

Issue Date: 07/11/2025
 Last Revision Date: N/A
 Superseded Date: N/A
 Version Number: 01

SAFETY DATA SHEET

Product Code: PRC-25038N

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SECTION 1 PRODUCT IDENTIFICATION

1.1 Product identifier

Product Name: Sofeel Dermal Filler Cannula

Chemical Family: Stainless Steel – CAS Number 65997-19-5, polypropylene M800E,

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

1.2.1 Relevant uses

Creation of secure peripheral venous access.

1.2.2 Uses advised against

None known.

SECTION 2 HAZARD IDENTIFICATION

2.1 Classification of the substance or mixture

Components CAS Number

Stainless Steel 65997-19-5

Silicone coating 71750-80-6

polypropylene M800E

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: Blood transfusions or infusion of i.v. solutions suitable for administration via peripheral veins. Intermittent intravenous drug administration.

Prophylactic creation of a secure venous access in patients who may require urgent intravenous drug administration, in particular prior to diagnostic or therapeutic procedures.

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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.

SECTION 5

FIRE FIGHTING MEASURES

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

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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 and use(s)

A Disinfect skin at puncture site.

B Before access, control the catheter and its connections and shape the wings.

C Remove protective needle cap.

D Puncture chosen vessel.

E When blood is visible in the needle hub, pull the needle back into the catheter for

2-3mm.

F Slowly insert the catheter into the vessel, unless there is resistance.

G Pull the needle completely .To prevent accidental needle-sticks, put protective cap on.

Either connect the catheter to the infusion set or close the line securely with the provided

luer lock cap. Fix the catheter and the line securely with adhesive tape.

H Cover puncture site with sterile material.

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SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters N/A

8.2 Exposure controls

SECTION 4 - FIRST AID MEASURES

SECTION 9 PHYSICAL/CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance Solid state - Stainless steel needles .

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

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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

N/A

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

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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

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END OF SDS

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