

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

SECTION 2 - HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Components	CAS Number
Stainless Steel	65997-19-5
Silicone coating	71750-80-6

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

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

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

Ingredients:	CAS Number	Percentage Weight
Stainless Steel	65997-19-5	97,0 - 100,0 %
Silicone coating	71750-80-6	< 3,0 %

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

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Solid state - Stainless steel needles with silicone coating.
Odor	Odorless
Odor threshold	N/A
pH	N/A
Melting point	1325 – 1530°C
Initial boiling point and boiling range	N/A
Flash point	N/A
Evaporation rate	N/A
Flammability (solid, gas)	N/A
Upper/lower explosive limits	N/A
Vapor pressure	N/A
Vapor density	N/A
Density	7,7 – 8,3 g/cm ³
Solubility(ies)	N/A
Partition coefficient: n-octanol/water	N/A
Auto-ignition temperature	N/A
Decomposition temperature	Not determined
Viscosity	N/A
Explosive properties	N/A
Oxidizing properties	N/A

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

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|------|--|-----|
| 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

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|------|------------------------------------|---|
| 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 |

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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.