

Material Safety Data Sheet

(CLP Regulation N°1272/2008)

1. Identification of mixture and the company

1.1 Commercial name

Name **Elsotemp**
 Type of product Temporary filling cement
 Reference TPS-*, TPP-*1 et TPP-* [* B (white), R (pink) et G (grey)]

1.2 Relevant use of product:

Temporary filling cement based on zinc oxide and synthetic materials, self-hardening, ready-to-use.

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 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):

Acute Tox. 4: H302 ; aquat. aigu 1: H400;
 eye irrit. 2: H319 ; aquat. chron. 1: H410

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

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

Pictogram

SGH 07



Warning

Signal word

Hazard statements

H302 Harmful if swallowed, cat.4
H319 Causes serious eye irritation, cat.2
H400 Very toxic to aquatic life, cat.1
H410 Very toxic to aquatic life with long lasting effects, cat.1

Precautionary statement(s)

P273 Avoid release to the environment
P280 Wear protective gloves /protective clothing /eye protection /face protection
P305+351+338 IF IN EYES, rinse cautiously with water for several minutes, remove contact lenses if present and easy to do, continue rinsing.

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: 030-013-00-7 CE: - CAS: 1314-13-2	Zinc oxide	30-40	Danger aquat. aigu 1 : H400 Danger aquat. chroniq. 1: H410	≥ 0,1 % ≥ 0,1 %
Index: 030-006-00-9 CE: - CAS: 7733-02-0	Zinc sulfate	10-20	Tox. aiguë 4: H302 Les. oc. 1: H318 Danger aquat. aigu 1: H400 Danger aquat. chroniq. 1: H410	≥ 1 % ≥ 1 % ≥ 0,1 % ≥ 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: Remove to fresh air. Keep airway clear. In case of unconsciousness place patient stably in side position for transportation. Seek medical advice.

Skin contact: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, seek medical attention.

Eye contact: Irrigate copiously with clean, fresh water at least 15 minutes keeping the eyelids opened. Seek medical advice.

Ingestion: Do not drink, do not induce vomiting, seek medical advice.

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: All are suitable.

5.2 Special hazards arising from the substance or mixture:

Avoid breathing vapours.

5.3 Tips for firefighters

Use self-contained breathing apparatus.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Wear gloves and suitable goggles. Do not breathe vapours. Eliminate all ignition sources (Basic precautions).

6.2 Environmental precautions:

Do not dump into drains.

6.3 Methods and material for containment and cleaning up:

Absorb with an inert material (sand, vermiculite). Wash the soiled area with 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

Keep out of reach of children.
Avoid contact with eyes. Do not swallow.
Do not breathe vapors. Close tightly the bottle after use.
Wash your hands thoroughly after handling. Wash soiled clothing before reuse.
Comply with conditions of use.

7.2 Conditions for safe storage, including any incompatibilities

Keep the product in its original pack, tightly closed and keep container dry.
Keep in a cool place at a temperature below 25°C.

7.3 Specific end use(s):

Dental professional use only.

8. Exposure controls / personal protection

8.1 Control parameters

Zinc oxide	France/Belgique / Espagne TLV : 10mg/m ³ Allemagne TLV 4 (aérosol inhalable) mg/m ³
Respiratory protection:	Not required in normal conditions of use.
Personal protective equipment:	
Hand protection:	Wear appropriate gloves.
Eye/face protection:	Wear protective goggles.
Skin and body protection:	Wear safety clothing.

Wash hands after use. Do not eat, drink or smoke during use.

8.2 Explosion parameters Not applicable

9. Physical & Chemical properties

9.1 Information regarding the physicals and chemicals properties

PH :	6-6.5
Appearance:	Paste
Color:	White/Pink/Grey (according to the product reference)
Odour:	None
PH:	6-6.5
Relative density at 20°C:	1.011

9.2 Other information None

10. Stability & reactivity

10.1 Reactivity:	Not available
10.2 Chemical stability:	Stable under normal condition of storage and use.
10.3 Possibility of hazardous reactions:	No hazardous reactions are foreseeable in normal condition of use and storage.
10.4 Conditions to avoid:	Humidity, heat.
10.5 Incompatible materials:	None
10.6 Hazardous decomposition products:	Not available
10.7 uncontrolled polymerization:	Not available.

11. Toxicological information

11.1 Information on toxicological effects

May cause sensitization by eye contact

11.2 Other information: Not applicable

12. Ecological information

12.1 Toxicity

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

12.2 Persistence and degradability: Not available

12.3 Bioaccumulative potential: Not available

12.4 Mobility in soil: Not available

12.5 Results of PBT and vPvB assessment: Not available

12.6 Other adverse effects: Not available

13. Disposal measures

13.1 Waste treatment methods

Do not dump residue into drain. The chemicals must be eliminated in keeping with applicable regulations. Packaging of chemical products must be eliminated in keeping with applicable regulations.

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

H302: Harmful if swallowed, acute toxicity category 4

H318: Causes serious eye damage, category 1

H319: Causes serious eye irritation, category 2

H400: Very toxic to aquatic life, Aquatic Acute 1

H410: Very toxic to aquatic life with long lasting effects, Aquatic Chronic 1

Precautionary Statements P

P273: Avoid release to the environment

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

P305+351+338: IF IN EYES, rinse cautiously with water for several minutes, remove contact lenses if present and easy to do, continue rinsing.

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