

## MATERIAL SAFETY DATA SHEET

according to Regulation (EC) No 1907/2006 of the European Parliament and of the Council

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

<b>1.1 Identification of the substance or preparation</b>	Temp Silic Crystal silicone (product code: TS1; TS1-5)
<b>1.2 Use of the substance/preparation:</b>	Silicone for stent
<b>1.3 Company/undertaking identification:</b>	Micerium S.p.A Via G. Marconi 83 16036 Avegno (GE) -Italy Phone: +39. 0185. 7887870 fax +39. 0185. 7887970
<b>1.4 Emergency telephone:</b>	Poison Control Center San Martino Hospital (Genova, Italy) Phone: +39 010 352808 (available 24 hours/ 24)

### 2. HAZARDS IDENTIFICATION

<b>Most important hazards:</b>	No special risks for human being and environment. Classification corresponds to actual EEC guidelines.
<b>Physical – chemical hazards:</b>	None
<b>Hazards for human health:</b>	
<b>Eyes:</b>	None
<b>Skin:</b>	None
<b>Inhalation:</b>	None
<b>Ingestion:</b>	None
<b>Over-exposure signs and symptoms:</b>	None
<b>Chronic effects:</b>	None
<b>Hazards for environment:</b>	None

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<b>3.1 Main ingredients:</b>	Mixture of polydimethyl polymethyl vinyl siloxane, polydimethyl polymethyl hydrogen siloxane, silica and paraffin.
<b>3.2 Dangerous ingredients:</b>	NA

### 4. FIRST AID MEASURES

<b>Immediate medical attention need:</b>	In case of eye contact and in case of swallowing
<b>Measure to be adopted when:</b>	
- It contacts eyes:	Rinse with plenty of water and contact a physician.
- It contacts skin:	Wash with plenty of water and soap.
- Inhaled:	NA
- Ingested:	Seek medical advice immediately.

### 5. FIRE-FIGHTING MEASURES

<b>General information:</b>	NA
<b>Suitable extinguishing media:</b>	CO <sub>2</sub> water
<b>Extinguishing media which shall not be used for safety reasons:</b>	NA
<b>Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases:</b>	NA
<b>Special protective equipment for fire-fighters:</b>	No special measures required

Legend: NA = not applicable; ND = not available data

## 6. ACCIDENTAL RELEASE MEASURES

<b>Personal precautions:</b>	None
<b>Environmental precautions:</b>	None
<b>Measures for cleaning/collecting:</b>	Wipe out with absorbent material

## 7. HANDLING AND STORAGE

<b>7.1 Handling:</b>	No special measures required
<b>7.2 Storage:</b>	Store at a dry place
<b>7.3 Specific use(s):</b>	NA

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<b>8.1 Exposure limit values:</b>	NA. The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace		
<b>8.2 Exposure controls:</b>	Normal hygienic measures		
<b>8.2.1 Occupational exposure controls:</b>			
<b>8.2.1.a Respiratory protection:</b>	Not required		
<b>8.2.1.b Hand protection:</b>	Not required		
<b>8.2.1.c Eye protection:</b>	Not required		
<b>8.2.1.d Skin protection:</b>	Not required		
<b>8.2.2 Environmental exposure controls:</b>	NA		

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>9.1 General information:</b>			
<b>Physical state:</b>	silicon		
<b>Colour:</b>	Different		
<b>Odour:</b>			
<b>9.2 Important health, safety and environmental information:</b>			
<b>pH:</b>	Neutral	<b>Density:</b>	1.46 (20°C) g/cm <sup>3</sup>
<b>Boiling point/boiling range:</b>	NA	<b>Solubility In/Miscibility with water:</b>	Partially soluble in toluene, petrol
<b>Flash point:</b>	NA	<b>Water solubility:</b>	Insoluble
<b>Flammability (solid, gas):</b>		<b>Partition coefficient: n-octanol/water:</b>	NA
<b>Explosive properties:</b>	NA	<b>Viscosity:</b>	ca.30 Pas
<b>Oxidising properties:</b>		<b>Vapor density:</b>	NA
<b>Vapor pressure:</b>	NA	<b>Evaporation rate:</b>	NA
<b>9.3 Other information:</b>			
<b>Miscibility:</b>	NA	<b>Melting point/melting range:</b>	NA

## 10. STABILITY AND REACTIVITY

<b>10.1 Conditions to avoid:</b>	NA
<b>10.2 Materials to avoid:</b>	Slight evaluation of hydrogen traces by contact with acids, bases, alcohols, powdered metals and metal oxides.
<b>10.3 Hazardous decomposition products:</b>	NA

## 11. TOXICOLOGICAL INFORMATION

LD/LC50 values relevant for classification: ND

### 11.1 Immediate effects due to:

11.1.1 Skin/ eye contact: No toxic, no absorption

11.1.2 Inhalation: NA

11.1.3 Ingestion: NA

### 11.2 Delayed effects due to:

11.2.1 Skin/ eye contact: NA

11.2.2 Inhalation: NA

11.2.3 Ingestion: NA

### 11.3 Chronic effects due to:

11.3.1 Skin/ eye contact: NA

11.3.2 Inhalation: NA

11.3.3 Ingestion: NA

11.4 Sensitizing effects: NA

11.5 Carcinogenicity, mutagenicity and reproductive toxicity: NA

Other toxicological information: During the long period of use as an impression material, no health diseases have been reported.

## 12. ECOLOGICAL INFORMATION

12.1 Ecotoxicity: ND

12.2 Mobility: ND

12.3 Persistence and degradability: ND

12.4 Bioaccumulative potential: ND

12.5 Results of PBT assessment: ND

12.6 Other adverse effects: ND

## 13. DISPOSAL CONSIDERATIONS

Recommendation: Use proper landfill disposal or incineration in accordance with local, state, and federal regulations.

## 14. TRANSPORT INFORMATION

Not classified as dangerous goods. Protect from humidity and store away from foodstuff, acid, and bases.

14.1 By sea (IMDG): NA

14.2 By road (ADR): NA

14.3 By rail (RID): NA

14.4 By Air (ICAO / IATA): NA

## 15. REGULATORY INFORMATION

Legend: NA = not applicable; ND = not available data

Labelling according to EU guidelines: No classification necessary to actual EEC guidelines

#### 16. OTHER INFORMATION

16.1 List of relevant R phrases:	NA
16.2 Training advice:	NA
16.3 Recommended restrictions on use:	Only for professional use
16.4 Further information:	NA
16.5 Sources of key data used to compile the Safety Data Sheet:	The above information is based on our and our supplier present knowledge and relates solely to the safety requirements of the product. The data does not signify any warranty with regards to the product's properties. However, user of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.
16.6 Changes from the previous version (if available):	NA
16.7 Released by:	Micerium S.p.A.