

Safety Data Sheet
According to Regulation (EC) 1907/2006
F-Splint-Aid & F-Splint-Aid Slim

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: **F-Splint-Aid**
F-Splint-Aid slim

1.2 Relevant identified uses of the Product and uses advised against

Medical Device Class IIA (according to 93/42/EEC)

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

1.3 Details of the supplier of the safety data sheet

Manufacturer / Supplier:

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

1.4 Emergency telephone number:

+41 (0) 91 946 29 48

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Dam. 1

Respiratory or skin sensitisation: Skin Sens. 1

Specific target organ toxicity - single exposure: STOT SE 3

Hazardous to the aquatic environment: Aquatic Chronic 1

Hazard Statements:

Causes skin irritation.

May cause an allergic skin reaction.

Causes serious eye damage.

May cause respiratory irritation.

Very toxic to aquatic life with long lasting effects.

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2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling
Bisphenol-A-bis-(2-hydroxypropyl)methacrylate
Bisphenol A epoxyate dimethacrylate
Triethylene glycol dimethacrylate
Hydroxypropyl methacrylate

Signal word: Danger

Pictograms



Hazard statements

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.
H410	Very toxic to aquatic life with long lasting effects.

Precautionary statements

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.

Additional advice on labelling

Medical devices (93/42/EWG) which are invasive or used in direct phys. contact with the human body, are exempted from provisions of Reg. (EC) No 1272/2008 (CLP/GHS) if they are in finished state and intended for the final user.

2.3. Other hazards

The non-polymerized material could irritate skin due to longer contact.

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SECTION 3: Composition / information on ingredients

3.2 Mixtures

Chemical characterization:

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

impregnated with

2. Fiber-Bond (bonding agent)

Viscous liquid of different dimethacrylates, photochemical initiators and stabilizers

Hazardous components (Fiber Bond)

Cas-Nr.	Description			Percentage
	EG. Nr.	Index Nr.	REACH-Nr.	
	Classification according to Regulation (EC) No 1272/2008[CLP]			
1565-94-2	Bisphenol-A-bis- (2-hydroxypropyl) methacrylate			45 - < 50 %
	Acute Toxic 4, Eye Dam. 1, Skin Sens. 1, Aquatic Chronic 1; H302 H318 H317 H410			
41637-38-1	Epoxyated bisphenol A dimethacrylate			20 - < 25%
	Skin Irrit. Two, eye irritation. 2, Skin Sens. 1, STOT SE 3; H315 H3 H317 H335			
109-16-0	Triethylene glycol dimethacrylate			15 - < 20 %
	203-652-6		01-2119969287-21	
	Skin Sens. 1; H317			
27813-02-1	Hydroxypropylmethacrylat			10 - < 15 %
	Eye Irrit. 2, Skin Sens. 1; H319 H317			

Full text of H and EUH statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Polymerized material is non-hazardous.

After contact with skin

After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

After contact with eyes

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

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After ingestion

Rinse mouth immediately and drink plenty of water.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Fire fighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Coordinate extinguishing measures with the environment.

5.2 Special hazards arising from the substance or mixture

Non-flammable.

5.3 Instructions for firefighting

Wear self-contained breathing apparatus and chemical protective clothing. Full protective suit.

Additional information

Precipitate gases/vapours/fog with water spray. Collect contaminated extinguishing water separately. Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

SECTION 6: Accidental release measure

6.1 Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Do not inhale gas/fumes/steam/aerosol.
Contact with skin, eyes and skin: use personal protective equipment

6.2 Environmental precautions

Do not allow to enter drains or bodies of water

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomaceous earth, acid binder, universal binder). Treat the collected material according to section Disposal.

6.4 Reference to other sections

Safe handling:	see section 7
Personal protective equipment:	see section 8
Disposal:	see section 13

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray. Only adequately trained personnel should handle this product. For use in dentistry only.

Advice on protection against fire and explosion

Protect from exposure to the light. Store not above 25°C.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations.

Advice on storage compatibility

No special measures are necessary.

7.3 Main use of the product:

In the dental practice for the splinting of mobile teeth

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

8.2. Exposure controls

Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Protective and hygiene measures

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

Eye/face protection

Suitable eye protection: goggles.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Skin protection

Wear suitable protective clothing.

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Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: continuous E Glass filaments impregnated with viscous liquid
Colour: white / yellow
Odour: characteristic

pH-Value: not determined

Changes in the physical state

Melting point: not determined
Initial boiling point and boiling range: 250 °C (Bonding)
Flash point: 113 °C (Bonding)

Flammability

Solid: not applicable
Gas: not applicable
Lower explosion limits: not determined
Upper explosion limits: not determined
Ignition temperature: 255 °C (Bonding)

Auto-ignition temperature

Solid: not applicable
Gas: not applicable
Decomposition temperature: not determined

Oxidizing properties

Not oxidizing.
Vapour pressure:
(at 20 °C) <1 hPa (Bonding)
Density (at 20 °C): 1,12 g/cm³ (Bonding)
Water solubility: insoluble (Bonding)

Solubility in other solvents

not determined
Partition coefficient: not determined
Vapour density: not determined
Evaporation rate: not determined

9.2. Other information

Solid content: not determined

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SECTION 10: Stability and reactivity

10.1 Reactivity

Stable under normal conditions

10.2 Chemical stability

Stable under normal conditions

10.3 Possibility of hazardous reactions

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

10.4 Conditions to avoid:

exposure to direct light radiation

10.5 incompatible materials:

Do not use in combination with self-etching bondings

10.6 Hazardous decomposition products

Incomplete combustion can produce toxic gases such as carbon monoxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Fiber glass: not concerned
Based on available data, the classification criteria are not met.

ATEmix tested

	Dose	Species
LD50,	oral 5000 mg/kg	Rat

CAS No	Chemical name			
	Exposure route	Dose	Species	Source
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate			
	oral	LD50 >5000 mg/kg	Rat	Manufacturer
109-16-0	Triethylene glycol dimethacrylate			
	oral	LD50 >5000 mg/kg	Rat	
	dermal	LD50 >2000 mg/kg	mouse	

Irritation and corrosivity

Causes skin irritation.
Causes serious eye damage.

Sensitising effects

Fiber Glass: Rare possibilities of allergy

May cause an allergic skin reaction. (Bisphenol-A-bis-(2-hydroxypropyl)methacrylate), (Bisphenol A epoxyate dimethacrylate), (Triethylene glycol dimethacrylate), (Hydroxypropyl methacrylate)

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Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

May cause respiratory irritation. (Bisphenol A epoxyate dimethacrylate)

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Additional information on tests

This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 [CLP].

Practical experience

Observations relevant to classification

When used and handled according to specifications, the product gives to the present knowledge and experience no adverse health effects .

SECTION 12: Ecological information

12.1 Toxicity

Fiber glass: not concerned

Bonding agent: very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

CAS – Nr.	Description				
	Aquatic Toxicity	Dosage	[h] [d]	Species	Source
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylat				
	Acute fish toxicity	LC50 >100 mg/l	96 h	Poecilia reticulata (Guppy)	Manufacturer
109-16-0	Triethylenglycoldimethacrylat				
	Acute fish toxicity	LC50 16.4 mg/l	96 h	Danio Rerio	OECD-Test Nr. 203
	Acute weeds toxicity	ErC50 >100 mg/l		Pseudokirchneriella subcapitata	OECD-Test Nr. 201

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

Partition coefficient n-Octanol/water

CAS-Nr.	Description	Log Pow
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylat	4.63
109-16-0	Triethylenglycoldimethacrylat	2.3

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12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The product has not been tested.

12.6. Other adverse effects

No information available.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

Waste disposal number of waste from residues/unused products

200139 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; separately collected fractions (except 15 01); plastics

Waste disposal number of used product

200139 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; separately collected fractions (except 15 01); plastics

Waste disposal number of contaminated packaging

200139 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; separately collected fractions (except 15 01); plastics

Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

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14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

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

EU regulatory information

2010/75/EU (VOC): 46,273 % (518,258 g/l)
2004/42/EC (VOC): 16,302 % (182,582 g/l)

National regulatory information

Employment restrictions: Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC).

Water contaminating class (D): 3 - highly water contaminating
Skin resorption/Sensitization: Causes allergic hypersensitivity reactions.

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%

Relevant H and EUH statements (number and full text)

H302 Harmful if swallowed.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H410 Very toxic to aquatic life with long lasting effects.

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Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.