

Material Safety Data Sheet

(Annex II of Regulation (UE) 2020/878 – modifying annexe II (EC) 1907/2006 - CLP Regulation N°1272/2008)

1. Identification of the substance/mixture and the company

1.1 Product identifier

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

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

Identified use(s)	Temporary filling cement based on zinc oxide and synthetic materials, self-hardening, ready-to-use
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1.3 Details of the supplier of the safety data sheet:

Name	G-PHARMA
Address	35, avenue du Gros Chêne - ZI des Bellevues - 95220 Herblay - France
Email	elsodent@elsodent.com
Phone	+ 33 (0)1 30 37 75 75

1.4 Emergency telephone number

ORFILA	+ 33 (0)1 45 42 59 59
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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) N° 1272/2008 (CLP)

Acute Tox. 4:	H302	Aquatic Chronic 1:	H410
Eye Dam. 1:	H318	Aquatic Acute 1:	H400
Aquatic Chronic 3:	H412	STOT SE 3:	H335

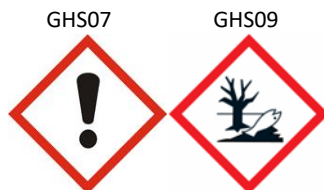
2.1.2 Additional information

Medical devices as defined in Regulation (EU) 2017/745 and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

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



Signal word

Hazard statement

Warning

H302: Harmful if swallowed.
H318: Causes severe eye damage
H400: Acute toxicity to the aquatic environment, Category 1
H410: Chronic aquatic toxicity, Category 1
H412: Harmful to aquatic organisms, causes long-term adverse effects
H225: Highly flammable liquid and vapours
H351: Likely to cause cancer.

Precautionary advices

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.
P264: Wash hands thoroughly after handling
P270: Do not eat, drink or smoke when using this product.
P271: Use only outdoors or in a well-ventilated area
P273: Avoid release to the environment.
P280: Wear protective gloves/protective clothing/eye protection/face protection
P301+P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P312: Call a POISON CENTER or doctor/physician if you feel unwell.
P310: Immediately call a POISON CENTER or doctor/physician.

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.**P305+P351+P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing**P330:** Rinse mouth.**P322:** Specific treatment (see on this label).**P363** Wash contaminated clothing before reuse.**P391** Collect spillage**P403+P233** Store in a well-ventilated place. Keep container tightly closed**P410** Protect from sunlight.**P501** Dispose of contents/container in accordance with local/regional/national/international regulationsAdditional information on hazards: Not Applicable**2.3 Other hazards** According to the criteria of the REACH decree, this mixture contains no substance of PBT or PvP.Additional information on hazards: Not Applicable

3. Composition / Information on ingredients

3.1 Product

EC Designation

Not Applicable

Classification according to Regulation (EU) MDR 2017/745

Class IIa

3.2 Mixtures

Index CE/CAS	Chemical name	Mass	Classification according to (CLP) N°1272/2008 (CE)	Generic threshold
Index: 030-013-00-7 CE: 215-222-5 CAS: 1314-13-2	Zinc oxide	30,0 - 45,0	Aquatic Acute 1, H400 Aquatic Chronic 1, H410	≥ 1 % ≥ 0.1 %
Index: 030-006-00-9 CE: 231-793-3 CAS: 7733-02-0	Zinc Sulfate	5,0 - 15,0	Acute Tox. 4 *, H302 Eye Dam. 1, H318 Aquatic Chronic 1, H410	≥ 1% ≥ 1% ≥ 0,1%
Index: 607-023-00-0 CE: 203-545-4 CAS: 108-05-4	Vinyl Acetate	< 1	Flam. Liq. 2, H225 Acute Tox. 4 *, H332 STOT SE 3, H335 Carc. 2, H351 Aquatic Chronic 3, H412	- ≥ 1 % ≥ 1 % ≥ 0.1 % ≥ 1 %

Note: The full text of H statements and R phrases is listed in section 2.2.

4. First aid measures

4.1 Description of first aid measures

Eye contact: Protect unharmed eye.

Rinse opened eye for several minutes under running water.

Call a doctor immediately.

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: Supply fresh air. If required, provide artificial respiration. Keep patient warm.

Consult doctor if symptoms persist.

Take affected persons into fresh air and keep quiet.

After swallowing: Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available

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

Auto-ignition temperature: Non applicable**Explosive Limit in Air:** Non applicable**Flammability:** Non-flammable**Unsuitable extinguishing media:** Do not use a concentrated jet of water which could spread the fire**Flash point:** No flash point

Fusion point: No data available

5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.
No further relevant information available.

5.3 Tips for firefighters

Protective equipment: Wear self-contained respiratory protective device.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes. In case of accidental contact with skin, wash hands thoroughly with soap and rinse.
In case of accidental contact with eyes, rinse thoroughly for few minutes and seek for medical advice if the problem persists.

6.2 Environmental precautions

Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to penetrate the ground/soil.
In case of seepage into the ground inform responsible authorities

6.3 Methods and materials 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 the eyes and skin.
Avoid all personal contact, including inhalation
Avoid physical damage to containers.
Remove and wash contaminated clothing before reuse.
Wear suitable gloves (nitrile or latex) and eye/face protection.
Wash hands before breaks and immediately after handling.
Observe manufacturer's storage and handling recommendations contained within this SDS.

7.2 Conditions for safe storage, including any incompatibilities

Store in a cool, dry, place at temperatures below 25°C. Keep out of direct light.
Store only in unopened original receptacles.
Store away from incompatible materials and foodstuff containers
Keep tightly closed containers.

Storage incompatibility:

Avoid strong acids, bases.
Avoid reaction with oxidising agents

7.3 Specific end use(s):

Dental professional use only.

8. Exposure controls / personal protection

8.1 Control parameters

Components with limit values that require monitoring at the workplace:
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Appropriate technical controls

Personal protective measures, such as personal protective equipment

Eye/face protection: Safety glasses.

Skin/hand protection: Mask, protective gloves and protection clothe.

Respiratory protection: Not required in normal conditions of use

8.2 Exposure parameters :

- Additional information about design of technical systems: No further data; see item 7.
- Personal protective equipment:
- General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Immediately remove all soiled and contaminated clothing.

- Breathing equipment: Suitable respiratory protective device recommended.

Protection of hands: Protective gloves

- 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 can not be calculated in advance and has therefore to be checked prior to the application.

- Penetration time of glove material

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

- Eye protection: Safety glasses with side shields.

9. Physical & Chemical properties

9.1 Information on basic physical and chemical properties

Appearance

General Physical state: Solid

Color: According to product specification (White, Grey and Pink)

Specific Physical Form: Pasty

Odor: Characteristic

Odor threshold: No data available.

PH: 6 - 7

Boiling point: Not determined.

Melting point: Not determined.

Flash point: No flash point

Evaporation rate: Not determined.

Flammability (solid, gas): Not classified

Flammability Limits (LEL): Not applicable.

Flammability Limits (UEL): Not applicable.

Vapor Pressure: Not applicable.

Vapor density (air = 1): Not determined.

Density: 2.6 - 3 g/cm³

Specific gravity: Not determined.

Solubility in water: Insoluble

Solubility-non-water: No data available

Reactivity in water: Not applicable

Partition coefficient: n-octanol/water: Not applicable

Decomposition temperature: No data available

Autoignition Temperature: Not applicable

9.2 Other information

9.2.1 Information on physical hazard classes:

9.2.2 other safety characteristics:

Important information on protection of health and environment, and on safety

Ignition temperature: Product is not selfigniting.

10. Stability & reactivity

10.1 Reactivity:

This material is considered to be non reactive under normal use conditions.

10.2 Chemical stability:

Stable under normal condition of storage and use.

10.3 Possibility of hazardous reactions:

Hazardous polymerisation will not occur.

10.4 Conditions to avoid:

No further relevant information available.

10.5 Incompatible materials:

No further relevant information available.

10.6 Hazardous decomposition products:

No dangerous decomposition products known.

10.7 Uncontrolled polymerization:

No further relevant information available.

11. Toxicological information

11.1 Information on toxicological effects

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation

This product may have a characteristic odour; however, no adverse health effects are anticipated.

Skin contact

Contact with the skin during product use is not expected to result in significant irritation.

Eye contact

Contact with the eyes during product use is not expected to result in significant irritation.

Ingestion

Gastrointestinal irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhoea.

Toxicological Data

If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

Acute Toxicity

	TOXICITY	IRRITATION
Zinc oxide	CL50 Inhalation(rat): >5.7 mg ZnO/l 4 heures DL50 Dermal (rat): >2000 mg/kg body weight. DL50 Ingestion(rat): >5000 mg ZnO/kg OECD 401	No data available
Zinc sulfate monohydrate	Oral LD50: 2150 mg/kg (rat)	Not Available
Vinyl acetate	orl-rat LD50:2900 mg/kg orl-mus LD50:1600 mg/kg skn-rbt LD50:2335 mg/kg ihl-rat LC50:11400 mg/m ³ /4H	No data available

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 Bio accumulative potential: Not applicable

12.4 Mobility in soil: Not applicable

12.5 Results of PBT and vPvB assessment: Not applicable

12.6 Endocrine-disrupting properties The product does not contain substances with endocrine disrupting properties

12.7 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

Substances/mixtures not classified as hazardous for transportation. No restriction for the road, boat or plane transportation.

This information regarding transportation follows the international transportation requirements.

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 Regulation (EU) MDR 2017/745

15.2 Chemical Safety Assessment

Not applicable

16. Other information**Abbreviations and acronyms:**

N/A: Not applicable

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

DNEL: Derived No-Effect Level (UK REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Eye Dam. 1: Causes severe eye damage

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Flam. Liq. 2: Flammable liquid

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Chronic aquatic toxicity, Category 1

Aquatic Chronic 3: Harmful to aquatic life with long lasting effects.

Acute Tox. 4: Acute toxicity (oral), Hazard Category 4

Some of the information presented and conclusions drawn herein are from sources other than direct test data on the product itself. The information in this MSDS was obtained from sources that we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or method of handling, storage, use and disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, G PHARMA do not assume responsibility and expressly disclaim liability for loss, damage, or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. If the product is used as a component in another product or used in a way other than recommended by the Company, this MSDS information may not be applicable.