

## 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 **PureFill 2**  
Type of product Light-cure composite  
Reference PUR-3\* & PUR-5\* (\* VITA Shade available)

#### 1.2 Relevant use of product:

Permanent dental composite

#### 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 N° 67/548/CEE (DPD)	Classification according to (CLP) N° 1272/2008 (CE)	Generic threshold
Index : N/A CAS : Proprietary	UDMA Modified	10-15%	Xi eyes irr, skin and resp.: R36/37/38 Skin sens. : R43	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	Boro alumino silicate	30 -70 %	Xi eyes, skin irr: R36/37/38	Skin irrit 2: H315 Eyes irrit 2: H319 STOT SE 3 : H335	≥ 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 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 allergic reaction, seek for medical advice.  
 Ingestion: Seek for medical advice.  
 Inhalation: Not applicable

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

Outreach opportunity for exposure or prolonged contact with skin.  
 Inhalation: May cause irritation (H335)  
 Ingestion: Slightly toxic. May cause gastric irritation  
 Skin contact: May cause irritation on contact (H319), may cause sensitization by prolonged or repeated exposure (H317).  
 Eye contact: Potentially irritating (H315).

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: Sand, chemical foam, carbon dioxide, dry chemicals  
 Special protective equipment: Not special measures required for small quantity (less than 1kg). For large quantity, wear approved respirator and protective gear. Use water spray to cool container

## 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 hands with soap and water in case of accidental contact with eyes

## 6.2 Environmental precautions:

Do not allow the product to enter sewers, surface and ground water.

## 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 contact with skin and eyes. For use in dentistry only. Wear latex or nitrile gloves. Replace cap immediately after use. Wash hands with soap and water if contact occurs

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

Store in a cool, dry, place at temperatures between 20°C and 25°C (50° - 77°F). 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.

- protective gloves

The glove material must be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time should be found out by the manufacturer of the protective gloves and has to be observed.

- Eye protection: Safety glasses.
- General protective and hygienic measures:

Usual hygienic measures for dental practice. Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin. Keep away from foodstuffs, beverages and feed. 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:	VITA Shade	Melting point:	Not established
Odour:	Ester-like	Flammability:	Not established
Boiling point:	Gel before boiling	Relative density:	Not established
Specific gravity:	~ 1.5-2.2	Vapour pressure (20°C):	0mbar

### 9.2 Other information

None

## 10- Stability & reactivity

### 10.1 Reactivity:

Not applicable

### 10.2 Chemical stability:

stable under normal condition of storage and use.

### 10.3 Possibility of hazardous reactions:

No dangerous reactions known

### 10.4 Conditions to avoid:

Avoid exposition to direct light and to high temperatures.  
Avoid contamination with other products.

## 10.5 Incompatible materials:

Free radicals (peroxides), reducing substances, heavy metal ions.

## 10.6 Hazardous decomposition products:

Carbon dioxide after combustion.

## 10.7 uncontrolled polymerization:

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

#### Acute toxicity for health:

Possibility of irritation or sensitization of the skin, if the product is not wash off rapidly (soap and water)

#### Chronical toxicity:

Possibility of sensitization of the skin, in case of extended or repeated contacts.

#### Signs and symptoms of exposure:

Irritation of skin, eyes and respiratory tracks. Sensitization of skin

### 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- 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

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

### S phrases:

S3: Keep the product in a well ventilated and cold area  
S9, S14: Avoid extreme temperatures, direct light, humidity, or any source of flame.

## 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  
Organic peroxide C: H242

## P phrases:

P210: Keep away from heat/sparks/open flames/hot surfaces. No smoking.  
P233: Keep container tightly closed.  
P235: Keep cool.  
P261 : Avoid breathing dust/fume/gas/mist/vapours/spray.  
P264: Wash hands thoroughly after handling.  
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.  
P403: Store in a well-ventilated place.  
P410: Protect from sunlight.

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