

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	PUREFILL FLOW & PUREFILL LIGHT FLOW
Type of product	Light-cure Flowable Composite
Product reference	PURF-4* & PURL4* (* VITA Shade available)

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

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 - 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
--------	-----------------------

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	Aquatic Chronic 2, H411
STOT SE 3:	H335	Aquatic Acute 1, H400
Skin irrit. 2:	H315	Aquatic Chronic 2, H410
Skin sens. 1B:	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 word

Hazard statement

Warning

H317: May cause an allergic skin reaction

H315: Causes skin irritation.

H319: Causes serious eye irritation

H335: May cause respiratory irritation

H400: Acute toxicity to the aquatic environment, Category 1

H410: Chronic aquatic toxicity, Category 1

H411: Toxic to aquatic life with long lasting effects

Precautionary advices

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 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 : 607-134-00-4 CE : 276-957-5 CAS : 72869-86-4	Urethane dimethacrylate	30-45 %	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 %
Cas : 43048-08-4	Dimethacrylate de tricyclodecane dimethanol	5 -15%	H317: Skin Sens. 1B H400: Acute aquatic toxicity, 1 H410: Chronic aquatic toxicity, 1	≥ 0,1% ≥ 0,1% ≥ 0,1%
CE : 233-814-1 CAS : 10373-78-1	Camphorquinone	< 1 %	H315 : Skin Irrit. 2 H319 : Eye Irrit. 2 H335 : STOT SE 3	≥ 1 % ≥ 1 % ≥ 1 %
CAS: 2440-22-4 EINECS: 219-470-5	2-(2H-benzotriazol-2-yl)-p- cresol	< 0.2%	H317: Skin Sens. 1B H410: Aquatic Chronic 1 H319: Eye Irrit. 2	≥ 0,1% ≥ 0,1% ≥ 1 %
Index : N/A CE : 266-046-0 CAS : 65997-17-3	Barium alumino silicate fillers	50 -70 %	Not classified	-

Note: The full text of H statements and R phrases is listed in section2.2.

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

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 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: Fluid

Color: According to product specification (VITA shades)

Specific Physical Form: Pasty

Odor: Odourless

Odor threshold: No data available

PH: Not determined

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: 1.8-2.0g/cm³
Specific gravity: 1.8 (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:

Explosive properties: Product does not present an explosion hazard

Solvent content:

VOC (EC) 0.0 g/l

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 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:	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	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 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.