

# Safety Data Sheet

## 1. Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Code: C700100  
Product name: ELITE SOFT RELINING

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

Intended use: Addition silicone for relining of removable prostheses.

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

Name: Zhermack S.p.a  
Full address: Via Bovazecchino  
District and Country: 45021 Badia Polesine (RO)  
Italy

Tel. +39 0425-597611

Fax +39 0425-53596

e-mail address of the competent person  
responsible for the Safety Data Sheet: tania.demetri@zhermack.com

### 1.4. Emergency telephone number

For urgent inquiries refer to: +39 0425-597611

## 2. Hazards identification.

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

The product is not classified as hazardous pursuant to the provisions set forth in Directives 67/548/EEC and 1999/45/EC and/or EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

### 2.2. Label elements.

This product is not subject to hazard labeling pursuant to Directives 67/548/EEC and 1999/45/EC and subsequent amendments and supplements.

Warning symbols: None.

Hazard sentences (R): None.

Caution recommendations (S): None.

### 2.3. Other hazards.

Information not available.

## 3. Composition/information on ingredients.

### 3.1. Substances.

Information not relevant.

**3.2. Mixtures.**

The product does not contain substances classified as being hazardous to human health or the environment pursuant to the provisions set forth in Directives 67/548/EEC and/or EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

**4. First aid measures.****4.1. Description of first aid measures.**

No harm to the staff authorised to use has been reported. However, in case of contact, inhalation or ingestion, the following general measures provided for a first aid shall be taken.

INHALATION: remove to open air. If respiration is difficult, administer artificial respiration and seek medical advice.

INGESTION: seek medical attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person.

EYES and SKIN: wash with plenty of water; if the irritation persists, seek medical advice.

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

No episodes of damage to health ascribable to the product have been reported.

**4.3. Indication of any immediate medical attention and special treatment needed.**

Information not available.

**5. Firefighting measures.****5.1. Extinguishing media.**

SUITABLE EXTINGUISHING MEDIA

The extinction equipment should be of the conventional kind: carbon dioxide, foam, powder and nebulised water.

EXTINGUISHING MEDIA WHICH SHALL NOT BE USED FOR SAFETY REASONS

None in particular.

**5.2. Special hazards arising from the substance or mixture.**

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products (carbon oxide, toxic pyrolysis products, etc).

**5.3. Advice for firefighters.**

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Hardhat with visor, fireproof clothing (fireproof jacket and trousers with straps around arms, legs and waist), work gloves (fireproof, cut proof and antistatic), a depressurised mask with facemask covering the whole of the operator's face or a self-respirator (self-protector) in the event of large quantities of fume.

**6. Accidental release measures.****6.1. Personal precautions, protective equipment and emergency procedures.**

Eliminate all sources of ignition (cigarettes, flames, sparks, etc.) from the leakage site. If there are no contraindications, spray solid products with water to

prevent the formation of dust. Use breathing equipment if fumes or powders are released into the air. Block the leakage if there is no hazard. Do not handle damaged containers or the leaked product before donning appropriate protective gear. For information on risks for the environmental and health, respiratory tract protection, ventilation and personal protection equipment, see the other sections of this sheet. These indications apply for both processing staff and those involved in emergency procedures.

#### **6.2. Environmental precautions.**

The product must not penetrate the sewers, surface water, ground water and neighbouring areas.

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

Use inert absorbent material (sand, vermiculite, diatomaceous earth, Kieselguhr, etc.) to soak up leaked product. Collect the majority of the remaining material and deposit it in containers for disposal. If there are no contraindications, use jets of water to eliminate product residues. Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

#### **6.4. Reference to other sections.**

Any information on personal protection and disposal is given in sections 8 and 13.

### **7. Handling and storage.**

#### **7.1. Precautions for safe handling.**

Before handling the product, consult all the other sections of this material safety data sheet. Do not eat, drink or smoke during use.

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

Normal storage conditions without particular incompatibilities.

#### **7.3. Specific end use(s).**

Information not available.

### **8. Exposure controls/personal protection.**

#### **8.1. Control parameters.**

Information not available.

#### **8.2. Exposure controls.**

Observance of safety measures used in handling chemical substances.

##### **RESPIRATORY PROTECTION**

None required.

##### **EYE PROTECTION**

None required.

##### **HAND PROTECTION**

None required.

##### **SKIN PROTECTION**

None required.

### **9. Physical and chemical properties.**

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

**C700100 - ELITE SOFT RELINING**

Appearance	dense liquid
Colour	pink
Odour	odourless
Odour threshold.	Not available.
pH.	Not available.
Melting or freezing point.	Not available.
Initial boiling point.	Not available.
Boiling range.	Not available.
Flash point.	Not available.
Evaporation Rate	Not available.
Flammability of solids and gases	Not available.
Lower inflammability limit.	Not available.
Upper inflammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density	Not available.
Specific gravity.	Not available.
Solubility	insoluble in water
Partition coefficient: n-octanol/water	Not available.
Ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not available.
Reactive Properties	Not available.

**9.2. Other information.**

Information not available.

**10. Stability and reactivity.****10.1. Reactivity.**

There are no particular risks of reaction with other substances in normal conditions of use.

**10.2. Chemical stability.**

The product is stable in normal conditions of use and storage.

**10.3. Possibility of hazardous reactions.**

No hazardous reactions are foreseeable in normal conditions of use and storage.

**10.4. Conditions to avoid.**

None in particular, however the usual precautions used for chemical products should be respected.

**10.5. Incompatible materials.**

Information not available.

**10.6. Hazardous decomposition products.**

In the event of thermal decomposition or fire, vapours potentially dangerous to health may be released.

**11. Toxicological information.**

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled according to good industrial practices.

**11.1. Information on toxicological effects.**

Poly dimethyl siloxane vinyl terminate

LD50 (Oral): > 15440 mg/kg

LD50 (Dermal): > 15440 mg/kg

**12. Ecological information.**

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or sewers or contaminate soil or vegetation.

**12.1. Toxicity.**

Information not available.

**12.2. Persistence and degradability.**

Information not available.

**12.3. Bioaccumulative potential.**

Information not available.

**12.4. Mobility in soil.**

Information not available.

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

Information not available.

**12.6. Other adverse effects.**

Information not available.

**13. Disposal considerations.****13.1. Waste treatment methods.**

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

**CONTAMINATED PACKAGING**

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

**14. Transport information.**

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

## 15. Regulatory information.

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

Seveso category. None.

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.

Contained substance.

Point. 46 ALKYL PHENOL POLYETHYLENE GLYCOL ETHER

Substances in Candidate List (Art. 59 REACH).

None.

Substances subject to authorisation (Annex XIV REACH).

None.

Healthcare controls.

Information not available.

### 15.2. Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

## 16. Other information.

### GENERAL BIBLIOGRAPHY

1. Directive 1999/45/EC and following amendments
2. Directive 67/548/EEC and following amendments and adjustments
3. Regulation (EC) 1907/2006 (REACH) of the European Parliament
4. Regulation (EC) 1272/2008 (CLP) of the European Parliament
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EC) 453/2010 of the European Parliament
7. The Merck Index. - 10th Edition
8. Handling Chemical Safety
9. Niosh - Registry of Toxic Effects of Chemical Substances
10. INRS - Fiche Toxicologique (toxicological sheet)
11. Patty - Industrial Hygiene and Toxicology
12. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
13. ECHA website

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product .

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.