

## Material Safety Data Sheet

(Regulation REACH n°1907/2006 and le regulation CLP N°1272/2008)

### 1- Identification of mixture and the company

#### 1.1 Commercial name

Name **PF Seal**  
Type of product Pits and fissures sealant  
Reference PF-3,6

#### 1.2 Relevant use of product:

Pits and fissures sealant

#### 1.3 Information concerning safety data sheet manufacturer:

Name: G-PHARMA  
Localization: 35, avenue du Gros Chêne - ZI des Bellevues  
BP 10279 Herblay  
95617 Cergy-Pontoise Cedex France  
Email: elsodent@elsodent.com  
Phone: + 33 (0)1 30 37 75 75

#### 1.4 Emergency telephone number

Number ORFILA: + 33 (0)1 45 42 59 59

### 2- Hazards Identification

The mixture meets the criteria for classification of Regulation 1272/2008 / EC amending Directives 67/548 / EEC and 1999/ 45 / EC and regulation 1907/2006 / EC (CLP). The mixture requires security sheet according to the requested requirements.

#### 2.1 Classification of the mixture

##### 2.1.1 Classification according to regulation (EC) N° 1272/2008 (CLP) :

Eyes irrit. 2 : H319; Skin irrit. 2: H315  
STOT SE 3 resp irrit : H335 Skin sens. 1: H317  
Tox. 4 : H302

##### 2.1.2 Classification according to the directive N° 67/548/CEE:

Xi: R36, R37, R38, Skin sens. : R43 Xn: R22

##### 2.1.3 Additional information

The full text of the classes and categories of danger: hazards H and R phrases are mentioned in Section 16.

#### 2.2 Label elements

Labeling according to Regulation (EC) No 1272/2008 (CLP) and its exemptions from Article 17 (relating to labeling and packaging requirements) provided for products with a capacity of less than 125 ml (Annex I of Regulations section 1.5.2.1)

##### Pictogram

SGH07



##### Signal Word :

Warning

##### Hazard statement

**H317:** Can cause a severe eye irritation

##### Precautionary statements

**P261:** Avoid breathing dust/fume/gas/mist/vapours/spray

**P272:** Contaminated work clothes should not leave the workplace

**P280:** Wear protective gloves/protective clothing/eye protection/face protection

Additional hazards information: Not Applicable

#### 2.3 Other hazards

The mixtures do not contain PBT or vPvP.

## 3- Composition / Information on ingredients

### 3.1 Product

EC designation: Not Applicable  
Classification according to the directive 93/42/EEC: Class IIa

### 3.2 Mixture

Index CE CAS	Chemical name	% Mass	Classification according to (CLP) N° 1272/2008 (CE)	Generic threshold
Index : N/A CAS : Proprietary	Methacrylate	60-80%	Skin irrit 2: H315 Eyes irrit 2: H319 STOT SE 3 : H335 Skin sens. : H317	≥ 1 % ≥ 1 % ≥ 1 % ≥ 0,1%

Note: The full text of hazard H and R-phrases is specified in section 16.

## 4- First aid measures

### 4.1 Description of first aid measures

Eye contact: Flush opened eye with running water for at least 5 minutes. Seek for medical advice.  
Skin contact: Remove contaminated clothing. Wash skin with soap and water. In case of irritation or skin rash, seek medical advice  
Swallowing: Wash mouth and seek medical advice.  
Inhalation: Remove to fresh air and keep at rest in a position comfortable for breathing. Seek for medical advice

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

Not available

### 4.3 Indication of any immediate medical attention and special treatment needed:

see section 4.1

## 5- Firefighting measures

### 5.1 Extinguishing media:

Suitable Extinguishing media: Not applicable  
Special protective equipment: Not applicable

### 5.2 Special hazards arising from the substance or mixture:

Not applicable

### 5.3 Tips for firefighters

None

## 6- Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures:

Avoid contact with skin and eyes. Wash hands with soap and water.

### 6.2 Environmental precautions:

Large amount: Remove the product following national, federal, regional or local current laws (by incineration).  
Remove the content the same way.

### 6.3 Methods and material for containment and cleaning up:

Wear gloves and protection goggles.  
Remove the spill with absorbent textile materials (paper towels, sand, sawdust).  
Wash the contaminated area with soap and water.

### 6.4 References to other sections

See Section 7 for a safe handling  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

## 7- Handling and Storage

### 7.1 Precautions for safe handling

Avoid skin and eyes contact. This product is for dental professional use only. Wash hands with water and soap in case of a contact with the product.

### 7.2 Conditions for safe storage, including any incompatibilities

Store in a cool, dry, place at temperatures below 25°C. Keep out of direct light. Do not store the product near a heat source or flame. Keep tightly closed containers.

### 7.3 Specific end use(s):

Dental professional use only.

## 8- Exposure controls / personal protection

### 8.1 Control parameters

Respiratory protection:	Not required in normal conditions of use.
Personal protective equipment:	Mask, protective gloves and protection clothe.
Eye protection:	Safety glasses.

Usual hygienic measures for dental practice.

Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin. Wash with soap and water in case on contact.

### 8.2 Explosion parameters

Not applicable

## 9- Physical & Chemical properties

### 9.1 Information regarding the physicals and chemicals properties

Appearance:	Off-white liquid paste	Flammability:	Not applicable
Odour:	Light	Relative density:	Not established
Boiling point:	> 200°C	Vapour pressure (20°C):	30 mm Hg to 20°C
Melting point:	Not applicable	Solubility in water:	Negligible
Flash point:	> 150°C		

### 9.2 Other information

None

## 10- Stability & reactivity

<b>10.1 Reactivity:</b>	Not applicable
<b>10.2 Chemical stability:</b>	stable under normal condition of storage and use.
<b>10.3 Possibility of hazardous reactions:</b>	No dangerous reactions known
<b>10.4 Conditions to avoid:</b>	Avoid exposition to direct light and to high temperatures. Avoid contamination with other products.
<b>10.5 Incompatible materials:</b>	Free radicals (peroxides), reducing substances, heavy metal ions.
<b>10.6 Hazardous decomposition products:</b>	Carbon dioxide after combustion.
<b>10.7 uncontrolled polymerization:</b>	Heat and intense light can induce polymerization.

Spontaneous polymerization can occur in the presence of free radicals. In the case of polymerization described above, a significant heat release will occur

## 11- Toxicological information

### 11.1 Information on toxicological effects

<u>Acute toxicity for health:</u>	May cause irritation or sensitization if the product is not wash rapidly.
<u>Chronical toxicity:</u>	Possibility of skin sensitization in case of a long and/or repeated exposure
<u>Signs and symptoms of exposure:</u>	Irritation of skin and eyes or respiratory tracts.

### 11.2 Other information:

Not applicable

## 12- Ecological information

### 12.1 Toxicity

No ecological toxicity or impacts on the environment have been identified for this product, in its packaging quantity.

**12.2 Persistence and degradability:** Not applicable

**12.3 Bioaccumulative potential:** Not applicable

**12.4 Mobility in soil:** Not applicable

**12.5 Results of PBT and vPvB assessment:** Not applicable

**12.6 Other adverse effects:** Not applicable

## 13- Disposal measures

### 13.1 Waste treatment methods

Large quantities: Disposal must be made according to local, state and federal regulations. Do not pour into the drain.

**13.2 Uncleaned packaging:** Disposal must be in accordance to all federal, national and local

## 14- Transport information

This information regarding the transportation follows the international transportation requirements.

No restriction for the road, boat or plane transportation.

Avoid high temperatures during transportation.

## 15- Informations réglementaires

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

Class IIa medical device according to the Directive 93/42 / EEC

**15.2 Chemical safety assessment:** Not applicable

## 16- Other information

### Symbol of potential danger:

Xi : Irritating

Xn: Toxic

### R phrases

R 25: Toxic if swallowed

R 36: Irritating to eyes.

R 37: Irritating for respiratory tracts

R 38: Irritating to skin.

R 43: Can cause skin sensitization

### S phrases:

S3: Keep the product in a well ventilated and cold area

### H phrases

H315, Category 2: Can cause skin rash

H319: Causes serious eye irritation.

STOT, SE 3, H335: Specific target organ toxicity - single exposure hazard category 3. May irritate respiratory tracts Category 1, skin sensitization,

H317: Can cause skin allergy

H302: Harmful if swallowed

### P phrases:

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

P264: Wash hands meticulously after use

P270: Do not eat, drink or smoke while manipulating the product

P271: Use only outdoor or in a well-ventilated area

P272: Contaminated work clothing should not be allowed out of the workplace

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P304 + P340: IF INHALATION: Move and keep the victim at rest outside where he can breath

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P302 + P352: IF ON SKIN: Wash with plenty of soap and water.  
P333 + P313: If skin irritation or rash occurs: Get medical advice/attention.  
P363: Wash contaminated clothing before reuse.  
P312: Call a POISON CENTER or doctor/physician if you feel unwell.  
P330: Rinse mouth

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