

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* - PURSH20* - (* shade 1, 2, 3)

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

Identified use(s)	Restorative permanent dental composite.
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1.3 Details of the supplier of the safety data sheet

Name	G-PHARMA SAS
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)**

Eyes irrit. 2:	H319;	Skin irrit. 2:	H315
STOT SE 3:	H335;	Skin sens. 1:	H317

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

GHS07

Signal wordHazard statementPrecautionary advicesWarning**H317:** May cause an allergic skin reaction**H315:** Causes skin irritation.**H319:** Causes serious eye irritation**H335:** May cause respiratory irritation**H411:** Toxic to aquatic life with long lasting effects**P261:** Avoid breathing dust/fume/gas/mist/vapours/spray.**P264:** Wash hands thoroughly after handling**P272:** Contaminated work clothing should not be allowed out of the workplace.**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**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

P314 Get medical advice/attention if you feel unwell
P321 Specific treatment (see on this label).
P332+P313 If skin irritation occurs: Get medical advice/attention.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention
P337+P313 If eye irritation persists: Get medical advice/attention.
P362 Take off contaminated clothing and wash before reuse
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 regulations

Additional 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 PpP.

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 : 607-134-00-4 CE : 276-957-5 CAS : 72869-86-4	Urethane dimethacrylate	20-30 %	H315: Skin Irrit. 2 H319: Eye Irrit. 2 H335: STOT SE 3 H317: Skin Sens. 1B H411 : Aquatic Chronic 2	≥ 1 % ≥ 1 % ≥ 1 % ≥ 0,1% ≥ 1 %
CE : 233-814-1 CAS : 10373-78-1	Camphorequinone	< 1 %	H315 : Skin Irrit. 2 H319 : Eye Irrit. 2 H335 : STOT SE 3	≥ 1 % ≥ 1 % ≥ 1 %
Index : N/A CE : 266-046-0 CAS : 65997-17-3	Barium alumino silicate specific fillers	70 -80 %	Not classified	-

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

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: Flush opened eye with running water for at least 5 minutes.
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

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

For the possibility of consulting a physician, refer to 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

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 the product to enter sewers, surface and ground water.

6.3 Methods and materials for containment and cleaning up

Wear gloves and protection goggles.

Polymerized the product and remove it.

Clean contaminated area with water and soap.

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

This product is for dental professionals only.

Wear suitable gloves (nitrile or latex) and eye/face protection.

Use according to good professional dental practice.

Observe precautions usually used when handling chemicals.

Avoid contact with skin and eyes. Do not swallow. Avoid generating dust.

Information on fire and explosion protection: No special measures required

7.2 Conditions for safe storage, including any incompatibilities

Store in a dry place at a storage temperature between 5 to 25 °C.

Keep well closed.

Storage and packaging requirements:

Keep container tightly sealed and only in the original container.

Store away from foodstuffs.

Protect from heat and direct sunlight.

Do not store near a source of heat or flame.

Store in cool, dry conditions in well-sealed receptacles

7.3 Specific end use(s):

Dental professional use only.

8. Exposure controls / personal protection

8.1 Control parameters - Appropriate technical controls

Components with limit values to be monitored in the working place:

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

8.2 Equipment

Respiratory Protection & Ventilation: Not necessary in normal condition of use.

Personal protective equipment: Wear goggles, mask, gloves and blouse

Keep away from food and drink.

Specific hygiene measure: Avoid contact with eyes or skin.

9. Physical & Chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state:	Paste.	Flammability Limits (LEL):	Not applicable.
Color:	Tooth-like color (VITA shades).	Flammability Limits (UEL):	Not applicable.
Specific Physical Form:	Not applicable.	Vapor Pressure:	Not applicable.
Odor:	Ester-like.	Vapor density (air = 1):	Not applicable.
Odor threshold:	No data available.	Density: 1.9g/cm³ Specific gravity:	1.9 (Ref Std: Water=1).
PH:	Not applicable.	Solubility in water:	Negligible.
Boiling point:	Not applicable.	Solubility-non-water:	No data available.
Melting point:	No data available.	Reactivity in water:	Not applicable.
Flash point:	No flash point.	Partition coefficient: n-octanol/water:	No data available.
Evaporation rate:	Not applicable.	Decomposition temperature:	No data available.
Flammability (solid, gas):	Not classified.	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.
10.2 Chemical stability:	Stable under normal condition of storage and use.
10.3 Possibility of hazardous reactions:	No dangerous reactions known
10.4 Conditions to avoid:	Avoid exposition to direct light and to high temperatures. Avoid contamination with other products.
10.5 Incompatible materials:	Free radicals (peroxides), reducing substances, heavy metal ions.
10.6 Hazardous decomposition products:	Carbon dioxide after combustion.
10.7 Uncontrolled polymerization:	No polymerization if used according to specifications. Heat and intense light can induce polymerization.

11. Toxicological information

11.1 Information on toxicological effects

Acute toxicity:	No information available.
Primary irritation:	Skin, eyes.
Sensitization:	May cause skin sensitization or irritation if the product is not removed rapidly.
Symptoms related to physicochemical and toxicological properties:	Not applicable.
Deferred and immediate effects and chronic effects of short-term exposure:	May cause allergic reactions in case of a long or repeated contact or exposure. When the product is used and handled properly as specified, in our experience and according to the information available to us, there are no adverse effects.
Signs and symptoms of exposure:	Irritation of skin or eyes and respiratory tract.

11.2 Other information: Not applicable.

12. Ecological information

Use according to good working procedures, avoiding release of the product into the environment or into the soil or sewerage networks and streams.

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 PvB assessment:	Not applicable.
12.6 Endocrine-disrupting properties	None of the ingredients is listed.
12.7 Other adverse effects:	Not applicable.

13. Disposal measures

Waste treatment methods

13.1 Product: 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 laws.

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

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

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1B: Skin sensitisation – Category 1B

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

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

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

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.