

Safety Data Sheet

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

POLYDENTIA SA

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1.1 Identification of the substance/preparation and of the company

Information on the product:

Transparent Polyester Matrices POLYDENTIA
 (various types, forms and sizes)

Medical Device Class I (according to 93/42/EEC) – Rule 5
 Main use of the product: help for dental fillings

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: +41 (0) 91 946 29 48

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

2. Composition

Substance	CAS No.
Product based on ethylene glycol polyterephthalate transformed into film.	25038-59-9

3. Hazards identification

Adverse human health effects:	Contact with molten product may cause thermal burns. Does not present any particular risk provided it is handled in accordance with good industrial hygiene and safety practice.
Physical and chemical hazards:	Does not present any hazard under normal conditions of use.
Classification/Specific hazards:	According to EU criteria, this product is not classified as a hazardous substance.

4. First aid measures

Inhalation:	Not specifically applicable, provided it is handled in accordance with good industrial hygiene and safety practice.
Contact with skin:	Not specifically applicable. Nevertheless, in the event of a fire, the molten product may cause burns. In this case: rinse with plenty of water, do not remove clothing (risk of sticking to skin). Call a doctor immediately.
Contact with eyes:	Get medical attention.
Ingestion:	Consult with a physician.

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5. Fire fighting measures

- Suitable extinguishing media: All extinguishing agents can be used (water, foam, powders, carbon dioxide, sand, ...)
- Unsuitable extinguishing media: None. In the event of a fire close by, use suitable extinguishing agents.
- Specific hazards: Combustible product which melts on heating.
 Risk of fire-spreading due to flow of hot or ignited liquid.
 On combustion releases: harmful or toxic vapours.
- Special fire fighting methods: Cool down the molten product.

6. Accidental release measures

- Personal protection: Mark out contaminated area with signs and prevent access to unauthorized personnel.
- Environmental protection: This product does not present any particular risk to the environment.
- Methods for cleaning up:
 Recovery: Recover the product by vacuuming/shovelling or scraping
 Cleaning/Decontamination: Vacuum or sweep the area.

7. Handling and storage

- Handling: Avoid the build up of dust. Respect the manufacturers handling advice.
- Storage: Store away from any flames and sheltered from bad weather conditions.
- Incompatible products: Oxidising materials.
- Packaging: Product is packed in a variety of recyclable or reusable packaging.

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
- Soft oral tissue protection: not required

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9. Physical and chemical properties

Appearance: flexible bands of various forms and sizes
 Odour: odourless
 Colour: transparent
 pH: not applicable
 Flammability: Yes. Flash point >350 °C; Auto ignition temperature: > 420 °C
 Solubility: not applicable
 Insolubility: insoluble in water and in common organic solvents
 Melting point: 250 to 260 °C
 Decomposition point: >350 °C
 Oxidising properties: not oxidising in accordance with EEC criteria
 Other data: Thickness of the band 0.05 mm, 0.075mm, 0.175mm

10. Stability and reactivity

Stability: Stable under normal conditions of use
 Hazardous reactions:
 Conditions to avoid: No hazardous reactions known under normal condition of use.
 Hazardous decomposition products: On combustion or thermal decomposition, may release toxic gases (oxides of Carbon : CO + CO₂).

11. Toxicological information

Local effects: Not applicable, given the products physical state
 Further information: Does not present any particular hazard, provided is handled in accordance With good industrial hygiene and practice.

12. Ecological information

Environmental conversion:
 - Persistence/Degradability: The product persists in the soil.
 Destination of the product: Ultimate destination of the product: soil.
 - Impact/Possible effects: Not dispersible. Readily recoverable. This product should not pose any particular problem to the environment.

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 IMO/IMDG: No hazardous material
 Air transport ICAO-II/IATA-DGR : No hazardous material

Customs Harmonized Tariff: 9018.4900

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15. Regulatory information

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.