

1.1 Identification of the substance/preparation and of the company

Information on the product:

Product name: myWedge

Medical Device Class I (according to 93/42/EEC) – Rule 5

Main use of the product: As a 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

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

2. Composition

myWedge (XS – S – M – L)

Thermoplastic material

3. Hazards identification

Special hazards information for human and environment: not applicable

4. First aid measures

General information: no special measures necessary

Inhalation: consult with a physician

Contact with skin: not applicable

Contact with eyes: not applicable

Ingestion: consult with a physician

5. Fire fighting measures

Suitable extinguishing media: not applicable

Unsuitable extinguishing media for safety reasons: not applicable

Special exposure hazards: not applicable

Special protective equipment for fire fighting: not applicable

6. Accidental release measures

Precautionary measures related to people:	not applicable
Environmental protective measures:	not required
Methods for cleaning up:	mechanical

7. Handling and storage

Handling:	-
Storage:	at room temperature, avoiding contact with acidic vapours
Further information about storage:	not required

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

9. Physical and chemical properties

Appearance:	small plastic parts
Odour:	none
Colour:	myWedge XS : purple myWedge S : orange myWedge M: green myWedge L: yellow
pH:	not applicable
Flammability:	not applicable
Solubility:	not applicable
Insolubility:	not applicable
Density:	not applicable
Melting point:	not applicable
Boiling point:	not applicable
Dimensions (L x W x T) :	myWedge XS : 16x2.4x2.2 mm myWedge S : 18x2.4x2.4 mm myWedge M : 19x2.4x2.7 mm myWedge L : 19x2.4x2.9 mm

10. Stability and reactivity

Shelf life:	not applicable
Conditions to avoid:	storage near acids
Material to avoid:	acidic solution
Hazardous decomposition products:	not applicable

11. Toxicological information

Not applicable; there are none unhealthy effects.

12. Ecological information

Not applicable

13. Disposal consideration

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

15. Regulatory information

Mark as ECC-guideline	Not necessary to mark
National regulations	Classification as VFB
Not subordinated	
R/S sets:	none
H/P 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.