



E.C. – Safety Data Sheet
(91/155/EEC)
F-SPLINT-AID

POLYDENTIA SA
Status 03.06.2009/GM
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1. Product identification/Preparation/Company undertaking

Product details:

Trade name: **F-Splint-Aid**
(*fiber glass band impregnated with bond*)

Medical Device Class II (according to 93/42/ECC)

Main use of the product: in the dental practice for the splinting of mobile teeth

Manufacturer/Supplier:

Polydentia SA
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CH-6805 Mezzovico

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Emergency information:

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2. Composition/information on ingredients

1. Sized E Glass (E Glass >98%, Size <2%)

impregnated with

2. Fiber-Bond

Composition:

Hydroxybutymethacrylat,
(2hydroxy-3-methacryloxy-propyloxy)-phenyl-propan
(2-methacryloxy-ethoxy)-phenyl-propan,
Dioxaoctamethylendimethacrylat
Glutarialdehyd

3. Hazards identification

1. Sized E Glass: Most important hazards / human health effects: Handling of glass filaments may cause temporary skin, eye und upper respiratory tract irritation.

2. Fiber-Bond: Irritates to eyes, breathing organs and skin.



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4. First-aid measures

Inhalation: Remove of scene of exposure
Skin contact: Clean immediately with soap and lukewarm water
Eye contact: Flush well with running water for 10 minutes. Seek medical advice if irritation.
Ingestion: Make person vomiting. Seek medical advice if irritation.
Allergy: Remove from scene of exposure

5. Fire-fighting measures

Suitable extinguishing media: CO₂, powder, foam (only the packaging burns if it is made of polyethylene or cardboard)

Unsuitable extinguishing media: Water jet

Special protective equipment for fire fighting: Breathing apparatus

6. Accidental release measures

Precautionary measures related to people: No specific recommendations

Environmental protective measures: Respect local regulations for transport of waste from inert products.

Methods of cleaning/adsorption: Take up with a cloth, polymerize in light and shovel in containers designed for filaments waste.

7. Handling and storage

Handling:

Instructions on safe handling: "sensitive people" should avoid long skin contact
Information on fire and explosion protection: No specific recommendations

Storage:

Requirements for storage areas and containers: light-safe, not above 25 °C
Packaging material: The product should be stored in its original packaging.



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8. Exposure controls/Personal protection

Engineering controls: No specific recommendations for product use in normal conditions.

Exposure limits: No specific recommendations

Personal protection: No specific recommendations

General protective measures: Keep common hygiene for the job

Breath protection: Not required

Hand protection: "sensitive people" should wear gloves

Eye protection: Safety goggles

Body protection: Common professional security clothes

9. Physical and chemical Properties

Appearances:

Form: solid, continuous glass filaments impregnated with liquid

Colour: white

Odour: like oil

Date relevant for safety

Changes in physical state: Melting point 1200 °C

Decomposition temperature: Only the Sized E Glass is decomposed from 400 °C

Autoignition: not applicable

Danger of Explosion: not applicable

Density: 2,6 g/ cm³

Solubility in water: Very slight solubility of the E Glass in water. Size is soluble in contact with organic solvents.

10. Stability and Reactivity

Thermal decomposition: No decomposition when used as prescribed.

Hazardous reaction: None, slow polymerization if incidence to the unprotected material;
Glass filaments are stable products causing no chemical hazardous reaction.

Hazardous decomposition products: When the combustion is kept going, small quantities of CO and CO₂ may result from the size decomposition.



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11. Toxicological information (for the uncured material)

Acute oral toxicity:

1. Fiber glass: not concerned
2. Bonding agent: (LD 50)16555mg/kg
(Species rat, Method FDA Guideline, OECD 401)

Skin Irritation

1. Fiber glass: not concerned
2. Bonding agent: non-irritant
Exposure time: 4h (Species rabbit, Method occlusive, FDA Draize, OECD 404)

Irritant effects on the eyes:

Exposure time: 24h
(Species rabbit eye, Method occlusive, FDA Draize, OECD 405)

Sensitivity:

1. Fiber glass -> Rare possibilities of allergy
2. Bonding agent -> not sensitizing
(Species guinea pig, Method GPMT)

Further information on toxicology:

Non-carcinogenic as app. II GefStoffV., no named on app. III of TRGS 900.

As existing experiences and information there are none unhealthy effects when used as prescribed.

12. Ecological information

Do not let into the water, the product is not biodegradable

13. Disposal considerations

Product uncured: Attention to the local/national laws of toxic waste if high quantities
Light polymerized: Attention to the local/national laws. Usually without special treatment.
Packaging: The bottle is of polyester and can be wasted without special treatment.

14. Transport information

Land transport ADR/RID and GGVS/GGVE (across the border/home):

ADR/RID: not restricted
GGVS/GGVE: not restricted / Mail Germany: allowed

Sea transport IMDG/GGV sea:

IMDG/GGV sea: not restricted

Air transport ICAO-II/IATA-DGR:

ICAO-II/IATA-DGR: not restricted

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15. Regulatory information

Glass filaments are not considered as dangerous for users.
Respect general health and Safety regulations.

Identification according EEC-guidelines: None
National laws: Classification as VbF: None
Water endangering class: 1 (self classification)

16. Other information

These information describe exclusive safety requirements of the product and are based on the present knowledge. They do not represent assurance of properties of the product as defined by the lawful guarantee of the regulation.