

# SAFETY DATA SHEET

## SOFRELINER TOUGH M-Paste

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

#### 1.1. Product identifier

**Product name** SOFRELINER TOUGH M-Paste

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

**Identified uses** 【Medical device】 Denture liner, a component of kit. For dental professionals only.

**Uses Not Recommended** Use only for intended applications.

#### 1.3. Details of the supplier of the safety data sheet

**Supplier** Tokuyama Dental Italy S.r.l.  
Via Chizzalunga, 1,  
36066 Sandrigo, Vicenza, Italy  
TEL: +39-0444-659650  
FAX: +39-0444-750345

**Contact person** <http://www.tokuyama-dental.com/tdc/contact.html>

**Manufacturer** Tokuyama Dental Corporation  
38-9, Taitou 1-chome, Taitou-ku, Tokyo  
110-0016, Japan  
TEL: +81-3-3835-2261  
FAX: +81-3-3835-2265

#### 1.4. Emergency telephone number

**Emergency telephone** Regional Medicines and Poisons Information Centre NI,  
Pharmacy Department  
Royal Hospital Suite, Grosvenor Road, Belfast  
Emergency telephone: 844 892 0111  
Telephone: +44 28 90 63 2032  
Fax: +44 28 90 24 8030  
E-mail address: [nirdic.nirdic@belfasttrust.hscni.net](mailto:nirdic.nirdic@belfasttrust.hscni.net)

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification (EC 1272/2008)

**Physical hazards** Not Classified

**Health hazards** Not Classified

**Environmental hazards** Not Classified

#### 2.2. Label elements

**Hazard statements** NC Not Classified

#### 2.3. Other hazards

This product does not contain any substances classified as PBT or vPvB.  
Endocrine disrupting properties: Not known.

## SOFRELINER TOUGH M-Paste

### SECTION 3: Composition/information on ingredients

#### 3.2. Mixtures

<b>DIMETHYL POLYSILOXANE (VINYL TERMINATED)</b>	<b>60-100%</b>
CAS number: 68083-19-2	

**Classification**  
Not Classified

<b>SILICON DIOXIDE</b>	<b>10-30%</b>
CAS number: 7631-86-9	EC number: 231-545-4

**Classification**  
Not Classified

The full text for all hazard statements is displayed in Section 16.

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

<b>General information</b>	Move affected person to fresh air at once. Get medical attention if any discomfort continues.
<b>Inhalation</b>	Move affected person to fresh air at once.
<b>Ingestion</b>	Try to induce vomiting. Get medical attention.
<b>Skin contact</b>	Wash skin thoroughly with soap and water.
<b>Eye contact</b>	Make sure to remove any contact lenses from the eyes before rinsing. Promptly wash eyes with plenty of water while lifting the eye lids. Continue to rinse for at least 15 minutes. Get medical attention if irritation persists after washing.

#### 4.2. Most important symptoms and effects, both acute and delayed

<b>General information</b>	No information available.
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#### 4.3. Indication of any immediate medical attention and special treatment needed

<b>Notes for the doctor</b>	No specific recommendations.
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### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

<b>Suitable extinguishing media</b>	Extinguish with the following media: Foam. Carbon dioxide or dry powder.
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#### 5.2. Special hazards arising from the substance or mixture

<b>Specific hazards</b>	When heated and in case of fire, irritating vapours/gases may be formed.
<b>Hazardous combustion products</b>	Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours.

#### 5.3. Advice for firefighters

<b>Protective actions during firefighting</b>	Avoid breathing fire gases or vapours.
<b>Special protective equipment for firefighters</b>	Wear chemical protective suit.

### SECTION 6: Accidental release measures

# SOFRELINER TOUGH M-Paste

## 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions** Wear protective clothing as described in Section 8 of this safety data sheet.

## 6.2. Environmental precautions

**Environmental precautions** No specific recommendations.

## 6.3. Methods and material for containment and cleaning up

**Methods for cleaning up** Eliminate all sources of ignition. No smoking, sparks, flames or other sources of ignition near spillage. Provide adequate ventilation. Absorb in vermiculite, dry sand or earth and place into containers.

## 6.4. Reference to other sections

**Reference to other sections** For waste disposal, see Section 13.

## **SECTION 7: Handling and storage**

### 7.1. Precautions for safe handling

**Usage precautions** All handling should only take place in well-ventilated areas.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage precautions** Store in a cool, dark place (0-25°C, 32-77°F). Keep away from heat, sparks and open flame.

**Storage class** Chemical storage.

### 7.3. Specific end use(s)

**Specific end use(s)** The identified uses for this product are detailed in Section 1.2.

## **SECTION 8: Exposure Controls/personal protection**

### 8.1. Control parameters

**Ingredient comments** No exposure limits known for ingredient(s).

### 8.2. Exposure controls

**Appropriate engineering controls** Provide adequate general and local exhaust ventilation.

**Eye/face protection** The following protection should be worn: Chemical splash goggles.

**Hand protection** Wear protective gloves.

**Other skin and body protection** Wear appropriate clothing to prevent any possibility of skin contact.

**Hygiene measures** Do not smoke in work area. Wash hands at the end of each work shift and before eating, smoking and using the toilet. Wash promptly with soap and water if skin becomes contaminated. Promptly remove any clothing that becomes contaminated. Use appropriate skin cream to prevent drying of skin. When using do not eat, drink or smoke.

**Respiratory protection** No specific recommendations.

## **SECTION 9: Physical and Chemical Properties**

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

**Appearance** Transparent paste

**Colour** Pink

**Odour** Not available.

## SOFRELINER TOUGH M-Paste

Odour threshold	Not available.
pH	pH (concentrated solution): 7
Melting point	Not available.
Initial boiling point and range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Evaporation factor	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	Not applicable.
Other flammability	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	1.1
Solubility(ies)	Not available.
Partition coefficient	Not available.
Auto-ignition temperature	Not available.
Decomposition Temperature	Not available.
Viscosity	Not available.
Explosive properties	Not explosive.
Oxidising properties	Not available.

### 9.2. Other information

Other information Not available.

## **SECTION 10: Stability and reactivity**

### 10.1. Reactivity

Reactivity May polymerise.

### 10.2. Chemical stability

Stability Stable at normal ambient temperatures and when used as recommended.

### 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions In contact with acids, alkalis or alcohols, generates hydrogen.

### 10.4. Conditions to avoid

Conditions to avoid Keep away from heat, sparks and open flame.

### 10.5. Incompatible materials

Materials to avoid Strong oxidising agents. Acids. Alkalis. Alcohols.

### 10.6. Hazardous decomposition products

## SOFRELINER TOUGH M-Paste

**Hazardous decomposition products** Heating may generate the following products: Toxic gases or vapours.

### SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

##### **Acute toxicity - Ingestion**

Calculation method : Not classified.

##### **Acute toxicity - Skin Contact**

Calculation method : Not classified. No data.

##### **Acute toxicity - Inhalation**

Calculation method : Not classified. No data.

##### **Skin corrosion/irritation**

Calculation method : Not classified.

##### **Serious eye damage/irritation**

Calculation method : Not classified.

##### **Skin sensitization**

Calculation method : Not classified.

##### **Respiratory sensitization**

Calculation method : Not classified.

##### **Germ cell mutagenicity**

Calculation method : Not classified.

##### **Carcinogenicity**

Calculation method : Not classified.

##### **Reproductive toxicity**

Calculation method : Not classified.

##### **Lactation**

Calculation method : Not classified.

##### **STOT - single exposure**

Calculation method : Not classified.

##### **STOT - repeated exposure**

Calculation method : Not classified.

##### **Aspiration hazard**

Calculation method : Not classified. Not applicable.

#### 11.2 Other information

Route(s) of entry Skin, Eyes, Ingestion, Inhalation, Health effects: See section 4.2.

Endocrine disrupting properties: Not known.

### SECTION 12: Ecological Information

#### **12.1 Toxicity**

**Toxicity - Aquatic invertebrates** Not classified.

**Toxicity - Fish** Not classified.

**Toxicity - Algae** Not classified.

**Toxicity - Sediment Compartment** Not classified.

**Toxicity - Terrestrial Compartment** Not classified.

## SOFRELINER TOUGH M-Paste

### **12.2 Persistence and degradability**

Not known.

### **12.3 Bioaccumulative potential**

Not known.

### **12.4 Mobility in soil**

Not known.

### **12.5 Results of PBT and vPvB assessment**

This product does not contain any substances classified as PBT or vPvB.

### **12.6 Endocrine disrupting properties**

Not known.

### **12.7 Other adverse effects**

Not known.

## **SECTION 13: Disposal considerations**

### **13.1 Waste treatment methods**

Dispose of contents/ container in accordance with the local/ regional/ national/ international regulations. Must not be disposed of together with household garbage. Dispose at suitable refuse site. Do not allow to enter drains, sewers or watercourses. Empty containers may retain some product residues and hence be potentially hazardous.

### **13.2 Additional Information**

Disposal should be in accordance with local, state or national legislation.

## **SECTION 14: Transport information**

### **General**

The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

### **14.1. UN number**

Not applicable.

### **14.2. UN proper shipping name**

Not applicable.

### **14.3. Transport hazard class(es)**

Not applicable.

### **14.4. Packing group**

Not applicable.

### **14.5. Environmental hazards**

**Environmentally hazardous substance/marine pollutant**

No.

### **14.6. Special precautions for user**

Not applicable.

### **14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code**

## SOFRELINER TOUGH M-Paste

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

### SECTION 15: Regulatory information

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU legislation (EC) No 1907/2006 (REACH).  
(EC) No 1272/2008 (CLP).  
(EU) No 2015/830.

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

### SECTION 16: Other information

**Classification procedures according to Regulation (EC) 1272/2008** Not Classified for Physical: Based on available data the classification criteria are not met. Not Classified for Health: Based on available data the classification criteria are not met. Not Classified for Environmental: Data lacking.

**Training advice** Ensure operatives are trained to minimise exposure. Only trained personnel should use this material.

**Revision comments**

**Revision date** 15/12/2022

**Revision** 4

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