

**E.C. – Safety Data Sheet  
 (91/155/EEC)  
 Endo-Stops (Stop-Card)**

**POLYDENTIA SA**  
 Status 14.09.2012/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  
 Strada Cantonale  
 CH-6805 Mezzovico-Vira  
 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 Directive 1999/45/EC.

**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.

**E.C. – Safety Data Sheet  
 (91/155/EEC)  
 Endo-Stops (Stop-Card)**

**POLYDENTIA SA**  
 Status 14.09.2012/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).



**E.C. – Safety Data Sheet  
 (91/155/EEC)  
 Endo-Stops (Stop-Card)**

**POLYDENTIA SA**  
 Status 14.09.2012/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**

Recommended use: for dental professional use  
 Restriction of use: keep away from children

This Safety Data Sheet completes the Technical Data Sheet of the product, but it doesn't replace it. It is based on our present-day knowledge and has been issued according to the Safety Data Sheet of the raw material supplier.