

Material Safety Data Sheet

(CLP Regulation N°1272/2008)

1. Identification of mixture and the company

1.1 Commercial name

Name	TopBase
Type of product	Relining dental material
Reference	TPU / TPD / TPCLU / TBCLD

1.2 Relevant use of product: TopBase readjusts the prosthesis to the gum creating the suction effect.

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 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):

TopBase is not a dangerous substance or mixture according to the Globally Harmonised System (GHS)

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

Labelling according to Regulation (EC) No 1272/2008 (CLP) and its exemptions from Article 17 (relating to labelling and packaging requirements) provided for products with a capacity of less than 125 ml (Annex I of Regulations section 1.5.2.1)

<u>Pictogram</u>	Not applicable
<u>Signal Word:</u>	Not applicable
<u>Hazard statement</u>	Not applicable
<u>Precautionary statements</u>	Not applicable.
<u>Additional hazards information:</u>	Not applicable

2.3 Other dangers

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 CAS: 502-44-3	2-oxepanone, homopolymer	≥ 99 %	-	-	-

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	First aid measures not required but get fresh air for personal comfort.
Skin contact	First aid measures not required but wash exposed skin with soap and water for hygienic reasons.
Eye contact	First aid measures not required, but rinse opened eye under running water for personal comfort to avoid mechanical irritation.
Ingestion	If a large quantity has been ingested or if you feel unwell, get medical advice/attention.

4.2 Most important symptoms and effects, both acute and delayed

None known.

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

Treat symptomatically - See section 4.1

5. Firefighting measures

5.1 Extinguishing media

Water spray (fog), Foam, Carbon dioxide (CO₂), Extinguishing powder.

5.2 Special hazards arising from the substance or mixture:

Unsuitable extinguishing media	Do not use a solid water stream as it may scatter and spread fire.
Specific hazards arising from the chemical	Thermal decomposition can lead to release of irritating and toxic gases and vapours: Carbon monoxide (CO).

5.3 Tips for firefighters

In the event of fire, wear self-contained breathing apparatus.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Ensure adequate ventilation, especially in confined areas.

6.2 Environmental precautions:

Do not flush into surface water or sanitary sewer system. See Section 12 for additional ecological information.

6.3 Methods and material for containment and cleaning up:

Methods for containment	Take up mechanically, placing in appropriate containers for disposal.
Methods for cleaning up	Use approved industrial vacuum cleaner for removal.

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

Ensure adequate ventilation, especially in confined areas. Protect from direct sunlight. Keep away from heat.

7.2 Conditions for safe storage, including any incompatibilities

Keep containers tightly closed in a dry, cool and well-ventilated place.

7.3 Specific end use(s):

Dental professional use and patients directly.

8. Exposure controls / personal protection

8.1 Control parameters

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region-specific regulatory bodies.

Appropriate engineering controls Ensure adequate ventilation, especially in confined areas.

Person protection measures, such as personal protective equipment

Eye/face protection No special technical protective measures are necessary

Hand Protection Protective gloves not really required.

8.2 Explosion parameters

Not applicable

9. Physical & Chemical properties

9.1 Information regarding the physicals and chemicals properties

Property	Value	Property	Value
Appearance	Solid, granules, white	Relative density	No information available
Odour	Odourless	Water solubility	Insoluble in water
Odour threshold	Not applicable	Solubility	No information available
Melting point / freezing point	58 - 60 °C / 136 140 °F	Partition coefficient	No information available
Boiling point / boiling range	Not determined	Autoignition temperature	No information available
Flash point	275 °C / 527 °F	Decomposition temperature	200 °C
Evaporation rate	No information available	Kinematic viscosity	No information available
Flammability (solid, gas)	Not determined	Dynamic viscosity	Not applicable
	Explosive limits	Explosive properties	Not explosive.
Upper explosive limits	Not applicable	Oxidising properties	Not oxidising.
Lower explosive limits	Not applicable	Density	1.1 g/cm ³ (@60°C)
Vapour pressure	Not determined	Bulk density	No information available
Vapour density	Not applicable		

9.2 Other information

None

10. Stability & reactivity

10.1 Reactivity:	There exists no specific test data for this product. For further information, see the subsequent subsections of this chapter.
10.2 Chemical stability:	Stable under normal condition of storage and use.
10.3 Possibility of hazardous reactions:	None under normal processing
10.4 Conditions to avoid:	To avoid thermal decomposition, do not overheat.
10.5 Incompatible materials:	Avoid contact with acids. Avoid contact with bases.
10.6 Hazardous decomposition products:	Possible decomposition and release of monomer at temperatures above 200°C.

11. Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure	Inhalation, Dermal.
Symptoms related to the physical, chemical and toxicological characteristics	None known.
Numerical measures of toxicity	Unknown Acute Toxicity 100 % of the mixture consists of ingredient(s) of unknown toxicity.

Acute toxicity	Caution - substance not yet fully tested. Due to the structure of the substance and studies made on similar products we assume that the product is unclassified. The polymer is not bioavailable because of its molecular size.
Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitisation	No sensitising effects known.
Aspiration hazard	No information available.

11.2 Other information: Not applicable

12. Ecological information

12.1 Toxicity

The polymer is not bioavailable because of its molecular size 100% of the mixture consists of components(s) of unknown hazards to the aquatic environment.

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

Disposal should be in accordance with applicable regional, national and local laws and regulations.

13.2 Uncleaned packaging:

Thoroughly emptied and clean packaging may be recycled.

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

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.