<td>No protective measures required.</td>
</tr>
<tr>
<td><strong>Skin protection</strong></td>
<td></td>
</tr>
<tr>
<td>Skin protection (except hands)</td>
<td>No protective measures required.</td>
</tr>
</tbody>
</table>

**Appropriate environmental exposure control**

Environmental exposure controls: Prevent entry into drains, sewers, waterways or soil.

### SECTION 9: Physical and chemical properties

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Viscous liquid.</td>
</tr>
<tr>
<td>Colour</td>
<td>Uncoloured. Diaphanous.</td>
</tr>
<tr>
<td>Odour</td>
<td>Perfume.</td>
</tr>
<tr>
<td>Comments, Odour limit</td>
<td>Not relevant.</td>
</tr>
<tr>
<td><strong>pH (as supplied)</strong></td>
<td><strong>Value:</strong> 6.5-7.5</td>
</tr>
<tr>
<td>Comments, Melting point / melting range</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Comments, Boiling point / boiling range</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Comments, Flash point</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Comments, Evaporation rate</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not relevant.</td>
</tr>
<tr>
<td>Comments, Explosion limit</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Comments, Vapour pressure</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Comments, Vapour density</td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Density</strong></td>
<td><strong>Value:</strong> 1.00 - 1.03 g/cm³</td>
</tr>
<tr>
<td>Comments, Partition coefficient: n-octanol / water</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Comments, Spontaneous combustibility</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Comments, Decomposition temperature</td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Viscosity</strong></td>
<td><strong>Value:</strong> 80-120 Poise</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not classified as explosive.</td>
</tr>
<tr>
<td>Oxidising properties</td>
<td>Not classified as oxidising.</td>
</tr>
</tbody>
</table>

#### 9.2. Other information

**Other physical and chemical properties**

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical and chemical properties</td>
<td>Electrical Conductivity: &gt;40 mS/cm</td>
</tr>
</tbody>
</table>

### SECTION 10: Stability and reactivity
10.1. Reactivity
Reactivity
Not reactive under normal use and storage conditions.

10.2. Chemical stability
Stability
Stable under normal storage and handling conditions.

10.3. Possibility of hazardous reactions
Possibility of hazardous reactions
None known.

10.4. Conditions to avoid
Conditions to avoid
None known.

10.5. Incompatible materials
Materials to avoid
No incompatible groups noted.

10.6. Hazardous decomposition products
Hazardous decomposition products
None known.

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.

Toxicological data for substances

<table>
<thead>
<tr>
<th>Substance</th>
<th>LD50 oral</th>
<th>Value: 5200 mg/kg</th>
<th>Animal test species: rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-y]urea]</td>
<td>LD50 dermal</td>
<td>Value: &gt; 5000 mg/kg</td>
<td>Animal test species: rabbit</td>
</tr>
<tr>
<td>LC50 inhalation</td>
<td>Value: &gt; 5,5 mg/l</td>
<td>Animal test species: rat</td>
<td></td>
</tr>
<tr>
<td>Duration: 1 h</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

SECTION 12: Ecological information

12.1. Toxicity

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

Toxicological data for substances
### 12.2. Persistence and degradability

**Persistence and degradability**

No data available.

### 12.3. Bioaccumulative potential

**Bioaccumulative potential**

No data available.

### 12.4. Mobility in soil

**Mobility**

No information.

### 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**
### 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.**

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).**  
H290 May be corrosive to metals.  
H314 Causes severe skin burns and eye damage.  
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**

DNEL: Derived No-Effect Level  
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  
PNEC: Predicted No-Effect Concentration

**Important data sources used to construct the safety data sheet**

SDS by product manufacturer  
SDSs for product components  
Decree on Concentrations known to be Hazardous (268/2014) (HTP-arvot 2014)

**Version**

1

**Responsible for safety data sheet**

CareFusion Finland 320 Oy