

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 MAX/Adhesive**
Type of product Universal dental adhesive system/adhesive.
Product No BMX-10

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

Identified use(s) 2 component universal dental adhesive system.

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

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):

Irrit oc. 2: H319 Sens cut. 1: H317
STOT SE 3: H335 Aquatic Chronic 2: H411
Irrit. Cut. 2: H315

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

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.

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 %
Index : N/A CE: 266-046-0 CAS : 65997-17-3	Barium alumino silicate	5-20%	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

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, patients 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: Non applicable.

Flammability: Non-Flammable.

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

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

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.

Avoid contact with skin and eyes. Do not swallow. Avoid generating dust. Do not breathe dust/fume/gas/mist/vapors/spray.

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 2 to 8 °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: 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 on basic physical and chemical properties

Appearance

Physical state Liquid.

Color Yellow opaque.

Specific Physical Form Not applicable.

Other properties

Odor Odorless.

Odor threshold No data available.

pH	Neutral.
Boiling point	Not determined.
Melting point	Not determined.
Flash point	Not determined.
Evaporation rate	Not determined.
Flammability (solid, gas)	Not determined.
Flammability Limits (LEL)	Not determined.
Flammability Limits (UEL)	Not determined.
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

No important information available.

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:	No information available.
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.
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:	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 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.