

Material Safety Data Sheet

(CLP Regulation N°1272/2008)

1. Identification of mixture and the company

1.1 Product identifier

Product name: **Phoenix MD**
Type of product: Bridges and temporary crowns
Product No: PH-50-A1, PH-50-A2, PH-50-A3, PH-20-A1, PH-20-A2, PH-20-A3

1.2 Relevant identified uses of the substance or mixture and uses advised against:

Material for bridges and temporary crowns, in dual cartridge of 50 ml or 10 ml.

1.3 Details of the supplier of the safety data sheet:

Name: G-PHARMA
Address: 35, avenue du Gros Chêne - ZI des Bellevues
BP 50072 Herblay
95612 Cergy-Pontoise Cedex France
Email: elsodent@elsodent.com
Phone: + 33 (0)1 30 37 75 75

1.4 Emergency telephone number

Call ORFILA at : + 33 (0)1 45 42 59 59

2. Hazards Identification

The mixture meets the classification criteria of Regulation No 1272/2008 amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation No 1907/2006/EC (CLP Regulation). The mixture requires a safety data sheet in accordance with the requirements.

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) No 1272/2008 (CLP):

Irrit oc. 2 : H319; Irrit. Cut. 2: H315
STOT SE 3: H335; Sens cut. 1: H317

2.1.2 Classification according to Directive 67/548 / EEC:

Xi: R36, R37, R38,
Sens. cut.: R43

2.1.3 Additional information

The full wording of the hazard classes and categories, hazard statements H and R phrases is mentioned in section 16.

2.2 Label elements

Labeling in accordance with Regulation (EC) No 1272/2008 (CLP) and its derogations from article 17 (relating to labeling and packaging requirements) for products with a capacity of less than 125 ml (Annex I to Regulation 1.5.2.1).

Pictogram

SGH07



Attention

Signal word

Hazard statement **H317** : May cause skin allergy.

Precautionary advices

P261 : Avoid breathing dust / fume / gas / mist / vapors / aerosols

P272 : Contaminated work clothing should not be removed from the workplace.

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

Additional information on hazards: Not applicable

2.3 Other hazard

According to the criteria of the REACH decree, this mixture does not contains any substance of PBT or vPvP.

3. Composition / Information on ingredients

3.1 Substances/mixtures

EC Designation: Not Applicable
 Classification according to Directive 93/42 / EEC: Class IIa

3.2 General information

Index CE CAS	Chemical name	% Mass	Classification according to Directive 67/548 / EEC (DPD)	Classification according to Regulation (EC) No 1272/2008 (CLP)	Generic threshold value
Index : N/A CE : - CAS : -	Methacrylate	30 - 40	Irritant Xi, oc., cut. resp. : R36/37/38 Sens. cut. : R43	STOT SE 3 : H335; Irrit oc. 2 : H319; Irrit. Cut. 2: H315; Sens cut. 1: H317	≥ 1 % ≥ 0,1 %
Index : N/A CE : - CAS : -	Benzoyl peroxyde	0,1 – 1	Explosif, E : R2 Comburant, O : R7 Irritant, Xi, oc. : R36 Sen. Cut. : R43	C : H242 (Peroxyde organique) Irrit. oc 2 : H319 Sens. Cut. 1: H317	≥ 1 % ≥ 0,1 %
Index : N/A CAS : - CE : -	Silica	30 - 40	Irritant Xi, oc., cut. resp. : R36/37/38	STOT SE 3: H335; Irrit oc. 2 : H319; Irrit. Cut. 2: H315;	≥ 1 % ≥ 1 %

Note: The full text of H statements and R phrases is listed in section 16.

4. First aid measures

4.1 Description of first aid measures

Inhalation: Not applicable under normal conditions of use.
 Ingestion: Not toxic under normal conditions of use (small amount).
 For a large amount ingested, induce regurgitation of the material.
 Skin contact: Wash with soap and water. If you have an allergic reaction, seek medical advice.
 Eye contact: Wash with plenty of water. Take medical advice if irritation persists.
 Other measures to be taken: Remove contaminated clothing (large quantities).

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

Possibility of irritation of the skin and eyes. Possibility of sensitization in case of exposure or prolonged contact with the skin.
 Inhalation: Not toxic under normal conditions of use.
 Ingestion: Potentially irritating in presence of large quantities of product.
 May cause digestive disorders.
 Skin contact: Potentially irritating, may cause sensitization by prolonged or repeated exposure.
 Eye contact: Potentially irritating.

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

Not available.

5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:	Water spray.	Unsuitable extinguishing media:	Not Applicable
Auto-ignition temperature:	Not Applicable	Flash point:	Not Applicable
Explosive Limit in Air:	Not Applicable	Fusion point:	Not Applicable
Flammability:	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 with soap and water in case of contact.

6.2 Environmental precautions:

Accidental spills or dispersions of large quantities:

Dispose of the product according to applicable national, federal, regional or local laws (by incineration). Dispose of the container in the same way as the product itself.

Accidental release or dispersion of small quantities:
 Polymerize the product before conventional disposal.

6.3 Methods and materials for containment and cleaning up

Wear gloves and goggles.
 Remove spilled material with absorbent textile materials.
 Wash the contaminated surface with soap and water.

6.4 References to other sections

Refer to Section 8 for Personal Protection
 Refer to Section 13 for disposal conditions

7. Handling and Storage

7.1 Precautions for safe handling

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

7.2 Conditions for safe storage, including any incompatibilities:

Avoid exposure to temperatures above 25 ° C.
 Store product in a dry, cool place, away from light and moisture.
 Do not store product near heat or flame.
 Keep containers tightly closed.

7.3 Specific end uses:

This product is for dental professionals only.

8. Exposure controls / personal protection

8.1 Control parameters

Respiratory Protection & Ventilation protection: Not required under normal conditions of use.
 Personal protective equipment: Goggles, mask, gloves and gowns.
 Special precautions for hygiene: Avoid prolonged contact with the skin.
 In case of contact with eyes, rinse immediately with plenty of water. Wash hands after use.

8.2 Explosion parameters

Not applicable

9. Physical & Chemical properties

9.1 Informations sur les propriétés physiques et chimiques essentielles :

Physical state:	clear paste, translucent	Vapor density (air = 1):	> 1
Odor:	Slight	Solubility in water:	insoluble
Melting point:	Not available	Flash point:	Not applicable
Specific gravity:	~ 1.2	Reactivity in water:	Not applicable
Boiling point:	Not available.	PH :	Not disponible
Autoignition Temperature:	Not available	Decomposition temperature:	Not available
Vapor Pressure:	Not Applicable		

9.2 Other information

None

10. Stability & reactivity

10.1 Reactivity:	Not applicable
10.2 Chemical stability:	Stable under storage conditions
10.3 Possibility of hazardous reactions:	None known
10.4 Conditions to avoid:	Avoid exposure to high temperatures.
10.5 Incompatible materials:	None.
10.6 Hazardous decomposition products:	Not known.
10.7 Uncontrolled polymerization:	May occur when large quantities of product are exposed to high temperatures.

11. Toxicological information

11.1 Information on toxicological effects

Potential acute health effects: Possibility of irritation or sensitization of the skin if the product is not washed out quickly.

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

Signs and Symptoms of Exposure to Product: Irritation of skin and eyes.

11.2 Other information: Not applicable

12. Ecological information

12.1 Toxicity

No ecological toxicity or environmental impact was detected for this product in the quantities present in the normal packaging. It is inert when 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

Large quantities: disposal according to applicable national, federal, regional or local laws. Do not pour into the sink.
Small quantities: removal by the conventional system, after polymerization

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

14. Transport information

This information on transport is quoted according to international transport rules.
No restrictions for road, sea or air transport. Avoid high temperatures during transport.

15. Regulation

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

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

15.2 Chemical Safety Assessment: Not applicable

16. Other information

Potential Hazard Symbol:

Xi: irritant
E: Explosive
O: oxidizer
STOT SE 3: Specific target organ toxicity - single exposure hazard class 3

Risk Phrases R

R 2: Risk of explosion by shock, friction, fire or other sources of ignition.
R 7: May cause fire.
R36: Irritating to eyes,
R37: Irritating to respiratory system,
R38: Irritating to skin,
R43: May cause sensitization by skin contact.

Safety Phrases S

S3: Store product in a cool, cool place.
S9, S14: Avoid extreme temperatures, light sources, flame sources and moisture.

Hazard statements H

Category 2, H315: Causes skin irritation,
H319: Causes serious eye irritation,

STOT, SE 3, H335: Specific target organ toxicity - Single exposure, Category 3: May cause respiratory irritation, Category 1, skin sensitization, H317: may cause skin allergy, Organic peroxide C: H242.

Precautionary advice (s)

P261: Avoid breathing dust / fume / gas / mist / vapors / spray.
P272: Contaminated work clothing should not be removed from the workplace.
P280: Wear protective gloves / protective clothing / eye protection / face protection.
P305 + P351 + P338: In case of contact with eyes, rinse cautiously with water for several minutes, remove contact lenses if victim is worn and can be easily removed. Continue to rinse.
P302 + P352: In case of skin contact, wash thoroughly with soap and water.
P333 + P313: In case of irritation or rash, consult a doctor.
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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