

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 **PURESHADE**
Type of product Light-cure restorative composite
Product reference PURSH4* (* shade 1, 2, 3)

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

1.2.2 Identified use(s)

Restorative permanent dental composite

1.3 Details of the supplier of the safety data sheet:

Name **G-PHARMA**
Address 35, avenue du Gros Chêne - ZI des Bellevues
BP 10279 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) 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 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



Signal word

Warning

Hazard statement

H317: Can cause a severe eye irritation

Precautionary advices

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 information on hazards: 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 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: N/A CAS: Proprietary	Methacrylate	15-25%	Skin irrit 2: H315 Eyes irrit 2: H319 STOT SE 3 : H335 Skin sens. : H317	≥ 1 % ≥ 1 % ≥ 1 % ≥ 0,1%
Index: N/A CAS: N/A	Barium alumino silicate specific fillers	70 -80 %	Skin irrit 2: H315 Eyes irrit 2: H319	≥ 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**

Eye contact: Flush opened eye with running water for at least 5 minutes. Seek for medical advice.

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: Not applicable

4.2 Most important symptoms and effects, both acute and delayed

Outreach opportunity for exposure or prolonged contact with skin.

Inhalation: May cause irritation (H335)

Ingestion: Slightly toxic. May cause gastric irritation.

Skin contact: May cause irritation on contact (H319), may cause sensitization by prolonged or repeated exposure (H317).

Eye contact: Potentially irritating (H315).

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**

Heat can cause polymerization with rapid release of energy which may melt the container

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. 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 persist.

6.2 Environmental precautions

Do not allow the product to enter sewers, surface and ground water.

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

When using, do not eat, drink or smoke.
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.

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. Do not store the product near a heat source or flame. Keep tightly closed containers.

7.3 Specific end use(s)

Dental professional use only.

8. Exposure controls / personal protection

8.1 Control parameters

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

Not applicable

9. Physical & Chemical properties

9.1 Information on basic physical and chemical properties

Appearance

General Physical state: solid
Color: tooth-like color (VITA shades)
Specific Physical Form: paste
Odor: Ester-like
Odor threshold: No data available
PH: Not applicable
Boiling point: Not applicable
Melting point: No data available
Flash point: No flash point
Evaporation rate: Not applicable
Flammability (solid, gas): Not classified

Flammability Limits (LEL): Not applicable
Flammability Limits (UEL): Not applicable
Vapor Pressure: Not applicable
Vapor density (air = 1): Not applicable
Density: 1.9g/cm³**Specific gravity:** 1.9 (Ref Std: Water=1)
Solubility in water: Negligible
Solubility-non-water: No data available
Reactivity in water: Not applicable
Partition coefficient: n-octanol/water: No data available
Decomposition temperature: No data available
Autoignition Temperature: No data available

9.2 Other information

9.2.1 Information on physical hazard classes: None

9.2.2 other safety characteristics: None

10. Stability & reactivity

10.1 Reactivity:

This material may be reactive with certain agents under certain conditions.
Spontaneous polymerization can occur in the presence of free radicals.
In case of polymerization described above, a significant heat release will occur.
Stable under normal condition of storage and use.

10.2 Chemical stability:

10.3 Possibility of hazardous reactions:

10.4 Conditions to avoid:

10.5 Incompatible materials:

10.6 Hazardous decomposition products:

10.7 Uncontrolled polymerization:

No dangerous reactions known
Avoid exposition to direct light and to high temperatures. Avoid contamination with other products.
Free radicals (peroxides), reducing substances, heavy metal ions.
Carbon dioxide after combustion.
Heat and intense light can induce polymerization.

11. Toxicological information

11.1 Information on toxicological effects

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 Not available

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 the 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

Symbol of potential danger:

Xi : Irritating

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

R phrases

R36: Irritating to eyes

R37: Irritating to respiratory system.

R38: Irritation to skin

R43: 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

P phrases

P210: Keep away from heat/sparks/open flames/hot surfaces. No smoking.

P233: Keep container tightly closed.

P235: Keep cool.

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

P264: Wash hands thoroughly after handling.

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.

P304 + P340: If inhaled: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P333 + P313: If skin irritation or rash occurs: Get medical advice/attention.

P363: Wash contaminated clothing before reuse.

P403: Store in a well-ventilated place.

P410: Protect from sunlight.

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