

Material Safety Data Sheet

(CLP Regulation N°1272/2008)

1. Identification of mixture and the company

1.1 Commercial name

Name **Prorez**
Type of product Temporary dental resin
Reference PRZ-16

1.2 Relevant use of product:

Dual-cure composite for temporary filling

1.3 Information concerning safety data sheet manufacturer:

Name : G-PHARMA
Localisation : 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 classification criteria of CLP Regulation 1272/2008 amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation 1907/2006/EC. Mixing requires a safety card in accordance with the 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, R43: skin sens., eyes & skin irrit., resp. irrit.,

2.1.2 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

Labelling in accordance with Regulation (EC) No 1272/2008 (CLP) and its derogations from Article 17 (concerning labelling and packaging requirements) for products with a capacity of less than 125 ml (Annex I of the Regulation 1.5.2.1).

Pictogram

SGH07



Signal word

Warning

H statement

H317 May cause an allergic skin reaction.

P statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P272 Contaminated work clothing should not be allowed out of 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

35, avenue du Gros Chêne - B.P. 10279 Herblay - 95617 Cergy Pontoise - France

3.2 Mixture

Index CE CAS	Chemical name	% Mass	Classification according to directive N° 67/548/CEE (DPD)	Classification according to Regulation (CLP) N° 1272/2008 (CE)	Generic threshold
Index : N/A CAS : -	Methacrylate	40-60	Irritat, Xi, eyes, resp. and skin: R36/37/38	Skin irrit 2: H315 Eyes irrit 2: H319 STOT SE 3 : H335	≥ 1 % ≥ 1 % ≥ 1 %
Index : N/A CAS : 94-36-0	Benzoyl peroxyde	0,1-1	R2; R7 Irrit, Xi, for eyes: R36 Skin sen.: R43	Organic Peroxid C : H242 Eye irrit.2: H319 Skin sens.1: H317	≥ 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

Inhalation: Not-applicable in normal conditions of use.
Swallowing: Rinse the mouth and drink a lot of water. If symptoms persist consult doctor.
Skin contact: Wash with soap and thoroughly rinse with water. Generally, the product does not irritate the skin.
In case of skin irritation or sensitization, seek for a medical advice
Eye contact: Rinse opened eye for several minutes under running water. Seek for a medical advice irritation persists.
Other measures to be taken: Take off contaminated clothe if large quantities of products are involved

4.2 Most important symptoms and effects, both acute and delayed Not-applicable

4.3 Indication of any immediate medical attention and special treatment needed: Not-applicable

5. Firefighting measures

5.1 Extinguishing media:

Suitable extinguishing agents: CO₂, powder or water spray. Fight larger fires with water spray or alcohol-resistant foam.

5.2 Special hazards arising from the substance or mixture: Not-applicable

5.3 Tips for firefighters Not-applicable

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 on contact.

6.2 Environmental precautions:

Big quantities: Dispose of in accordance to all federal, national and local regulations.
Small quantities: Polymerize and dispose of normally. 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 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. Wash with soap and water in case on contact.
A good ventilation of the workplace is necessary.

7.2 Conditions for safe storage, including any incompatibilities

Store in the original containers.
Avoid exposure to temperature above 25 ° C.

Store in a dry, cool place, away from light and moisture.
Keep containers tightly closed.

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 and protection clothe. Protective gloves 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:	Beige (Part A) and white paste (Par B)	Danger of explosion: No explosion hazard.
Odor:	Characteristic	Vapour pressure: Negligible at room temperature
PH-value:	7	Density at 20 °C: 1.2 g/cm ³
Melting point/Melting range:	Not applicable	Vapour density: Not applicable
Boiling point/Boiling range:	Not applicable	Solubility in / Miscibility with water: Nearly insoluble.
Flash point:	Not applicable	Oxidative properties: No
Flammability:	Not applicable	Specific gravity: ~ 2.2

9.2 Other information Not applicable

10. Stability & reactivity

10.1 Reactivity:	Not applicable
10.2 Chemical stability:	Generally stable under normal handling and storage conditions.
10.3 Possibility of hazardous reactions:	No dangerous reactions known.
10.4 Conditions to avoid:	Avoid exposition to direct light and to high temperatures
10.5 Incompatible materials:	Not applicable
10.6 Hazardous decomposition products:	None under normal handling and storage conditions
10.7 uncontrolled polymerization:	Unknown

11. Toxicological information

11.1 Information on toxicological effects

Acute toxicity: 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 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 have been identified for this product in the quantities present in the normal packaging. It is inert once polymerized.

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

Big quantities Dispose of in accordance to all federal, national and local regulations.
Small quantities Polymerize and dispose of normally.

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

Hazards Statements H

Xi : irritating

E : Explosive

O : Oxidizer

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: Irritating to skin.

S phrases

S3/9/14: Keep in a cool, well-ventilated place. Avoid extreme temperatures, strong light sources, moisture and flames.

H phrases

Catégorie 2, H315 : Causes skin irritation.

H319 : Causes serious eye irritation.

STOT, SE 3, H335 : Specific target organ toxicity - single exposure hazard category 3. May cause respiratory irritation.

Catégorie 1, skin sensitization, H317: May cause an allergic skin reaction.

Organic peroxyd 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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