

**Safety Data Sheet**

1907/2006/EU (Annex II, article 31) – 453/2010/EU

**Endo-Stops (Stop-Card)**

**POLYDENTIA SA**

Status 09.04.2015/AR

Page 1 of 3

**1.1 Identification of the substance/preparation and of the company**

Information on the product:  
**“Endo-Stops” and “Stop-Card”**

Medical Device Class (according to 93/42/EEC): I – Rule 5  
 Main use of the product: **Identification of dental hand instruments**

**1.2 Information on the manufacturer:**

Polydentia SA  
 Via Cantonale 47  
 6805 Mezzovico-Vira (Switzerland)  
 Phone: +41 (0) 91 946 29 48  
 Fax : +41 (0) 91 946 32 03  
 Email : info@polydentia.com

**1.3 Information provided by:**

Phone: +41 (0) 91 946 29 48                      Emergency telephone: +41 (0) 91 946 29 48

**2. Composition (Substance)**

Polydimethylsiloxane with vinyl groups, auxiliary and pigments

**3. Hazards identification**

Physical and chemical hazards for people and environment: none  
 The preparation is not classified as dangerous according to EU Directive.

**4. First aid measures**

*After inhalation:*                      Material cannot be inhaled under normal conditions.  
*After contact with skin:*            No special measures required.  
*After contact with eyes:*           No special measures required.  
*After ingestion:*                      No first aid necessary.

**5. Fire fighting measures**

*Suitable extinguishing media:* Extinguishing powder, foam, sand, CO2  
*Extinguishing media which must not be used for safety reasons:* None known  
*Special hazards caused by the material, its products of combustion or flue gases:* None known  
*Special protective equipment for fire fighting:* Use respiratory protection independent of recirculated air and suitable protective garments.  
*Combustion products:* Silicon dioxide, traces of carbon oxide, carbon dioxide and formaldehyde.

**6. Accidental release measures**

*Personal precautions:*              No special measures required.  
*Environmental precautions:*      Avoid spreading and prevent the product from entering sewers or surface waters.  
*Methods for cleaning up:*            Sweep and scrap into a waste bin.



## Safety Data Sheet

1907/2006/EU (Annex II, article 31) – 453/2010/EU

### Endo-Stops (Stop-Card)

**POLYDENTIA SA**

Status 09.04.2015/AR

Page 2 of 3

## 7. Handling and storage

### Handling

*Precautions for safe handling:* No special protective measures required.

*Precautions against fire and explosion:* No special precautions are required.

### Storage

*Conditions for storage rooms and vessels:* None known

*Advice for storage of incompatible materials:* Not applicable

*Further information for storage:* Keep the pack tightly close

## 8. Exposure controls / Personal protection

*Additional information about the technical concept of the product:* None

*Exposure limited and controlled:* Not applicable

*General protection and hygiene measures:* None required

*Respiratory protection:* Non required

*Eye protection:* Not required

*Skin protection:* Not required

*Soft oral tissue protection:* Not required

## 9. Physical and chemical properties

Appearance: solid, elastic

Odour: odourless

Colour: according to product specification (transparent or in various colours)

Ignition temperature: >400 °C

Flash point: not applicable

Lower explosion limit: not applicable

Upper explosion limit: not applicable

Vapour pressure: not applicable

Density: 1,17 g/cm<sup>3</sup>

Water solubility: insoluble

Liposolubility: not applicable

pH-Value: not applicable

Viscosity: not applicable

## 10. Stability and reactivity

*Stability:* Product is stable under normal handling and storage.

*Conditions to avoid:* Remove all sources of ignition, avoid storing in moist and warm conditions.

*Materials to avoid:* None known.

*Dangerous products of decomposition:* Measurements have shown the formation of small amounts of formaldehyde at temperatures above about 400 °C (302 °F).

**Safety Data Sheet**

1907/2006/EU (Annex II, article 31) – 453/2010/EU

**Endo-Stops (Stop-Card)**

**POLYDENTIA SA**

Status 09.04.2015/AR

Page 3 of 3

**11. Toxicological information**

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

**12. Ecological information**

Product not soluble and not hazardous for water. No expected damaging effects to aquatic organisms. Material not biodegradable on the basis of its structure. Bioaccumulation is not expected to occur.

**13. Disposal consideration**

Avoid spreading and prevent the product from entering sewers or surface waters.  
Used products can be discharged into a waste bin, according to any national or regional provisions which may be in force.

**14. Transport information**

Land ADR/RID: No hazardous material  
Sea: INO/IMDG: No hazardous material  
Air transport ICAO-II/IATA-DGR: No hazardous material  
UN regulation: - /

Customs Harmonized Tariff No. 9018.4900

**15. Regulatory information**

None of the ingredients is listed.  
Mark as ECC-guideline / Not necessary to mark  
National regulations / Classification as VFB / Not subordinated

Warning Label:

R sets: none

S sets: none

**16. Other information**

**FOR PROFESSIONAL USE ONLY**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.  
The receiver of this product must take responsibility for observing existing laws and national regulations.

POLYDENTIA SA is not held liable for any damage resulting from handling or contact with above mentioned products.