

## 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: Notre Dam  
Type of product: Dental dam  
Reference: ND-4 / ND-10

#### 1.2 Relevant use of product:

Light-cure dental dam

#### 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: H335; Skin sens. 1: H317

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

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

##### 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 mixture	15-25%	Skin irrit 2: H315 Eyes irrit 2: H319 STOT SE 3 : H335 Skin sens. : H317	≥ 1 % ≥ 1 % ≥ 1 % ≥ 0,1%
Index : N/A CAS : N/A	Silica	5-20 %	Skin irrit 2: H315 Eyes irrit 2: H319	≥ 1 % ≥ 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 eyes with plenty of water, keeping eyes open, for at least 5 minutes.  
Seek medical advice.

Skin contact: Wash skin with soap and water. In case of allergic reaction, seek medical advice.

Ingestion: Seek medical advice.

Inhalation: Not applicable under normal conditions of use.

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

Eye contact: Possible irritation on contact (H319)

Skin contact: May cause irritation on contact (H319), may cause sensitization by prolonged or repeated exposure (H317).

Inhalation: Non-toxic under normal conditions of use.

Ingestion: Potentially irritating in the presence of large amounts of product.  
May cause digestive disorders.

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

Not available

## 5. Firefighting measures

### 5.1 Extinguishing media:

Suitable extinguishing media: Use CO<sub>2</sub>, sand, dry chemical or foam.

Auto-ignition temperature: Not applicable

Flammability: Not flammable.

Unsuitable extinguishing media: Not applicable

Explosive limit in air: Not Applicable

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

Heat can cause polymerization with rapid release of energy which may melt the container.

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 with soap and water in case of contact. No special measures required for small quantity (less than 1 kg).

For large quantities, wear approved respirator and protective clothing.

Use water spray to cool container.

### 6.2 Environmental precautions:

Prevent spillage into waterways, sewers, or drains.

Large quantities: Dispose of product in accordance with national, federal, state or local regulations (by incineration).

Dispose of the container in the same manner as the product itself.

Small quantities: polymerize the product before conventional disposal.

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

Wear protective gloves and goggles.

Remove spillage with absorbent textile materials. Then wash the contaminated surface with soap and water.

### 6.4 References to other sections

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

Replace the cap immediately after use.

Avoid contact with skin and eyes.

This product is for dental professionals only.

Wash hands with soap and water if contact occurs.

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

Store in a cool place at a temperature between 5°C and 25°C.

Keep away from direct light.

### 7.3 Specific end use(s):

Dental professional use only.

## 8. Exposure controls / personal protection

### 8.1 Control parameters

Respiratory Protection & Ventilation: Work in a well-ventilated area.

Personal protective equipment: Rubber or PVC gloves.

Eye protection: Required.

Special hygiene measures :

Avoid prolonged contact with the skin.

In case of contact with eyes, rinse immediately with plenty of water.

Wash hands after use.

Follow good housekeeping and industrial hygiene practices when handling this material.

Remove all open flames or heat sources.

### 8.2 Explosion parameters

Not applicable

## 9. Physical & Chemical properties

### 9.1 Information regarding the physicals and chemicals properties

Appearance:	white colour, fluid paste	Vapour pressure (20°C):	Negligible, at room temperature
Odour:	Ester	Solubility in water:	Insoluble
Boiling point:	Not established	Flash point:	Not applicable
Specific Gravity:	1.5-2.0	Reactivity in water:	Not applicable
Melting point:	Not established	Explosion limits in air:	Not applicable
Flammability:	Not applicable	Decomposition temperature:	Not applicable
Density:	Not established	Oxidizing properties :	Not established

## 9.2 Other information

None

## 10. Stability & reactivity

<b>10.1 Reactivity :</b>	Stable under normal conditions
<b>10.2 Chemical stability:</b>	Stable
<b>10.3 Possibility of hazardous reactions:</b>	None known
<b>10.4 Conditions to avoid:</b>	Avoid heat, ignition sources, aging, contamination, and direct light sources.
<b>10.5 Incompatible materials:</b>	Free radicals e.g. peroxides, reducing substances and/or heavy metals.
<b>10.6 Hazardous decomposition products:</b>	None under normal conditions of use. Release of acrylic residues when burned.
<b>10.7 Uncontrolled polymerization:</b>	Heat and intense light may cause polymerization.

Spontaneous polymerisation may occur in the presence of radical formers. Under these conditions it may polymerise with the release of heat.

## 11. Toxicological information

### 11.1 Information on toxicological effects

Potential acute health effects: Irritating to eyes, skin or mucous membranes. Sensitization possible by prolonged exposure or contact with eyes or skin.

Potential chronic health effects: May cause sensitization by prolonged or repeated exposure or contact with the skin.

Signs and symptoms of exposure : Skin or eye irritation.

**11.2 Other information:** Not applicable

## 12. Ecological information

### 12.1 Toxicity

No ecological toxicity or impact on the environment has been identified for this product in the quantities present in the normal packaging. It is inert once polymerized. Not a polluting agent according to the CLP classification. Do not allow the product to enter sewers, surface and ground water.

**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 down the drain.

Small quantities: Dispose normally after polymerization.

**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. Regulation

### 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

STOT SE 3: Specific target organ toxicity - single exposure hazard category 3

### R phrases

R 36: Irritating to eyes

R 37: Irritating to respiratory system.

R 38: Irritation to skin

R 43: Can cause skin sensitization

### 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 tracks Category 1, skin sensitization,

H317: Can cause skin allergy

### P phrases:

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

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.

P302 + P352 : IF ON SKIN: Wash with plenty of soap and water.

P304 + P340: If inhaled: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P333 + P313 : If skin irritation or rash occurs: Get medical advice/attention.

P363 : Wash contaminated clothing before reuse.

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