

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	HEALBOND UNIVERSAL
Type of product	Dental adhesive system
Product No	BMP-5

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

Identified use(s)	One components, self-etching, light cure universal adhesive system
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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) No 1272/2008 (CLP):**

Liq. inflam. 2:	H225	Irrit. Cut. 2:	H315
Irrit oc. 2:	H319	Sens cut. 1:	H317
STOT SE 3:	H335		

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

GHS02



GHS07

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 effectsPrecautionary 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.

3. Composition / Information on ingredients

3.1 Substances/mixtures

EC Designation: Not applicable.
 Classification according to Regulation (EU) MDR 2017/745: Class IIa

3.2 General information

Index CE CAS	Chemical name	Mass	Classification according to Regulation (EC) No 1272/2008 (CLP)	Generic threshold value
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	Camphorquinone	< 1 %	H315 : Skin Irrit. 2 H319 : Eye Irrit. 2 H335 : STOT SE 3	≥ 1 % ≥ 1 % ≥ 1 %
CAS : 85590-00-7	Phosphate methacrylate	10-20%	H315: Skin irrit 2 H319: Eyes irrit 2 H335: STOT SE 3	≥ 1 % ≥ 1 % ≥ 1 %
Index : 603-002-00-5 CE : 200-578-6 CAS : 64-17-5	Ethanol	10-30%	H225: Liq. Inflam. 2	≥ 1 %

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

General information: Immediately remove any clothing soiled by the product and consult a physician if symptoms appear which may be caused by the product.
Inhalation: Supply fresh air and to be sure call for a doctor. In case of unconsciousness place patient stably inside position for transportation.
Ingestion: Get medical advice / attention.
Skin contact: Immediately wash with water and soap and rinse thoroughly.
Eye contact: Rinse eyes for several minutes under running water and consult a physician.
Other measure: Remove all contaminated clothes (large quantity).

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

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: CO₂, powder, or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire extinguishing methods suitable to surrounding conditions.
Auto-ignition temperature: Product is not self-igniting.
Explosive Limit in air: Product does not present an explosion hazard.
Flammability: Highly flammable liquid and vapor.
Unsuitable extinguishing media: Water with full jet.

Flash point: Not determined.
Fusion point: Not determined.

5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.
No further relevant information available.

5.3 Tips for firefighters

Protective equipment: Wear self-contained respiratory protective device.

Additional information

Dispose of fire debris and contaminated firefighting water in accordance with official regulations.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Do not inhale vapors / aerosols.
Avoid contact with the substance.
Provide fresh air in enclosed spaces.

6.2 Environmental precautions

Do not allow to enter water / groundwater drains / surface.

6.3 Methods and materials for containment and cleaning up

Absorb with a liquid binder.
Clean contaminated area.

6.4 References to other sections

Refer to Section 8 for Personal protection.
Refer to Section 13 for disposal conditions.

7. Handling and Storage

7.1 Precautions for safe handling

This product is for dental professionals only.
Use according to good professional dental practice.
Observe precautions usually used when handling chemicals.

Information on fire and explosion protection: Keep away from heat and fire.
Arrange to avoid electrostatic charge.

7.2 Conditions for safe storage, including any incompatibilities

Store in a dry place at a storage temperature between 2 to 8 °C.
Keep well closed.

Storage and packaging requirements: Keep only in the original container.
Store away from foodstuffs.
Do not store near a source of heat or flame.

7.3 Specific end uses: 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:

No CAS	Name	Technique	Value in mg/m3 (ppm)
64-17-5	Ethanol	TRGS900	500 ou 960

8.2 Equipment

Respiratory Protection & Ventilation: Necessary when aerosols.

Not required under normal conditions of use (small quantities).

Personal protective equipment: Wear goggles, mask, gloves and blouse.
Keep away from food and drink.
Avoid contact with eyes or skin.

9. Physical & Chemical properties

9.1 Information sur les propriétés physiques et chimique essentielles

Appearance

Physical state	Liquid.
Color	Yellow.
Specific Physical Form	Not applicable.

Other properties

Odor	Ester-like odor.
Odor threshold	No data available.
pH	2.5-3.5
Boiling point	Not determined.
Melting point	Not determined.
Flash point	Not determined.
Evaporation rate	Not determined.
Flammability (solid, gas)	Not applicable.
Flammability Limits (LEL)	Not applicable.
Flammability Limits (UEL)	Not applicable.
Vapor Pressure	Not determined.
Vapor density (air = 1)	Not determined.
Density	1.1 g/cm ³
Specific gravity	Not determined.
Solubility in water	Not miscible.
Solubility-non-water	Not determined.
Reactivity in water	Not determined.
Partition coefficient: n-octanol/water	Not determined.
Decomposition temperature	Not determined.
Autoignition Temperature	Not self-igniting.

9.2 Other information

Information about physical hazard classes

Explosives Product does not present an explosion hazard.

10. Stability & reactivity

10.1 Reactivity:	No further relevant information available.
10.2 Chemical stability:	Stable under storage conditions.
10.3 Possibility of hazardous reactions:	No dangerous reactions known.
10.4 Conditions to avoid:	Heat, direct sunlight and radicals.
10.5 Incompatible materials:	Alkali metals, hybrids, strong oxidizing agents, radical initiators.
10.6 Hazardous decomposition products:	Carbon monoxide and carbon dioxide.
10.7 Uncontrolled polymerization:	No polymerization if used according to specifications.

11. Toxicological information

11.1 Information on toxicological effects	
Acute toxicity:	Ethanol), LD50 (oral, rat) = 6200 mg / kg.
Primary irritation:	Skin, eyes.
Sensitization:	No information available.
Symptoms related to physicochemical and toxicological properties:	Not applicable.
Deferred and immediate effects and chronic effects of short-term exposure:	Allergic reactions to methacrylate products after long-term exposure are possible. 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.
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:	Water hazard classification: WGK = 1 (Slightly polluting substance).
12.2 Persistence and degradability:	No further relevant information available.
12.3 Bio accumulative potential:	No further relevant information available.
12.4 Mobility in soil:	No information available.
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

14. Transport information

For 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.

Land transport ADR / RID and GGVS / GGVE (Germany): UN 1170 ETHANOL, 3, II

Maritime transport IMDG: 1170 ETHANOL, 3, II EMS F-E S-D

Air transport ICAO-TI and IATA-DGR: UN 1170 ETHANOL, 3, II

15. Regulation**15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture:**

Class IIa medical device according to Directive 93/42 / EEC.

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.