**SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**

**1.1 Product identifier**

Product Name: Surgical needles  
Chemical Family: Stainless Steel – CAS Number 65997-19-5

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

**1.2.1 Relevant uses**  
Semi-finished product used for surgical sutures after being changed into a medical device by our customer.

**1.2.2 Uses advised against**  
None known.

**1.3 Details of the supplier of the safety data sheet**

Company: Suturex & Renodex  
Address: 4, rue Jacques Chemel  
Zone de Vialard  
24 200 Carsac-Aillac / FRANCE  
Phone: + 33 (0)5 53 31 34 35

**1.4 Emergency telephone number**

Emergency Phone: + 33 (0)5 53 31 34 34

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**SECTION 2 - HAZARDS IDENTIFICATION**

**2.1 Classification of the substance or mixture**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stainless Steel</td>
<td>65997-19-5</td>
</tr>
<tr>
<td>Silicone coating</td>
<td>71750-80-6</td>
</tr>
</tbody>
</table>

**2.2 Label elements**  
N/A

**2.3 Other hazards**

Emergency Overview: The products are extremely sharp and have the potential to cause extreme injury.

**Relevant Route(s) of Exposure:** Skin contact  
**Eyes:** Eye damage  
**Skin:** Skin penetration  
**Ingestion:** Tissue damage

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**SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS**

**Product description:** Surgical needles made from stainless surgical steel according to ASTM F899 with a silicone coating.

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS Number</th>
<th>Percentage Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stainless Steel</td>
<td>65997-19-5</td>
<td>97.0 - 100.0 %</td>
</tr>
<tr>
<td>Silicone coating</td>
<td>71750-80-6</td>
<td>&lt; 3.0 %</td>
</tr>
</tbody>
</table>

**Comment on component parts:** Stainless steel is an alloy and is not known as hazardous in its solid state. The components are of medical grade and therefore not known as hazardous.
SECTION 4 - FIRST AID MEASURES

4.1 Description of first aid measures

General information: In case of a needle penetration, seek urgent medical attention to avoid further tissue damage.

Eyes: Seek urgent medical attention.
Skin: Seek urgent medical attention.
Ingestion: Seek urgent medical attention.
Inhalation: Not applicable in solid form.

4.2 Most important symptoms and effects, both acute and delayed

The product is extremely sharp and penetrates body tissues easily.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to Physicians: Austenitic stainless steel particles are non-magnetic or only slightly magnetic and may not respond to a magnet placed over the eye. In such cases seek hospital treatment. Surgical needles are visible with X-Ray devices.

SECTION 5 - FIREFIGHTING PROCEDURES

5.1 Extinguishing media: N/A

5.2 Special hazards arising from the substance or the mixture: N/A

5.3 Advice for firefighters: N/A

SECTION 6 - ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

There is no need for special precautions, when the needle is handled under normal conditions.

6.2 Environmental precautions

Check current local, state and national regulations for proper disposal methods.

6.3 Methods and material for containment and cleaning up

N/A

6.4 Reference to other sections

N/A

SECTION 7 - HANDLING AND STORAGE

7.1 Precautions for safe handling

Needle tips are fragile and extremely sharp. Handle the product with care. Use appropriate personal protection.

7.2 Conditions for safe storage, including any incompatibilities

The products should be stored in cool, dry and well-ventilated area. Protect from physical damage.

7.3 Specific end use(s)

See product information (D114 & D216).

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

N/A

8.2 Exposure controls

See 6.1
Material Safety Data Sheet
Surgical needles

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Solid state - Stainless steel needles with silicone coating.</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>N/A</td>
</tr>
<tr>
<td>pH</td>
<td>N/A</td>
</tr>
<tr>
<td>Melting point</td>
<td>1325 – 1530°C</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>N/A</td>
</tr>
<tr>
<td>Flash point</td>
<td>N/A</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>N/A</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>N/A</td>
</tr>
<tr>
<td>Upper/lower explosive limits</td>
<td>N/A</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>N/A</td>
</tr>
<tr>
<td>Vapor density</td>
<td>N/A</td>
</tr>
<tr>
<td>Density</td>
<td>7.7 – 8.3 g/cm³</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>N/A</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>N/A</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>N/A</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Not determined</td>
</tr>
<tr>
<td>Viscosity</td>
<td>N/A</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>N/A</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>N/A</td>
</tr>
</tbody>
</table>

9.2 Other information

None

SECTION 10 - STABILITY AND REACTIVITY

10.1 Reactivity
No dangerous reactions known if used as directed

10.2 Chemical stability
The product is stable under standard conditions

10.3 Possibility of hazardous reactions
N/A

10.4 Conditions to avoid
See SECTION 7.2

10.5 Incompatible materials
Strong acids, oxidizing agents, ammonia nitrate, sulfur, alkalis, selenium, nickel nitrate and sodium azide

10.6 Hazardous decomposition products
Toxic metal fumes and oxides are emitted when product is heated above the melting point

SECTION 11 - TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:
No adverse health effects are known or anticipated from contact with these products under standard conditions

SECTION 12 - ECOLOGICAL INFORMATION

12.1 Toxicity:                          N/A
12.2 Persistence and degradability:    N/A
12.3 Bioaccumulative potential:        N/A
12.4 Mobility in soil:                 N/A
12.5 Results of PBT and vPvB assessment: N/A
SECTION 13 - DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:
Contaminated needles must be disposed of according to the nature of the contaminant. Check current local, state and national regulations for proper disposal methods.

SECTION 14 - TRANSPORT INFORMATION

14.1 UN number: N/A
14.2 UN Proper Shipping Name: Surgical needles
14.3 Transport hazard class(es): N/A
14.4 Packing group: N/A
14.5 Environmental hazard: N/A
14.6 Special precautions for user No special precautions required – non-hazardous for road, sea or air.
14.7 Transport in bulk: N/A

SECTION 15 - REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture: N/A
15.2 Chemical Safety Assessment: N/A

SECTION 16 - OTHER INFORMATION

16.1 Hazard statements: N/A
16.2 Abbreviations and acronyms: N/A=Not Applicable
16.3 Other information: Source: ECHA - Guidance on the compilation of safety data sheets

DISCLAIMER:
According to our knowledge, the information contained herein is accurate. However, Suturex & Renodex doesn’t assume any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user.

All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.