

Product Safety Data Sheet



EVA SOFT



1 Identification of the substance /preparation /company

Product details

Trade name:	B-FORM EVA SOFT
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 Hazards identification

Classification of the substance or mixture

Classification according to the directive 67/548 / EEC or Directive 1999/45 / EC: The product is not classified as dangerous

Specific hazard statements for humans and the environment:

It is believed that the product does not present risks to human health in the form in which it is placed on the market. The product is stable and inert under normal handling and storage conditions. It does not present risks relevant to the environment.

Elements of the label

Labeling according to the regulation CE n. 1272/2008:	Not applicable
Hazard pictograms:	Not applicable
Warning:	Not applicable
Hazard statements:	Not applicable

3 Composition / information on ingredients

Chemical characterization

CAS-Number:

24937-78-8

Designation:

Ethylenvinylacetat (EVA)

4 First aid measures

Description of first aid measures

General indications:

No specific measures are necessary.

Inhalation:

Dusts or vapors emitted by thermal action. Remove the patient from the polluted area; entrust to the doctor's care.

Skin contact:

Cool the affected part with the molten material with cold water and call the doctor. Do not remove the product that is solidified by the skin. Treat as a burn.

Eye contact:

Wash with running water for a few minutes keeping the eyelids wide open.

Ingestion:

No specific measures are required if the product is ingested as such. Call the doctor if necessary.

5 Firefighting measures

Fire fighting

Suitable extinguishing media: Water spray, foam, chemical powder, carbon dioxide.

Special hazards arising from the substance or mixture

Combustion products: carbon dioxide, carbon monoxide (as air / oxygen decreases) and any unburnt hydrocarbons.

Recommendations for firefighters

Protective equipment: Use appropriate personal protective equipment (self-contained breathing apparatus, helmet, protective goggles, overalls, fire-resistant gloves and boots).

Other information:

Cool containers close to flames with water spray.

6 Accidental release measures

Personal precautions:

Avoid walking on granules to avoid slipping.

Environmental precautions:

Do not allow product to enter drains or watercourses.

7 Handling and storage

Handling

Information for safe handling:

When using do not eat, drink or smoke.

Provide suction extractors if dust is formed.

Storage

Storage conditions:

Store dry and dark at max 20 °C

8 Exposure controls

Technical measures:	not applicable for this concentration.
Personal protective clothing:	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, one colored or multicolored
Odor	-	Odorless
Density	ISO 1183	0,96 g/cm ³
Water absorption after 24 h at 23 °C	ISO 62 Methode 1	< 0,2%
UV – stabilized	-	Yes

9.2 Mechanical properties

Properties	Guideline	Value
Tensile strength	ISO 527	>18 Mpa
Flexional strength	ISO 527	-
Impact strength 23 °C	ISO 179/1eU	No fracture
Notched 23 °C	ISO 179/1eU	No fracture
Yield strain	ISO 179	-
Yield stress	ISO 527	13 Mpa
Elongation at tear	ISO 527	800 – 900 %
E-modulus	ISO 527	15 Mpa
Hardness Shore A	DIN 53505	85
Hardness Shore D	DIN 53505	-
Rockwell Hardness	ISO 2039-1	-

9.3 Thermal properties

Properties	Guideline	Value
Vicat softening point	ISO 306 Methode B	42 °C
Thermoform resistance	ISO 75 Methode A	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

Acute toxicity:	Not demonstrated
Irritation on the skin:	No irritant effects.
Eye irritation:	No sensitizing effects known.

12 Ecological information

Aquatic toxicity:	No further relevant information available.
Persistence and degradability:	The product is essentially composed of a high molecular weight polymer, not considered ecotoxic.
Bioaccumulative potential:	Does not accumulate in organisms.
Further information:	The product is a non-biodegradable polymer.

13 Disposable considerations

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

14 Regulatory information

Not applicable

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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