

**Safety Data Sheet**

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

**POLYDENTIA SA**

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

Information on the product:

**“The Wedge” - Interdental Plastic Wedge POLYDENTIA**

Medical Device Class (according to 93/42/EEC): I

Main use of the product: help for cavity preparation during restorative procedures

**1.2 Information on the manufacturer:**

Polydentia SA  
 Via Cantonale 47  
 6805 Mezzovico-Vira (Switzerland)  
 Phone: 0041 (0) 91 946 29 48  
 Fax : 0041 (0) 91 946 32 03  
 Email : info@polydentia.com

**1.3 Information provided by:**

Phone: 0041 (0) 91 946 29 48

Emergency telephone: 0041 (0) 91 946 29 48

**2. Composition**

**Substance**

Copolyester

**3. Hazards identification**

Physical and chemical hazards:

Thermal decomposition giving toxic products (see chapter 10).

The preparation is not classified as dangerous according to EU Directive.

The product does not have to be labelled due to the calculation procedure of the “general Classification guideline for preparations of the EU” in the latest valid version.

**4. First aid measures**

*General information:* No special measures required  
*After inhalation:* Seek medical treatment in case of complaints.  
*After contact with skin:* If burned by contact with molten material, cool as quickly as possible with cold water. Do not pull solidified material away from the skin.  
*After contact with eyes:* If molten material contacts the eye, rinse opened eye for several minutes under running water. Get medical attention if symptoms persist.  
*After ingestion:* Consult with a physician in case of problems.

**5. Fire fighting measures**

*Suitable extinguishing media:* CO<sub>2</sub>, powder/foam or water jet.

*Special hazards caused by the material, its products of combustion or flue gases:*

Carbon monoxide, ammonia, amino derivatives,  
 Hydrogen cyanid (in case of temperature exceeding 500 °C)



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**6. Accidental release measures**

Methods for cleaning up: sweep or scoop up and remove.

**7. Handling and storage**

*Storage:* In closed original container.

*Prevention of fire:* Minimize dust generation and accumulation.

**8. Exposure controls / Personal protection**

Precautionary measures To be taken during use: Usual in dental practice

Respiratory protection: Not required

Hand protection: Not required

Eye protection: Not required

Skin protection: Not required (when material is heated, wear gloves to protect against thermal burns)

Soft oral tissue protection: Not required

**9. Physical and chemical properties**

Appearance: wedge (solid)

Odour: odourless

Colour: according to product specification (colourless or mass coloured)

Melting point: 155 °C

Decomposition temperature: 300-350 °C

Solubility: soluble in phenol, metacresol, benzyl alcohol (when hot), formic acid, sulphuric acid

Flash point: not applicable, combustible solid

Density at 20 °C: > 1g /cm<sup>3</sup>

Danger of explosion: product is not explosive

**Sizes and colour:** Ultrasmall (blue), Small (green), Medium (yellow), Large (colourless)

**10. Stability and reactivity**

Stability: Materials containing similar structural groups are stable under normal handling and storage.

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

Dangerous reactions: No dangerous reaction known.

Dangerous products of decomposition: Thermal decomposition giving toxic products: carbon monoxide, ammonia, amino derivatives.

**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.



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**12. Ecological information**

Generally not hazardous for water. Inert polymer, not biodegradable on the basis of its structure.

**13. Disposal consideration**

Dustbin

N.B. Respect 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

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.