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

1.1 Product identifier
Trade name: **Fiber-Bond**

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: Dental adhesive for the application of Fiber-Splint glass fiber tapes in splinting procedures

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:
0041 (0) 91 946 29 48

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:
Acute toxicity: Acute Tox. 4
Skin corrosion/irritation: Skin Irrit. 2
Serious eye damage/eye irritation: Eye Dam. 1
Respiratory or skin sensitisation: Skin Sens. 1
Hazardous to the aquatic environment: Aquatic Chronic 1
Hazard Statements:
Harmful if swallowed.
Causes skin irritation.
Causes serious eye damage.
May cause an allergic skin reaction.
Very toxic to aquatic life with long lasting effects.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling
Bisphenol-A-bis-(2-hydroxypropyl)methacrylate
Triethylene glycol dimethacrylate
Hydroxypropyl methacrylate
2,4,6-Trimethyl-benzoyl-diphenylphosphinoxyde

Signal word: Danger

Pictograms:

Hazard statements

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

Precautionary statements

P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
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.
P391	Collect spillage.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate			35 - < 40 %
	Acute Tox. 4, Eye Dam. 1, Skin Sens. 1, Aquatic Chronic 1; H302 H318 H317 H410			
109-16-0	Triethylene glycol dimethacrylate			20 - < 25 %
	203-652-6		01-2119969287-21	
	Skin Sens. 1; H317			
72829-09-5	1,12-Dodecane dioldimethacrylate			10 - < 15 %
	Skin Irrit. 2, Eye Irrit. 2; H315 H319			
27813-02-1	Hydroxypropyl methacrylate			10 - < 15 %
	248-666-3		01-2119490226-37	
	Eye Irrit. 2, Skin Sens. 1; H319 H317			
72869-86-4	7,7,9-(resp. 7,9,9-)Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecane-1,16-dioldimethacrylate			5 - < 10 %
	276-957-5			
	Aquatic Chronic 3; H412			
75980-60-8	2,4,6-Trimethyl-benzoyl-diphenylphosphinoxyde			< 1 %
	278-355-8			
	Repr. 2, Skin Sens. 1, Aquatic Chronic 2; H361f H317 H411			

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

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

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.

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: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

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

Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

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

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.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

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.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

DNEL/DMEL values

CAS No	Substance			
DNEL type		Exposure route	Effect	Value
27813-02-1	Hydroxypropyl methacrylate			
Worker DNEL, long-term		inhalation		14,7 mg/m³
Worker DNEL, long-term		dermal		4,2 mg/kg bw/day

PNEC values

CAS No	Substance	
Environmental compartment		Value
27813-02-1	Hydroxypropyl methacrylate	
Freshwater		0,904 mg/l
Freshwater sediment		6,28 mg/kg
Micro-organisms in sewage treatment plants (STP)		10 mg/l
Soil		0,727 mg/kg

Additional advice on limit values

To date, no national critical limit values exist.

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.

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:	Liquid
Colour:	
pH-Value:	not determined

Changes in the physical state

Melting point:	not determined
Initial boiling point and boiling range:	200 °C

Flash point:	> 93 °C
Flammability	
Solid:	not applicable
Gas:	not applicable
Lower explosion limits:	not determined
Upper explosion limits:	not determined
Ignition temperature:	113 °C
Auto-ignition temperature	
Solid:	not applicable
Gas:	not applicable
Decomposition temperature:	not determined
Oxidizing properties	
Not oxidising.	
Vapour pressure: (at 20 °C)	<1 hPa
Density:	1,09 g/cm³
Water solubility:	The study does not need to be conducted because the substance is known to be insoluble in water.
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

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

none

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Harmful if swallowed.

ATEmix calculated

ATE (oral) 1270,4 mg/kg

CAS No	Chemical name					
	Exposure route	Dose		Species	Source	Method
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate					
	oral	LD50 mg/kg	>5000	Rat	Manufacturer	
109-16-0	Triethylene glycol dimethacrylate					
	oral	LD50 mg/kg	>5000	Rat		
	dermal	LD50 mg/kg	>2000	mouse		
72829-09-5	1,12-Dodecane dioldimethacrylate					
	oral	LD50 mg/kg	>2000	Rat	analogy	
27813-02-1	Hydroxypropyl methacrylate					
	oral	LD50 mg/kg	>2000	Rat		OECD 401
	dermal	LD50 mg/kg	>5000	Rabbit	Manufacturer	FDA 1959 Draize
72869-86-4	7,7,9-(resp. 7,9,9-)Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecane-1,16-dioldimethacrylate					
	oral	LD50 mg/kg	>2000	Rat	OECD 401, limit test	
75980-60-8	2,4,6-Trimethyl-benzoyl-diphenylphosphinoxyde					
	oral	LD50 mg/kg	>5000	Rat		
	inhalative	Data lacking				

Irritation and corrosivity

Causes skin irritation.
Causes serious eye damage.

Sensitising effects

May cause an allergic skin reaction. (Bisphenol-A-bis-(2-hydroxypropyl)methacrylate; Triethylene glycol dimethacrylate; Hydroxypropyl methacrylate; 2,4,6-Trimethyl-benzoyl-diphenylphosphinoxyde)

Carcinogenic/mutagenic/toxic effects for reproduction

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

STOT-single exposure

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

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

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

SECTION 12: Ecological information

12.1. Toxicity

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

CAS No	Chemical name						
	Aquatic toxicity	Dose		[h] | [d]	Species	Source	Method
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate						
	Acute fish toxicity	LC50 mg/l	>100	96 h	Poecilia reticulata (Guppy)	Manufacturer	
109-16-0	Triethylene glycol dimethacrylate						
	Acute fish toxicity	LC50 mg/l	16,4	96 h	Danio rerio	OECD-Test Nr. 203	
	Acute algae toxicity	ErC50 mg/l	>100		Pseudokirchneriella subcapitata	OECD-Test Nr. 201	
72829-09-5	1,12-Dodecane dioldimethacrylate						
	Acute fish toxicity	LC50 mg/l	>100	96 h	Guppy (Poecilia reticulata)	Manufacturer	
27813-02-1	Hydroxypropyl methacrylate						
	Acute fish toxicity	LC50	493 mg/l	96 h	Leuciscus idus	DIN 38412 /15	
	Acute algae toxicity	ErC50 mg/l	>97,2	72 h	Pseudokirchneriella subcapitata		OECD 201
	Acute crustacea toxicity	EC50 mg/l	>143	48 h	Daphnia magna		OECD 202
72869-86-4	7,7,9-(resp. 7,9,9-)Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecane-1,16-dioldimethacrylate						
	Acute fish toxicity	LC50 mg/l	10,1	96 h	Brachydanio rerio	OECD 203	
75980-60-8	2,4,6-Trimethyl-benzoyl-diphenylphosphinoxyde						
	Acute fish toxicity	LC50 mg/l	6,53	96 h	Oryzias latipes		
	Acute crustacea toxicity	EC50 mg/l	3,53	48 h	Daphnia magna	OECD Guideline 202,	

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 No	Chemical name	Log Pow
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate	4,63
109-16-0	Triethylene glycol dimethacrylate	2,3
72829-09-5	1,12-Dodecane dioldimethacrylate	8,104
27813-02-1	Hydroxypropyl methacrylate	0,97
72869-86-4	7,7,9-(resp. 7,9,9-)Trimethyl-4,13-dioxo-3,14-dioxa-5,12-diaza-hexadecane-1,16-dioldimethacrylate	3,39
75980-60-8	2,4,6-Trimethyl-benzoyl-diphenylphosphinoxyde	3,257

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.

Contaminated packaging

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

SECTION 14: Transport information

14.6. Special precautions for user

No information available.

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

not applicable

SECTION 15: Regulatory information

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

EU regulatory information

2010/75/EU (VOC):	49,563 % (540,233 g/l)
2004/42/EC (VOC):	52,235 % (569,364 g/l)
Information according to 2012/18/EU (SEVESO III):	E1 Hazardous to the Aquatic Environment

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%

Classification for mixtures and used evaluation method according to Regulation (EC) No. 1272/2008 [CLP]

Classification	Classification procedure
Acute Tox. 4; H302	Calculation method
Skin Irrit. 2; H315	Calculation method
Eye Dam. 1; H318	Calculation method
Skin Sens. 1; H317	Calculation method
Aquatic Chronic 1; H410	Calculation method

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.
H361f	Suspected of damaging fertility.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Further Information

The information is based on present level of our knowledge. It does not, however, give assurances of product properties and establishes no contract legal rights. The receiver of our product is singulary responsible for adhering to existing laws and regulations.