

Product Safety Data Sheet



1 Identification of the substance / preparation / company

Product details

Trade name:	B-FORM SPLINT
Application of the substance:	Manufacture of dental deep drawing splints with thermoforming technique
Manufacturer / Distributor:	BART MEDICAL S.r.l. Viale Vincenzo Randi, 118 48124 Ravenna (RA) – Italy E-mail: sales@bartmedical.com
Emergency telephone numbers:	BART MEDICAL S.r.l. – Italy Telephone number: (+39) 0544 523326 Fax: (+39) 0544 523326 - H 24

2 Composition / information on ingredients

Chemical characterization

CAS-Number:	63407-54-5
Designation:	Polyethylenterephthalat-Glycol Copolyester (PET-G)

3 Hazard identification

Non-hazardous substance or mixture according to Regulation EC No. 1272/2008.
No labeling required according to EC Directives 2006/121 / EC 0 1999/45 / EC

4 First aid measures

There are no such dangers as to require special first aid measures.

5 Fire-fighting measures

Extinguishing media:	Water spray, carbon dioxide, foam.
Protection measures in case of fire:	self-contained breathing apparatus and protective clothing should be available to extinguishers of fires.
Extinguishing media to be avoided:	None in particular.
Special fire-fighting procedures:	None.
Further information:	None

6 Accidental release measures

Clean and remove the dispersed or leaked product to avoid slipping and dispersion of the product into the environment.

7 Handling and storage

Handling

Information for safe handling:	When using do not eat, drink or smoke. Provide suction extractors if dust is formed.
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Storage

Storage conditions:	Store dry and dark at max 20 °C
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8 Exposure controls

Technical measures:	not applicable for this concentration.
Protective clothing personal:	not required.
Respiratory protection:	none.
Hand protection:	not required.
Eye protection:	not required. Avoid contact with eyes

9 Physical / chemical / mechanical and biological properties

9.1 General properties

Properties	Guideline	Value
Form	-	Solid
Color	-	Transparent
Odor	-	Odorless
Density	ISO 1183	1,27 g/cm ³
Water absorption after 24 h at 23 °C	ISO 62 Methode 1	0,2%

9.2 Mechanical properties

Properties	Guideline	Value
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Tensile strength	ISO 527	50 Mpa
Flectional strength	ISO 527	-
Impact strength 23 °C	DIN 53453	No fracture
Notched 23 °C	DIN 53453	16 KJ/m ²
Yield strain	ISO 527	-
Yield stress	ISO 527	> 45 Mpa
Elongation at tear	ISO 527	> 200 %
E-modulus	ISO 527	2050 Mpa
Hardness Shore A	DIN 53505	-
Hardness Shore D	DIN 53505	78
Rockwell Hardness	ISO 2039-1 H358/30	115

9.3 Thermal properties

Properties	Guideline	Value
Vicat softening point	ISO 306	80 °C
Thermoform resistance	ISO 75 Methode A ISO 75 Methode B	63 °C 70 °C
Continuous stress temperature	ISO 75	60 °C

9.4 Biological properties / Biocompatibility

The material has been tested on biocompatibility according to DIN EN ISO 10993. It meets the requirements regarding biological compatibility for medical devices products.

10 Stability and reactivity

Thermal decomposition / Conditions to avoid:

No decomposition by intended use.

11 Toxicological information

By handling the product appropriately and observing the usual occupational hygiene measures, no known harmful effects on health have emerged.

12 Ecological information

There are no known harmful effects on the environment.

13 Disposal consideration

The material can be recycled after separation or deposited on like commercial or household waste.

14 Transport information

There are no regulatory classifications, phrases or labeling or requests.

15 Regulatory information

The material can be recycled after separation or disposed of as urban waste.

16 Other informations

The aforementioned data are given most conscientiously but without any obligation. Any processing details are provided merely for guidance: it is the user's responsibility to check the suitability of the product for the intended application.

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