

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 CIRUS +
Type of product Light-cure restorative composite
Product reference CIRU+-3* & CIR+-20* (* VITA Shade available)

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

-Identified use(s) Restoration 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) No 1272/2008 (CLP)

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

2.1.3 Additional information

N/A

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: 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

Precautionary advices

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: None

2.3 Other hazards

N/A

3. Composition / Information on ingredients

3.1 Product

EC Designation

Not Applicable

Classification according to Regulation

Class IIa

(EU) MDR 2017/745

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 hazard H and R-phrases is specified in section 2.2.

4. First aid measures

4.1 Description of first aid measures

Inhalation: N/A

Skin contact: Remove contaminated clothing. Wash skin with soap and water. In case of allergic reaction, seek for medical advice.

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

Ingestion: Seek for medical advice.

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

N/A

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. Wash hands with soap and water in case of accidental contact with eyes.

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

Avoid contact with skin and eyes. For use in dentistry only. Wear latex or nitrile gloves. Replace cap immediately after use. Wash hands with soap and water if contact occurs.

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

Usual hygienic measures for dental practice. Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin. Keep away from foodstuffs, beverages and feed. Wash with soap and water in case on contact.

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

N/A

9. Physical & Chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state: Paste. **Color:** Tooth-like color (VITA shades).

Specific Physical Form:	Not applicable.	Flammability Limits (UEL):	Not applicable.
Odor:	Ester-like.	Vapor Pressure:	Not applicable.
Odor threshold:	No data available.	Vapor density (air = 1):	Not applicable.
PH:	Not applicable.	Density: 1.9g/cm³Specific gravity:	1.9 (Ref Std: Water=1).
Boiling point:	Not applicable.	Solubility in water:	Negligible.
Melting point:	No data available.	Solubility-non-water:	No data available.
Flash point:	No flash point.	Reactivity in water:	Not applicable.
Evaporation rate:	Not applicable.	Partition coefficient: n-octanol/water:	No data available.
Flammability (solid, gas):	Not classified.	Decomposition temperature:	No data available.
Flammability Limits (LEL):	Not applicable.	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

13.1 Waste treatment methods

Large quantities: Disposal must be made according to local, state and federal regulations. Do not pour down the drain.
Small quantities: Dispose normally after polymerization.

13.2 Uncleaned packaging

Disposal must be in accordance to all European, federal, national and local directives.

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

Not defined

15.2 Chemical Safety Assessment

Not defined

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.