

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 **InnoCem**
Type of product Permanent resin cement

1.2 Relevant use of product:

Dual cure and self-etching permanent resin cement

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



Warning

Signal Word :

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 CE : - CAS : 72869-86-4	Urethane dimethacrylate	20-40	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 : 85590-00-7	Phosphate methacrylate	10-30	Xi eyes, skin irr: R36/37/38	Skin irrit 2: H315 Eyes irrit 2: H319 STOT SE 3 : H335	≥ 1 % ≥ 1 %
Index : N/A CAS : 65997-17-3	Barium alumino silicate	25-40	Irritant Xi, oc., cut. resp. : R36/37	STOT SE 3: H335; Irrit oc. 2 : H319; Irrit. Cut. 2: H315;	≥ 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

Inhalation: Not applicable, in normal condition use.
 Swallowing: No toxic, in normal condition use. (Small quantity).
 For a large quantity swallowed, induce a regurgitation of the product.
 Skin contact: Wash with soap and water. In case of an allergic reaction, seek medical device.
 Eye contact: Rinse abundantly with water. If the irritation persists seek medical advice.
 Other measure: Remove all contaminated clothes (large quantity)

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:

Not available.

5- Firefighting measures

5.1 Extinguishing media:

Suitable Extinguishing media: Water spray	Flammable temperature:	Not Applicable
Explosion limits in air: Not Applicable	Flammable:	No
Melting point: Not Applicable	Flashing point:	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 skin and eye contact. In case of contact, wash with soap and water

6.2 Environmental precautions:

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

Small quantity: Polymerized the product before a normal removal.

6.3 Methods and material for containment and cleaning up:

- Wear gloves and goggles.
- Absorb with liquid binding material.
- Clean up affected area with water and soap.

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

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

7.2 Conditions for safe storage, including any incompatibilities

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

7.3 Specific end use(s):

- Dental professional use only.

8- Exposure controls / personal protection

8.1 Control parameters

- Respiratory and ventilating protection: Not necessary in normal condition of use.
- Personal protective equipment: Goggles, mask, gloves and blouse
- Specific hygiene measure: Avoid prolonged contact with skin.
- In case of eye contact, rinse opened eye for several minutes. Wash hands after each use.

8.2 Explosion parameters

- Not applicable

9- Physical & Chemical properties

9.1 Information regarding the physicals and chemicals properties

- | | | |
|--|----------------------|------------------|
| Appearance: Beige paste (part A), White (Part B) | Auto flammability: | Not applicable |
| Odour: Light smell | Solubility in water: | Almost insoluble |
| Boiling point: Not applicable | Flash point: | Not applicable |
| Specific gravity: Not applicable | Reactivity in water: | Not applicable |
| Melting point: Not applicable | PH: | Neutral |

9.2 Other information

- None

10- Stability & reactivity

- | | |
|--|------------------------------|
| 10.1 Reactivity: | Not applicable |
| 10.2 Chemical stability: | stable |
| 10.3 Possibility of hazardous reactions: | No dangerous reactions known |
| 10.4 Conditions to avoid: | High temperature |
| 10.5 Incompatible materials: | Not applicable |
| 10.6 Hazardous decomposition products: | Unknown |

11- Toxicological information

11.1 Information on toxicological effects

Acute toxicity for health:

May cause skin sensitization or irritation if the product is not removed rapidly.

Chronical toxicity:

May cause skin sensitization in case of a long or repeated contact or exposure to the product.

Signs and symptoms of exposure:

Irritation of skin or eyes and respiratory tract

11.2 Other information:

Not applicable

12- Ecological information

12.1 Toxicity

No ecological or environmental impact known, in the quantity of a regular packaging. It is inert after polymerization

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.

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

E: Explosive

O: Comburant

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

R phrases

R2: Risk of an explosion by shock, friction, fire or other sources of ignition

R7: May cause a fire

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:

- P261: Avoid breathing dust/fume/gas/mist/vapours/spray.
- P272: Contaminated work clothes should not leave the work place
- 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.
- P333 + P313: If skin irritation or rash occurs: Get medical advice/attention.
- P363: Wash contaminated clothes before reuse
- P312: Call the POISON CONTROL CENTER or a doctor if not feeling well
- P330: Rinse mouth

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