

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/Primer
Type of product	Universal dental adhesive system/Primer.
Product No	BMX-10

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

Identified use(s)	2 components universal dental adhesive system (Primer + Adhesive).
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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

Call 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):**

- | | | |
|---|-----------------|------|
| 2 | Liq. inflam. 2: | H225 |
| 3 | Irrit oc. 2: | H319 |
| 4 | STOT SE 3: | H335 |
| 5 | Irrit. Cut. 2: | H315 |
| 6 | Sens cut. 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.

6.1 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

Pictogram

GHS07



SGH02



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**H361fd:** Suspected of damaging fertility. Suspected of damaging the unborn child.**H302:** Harmful if swallowed.**H370:** Causes damage to organs: Nervous system**H373:** May cause damage to organs through prolonged or repeated exposure: Liver Lung**H400:** Very toxic to aquatic life.**H410:** Very 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 regulationsAdditional information on hazards: Not Applicable.

6.2 Other hazards

According to the criteria of the REACH decree, this mixture contains no substance of PBT or PpP.

3. Composition / Information on ingredients

3.1 Substances/mixtures

EC Designation:

Not applicable.

Classification according to Directive 93/42 / EEC:

Class IIa

3.2 General information

Index CE CAS	Nom chimique	Masse	Classification selon le règlement(CE) N° 1272/2008 (CLP)	Valeur seuil générique
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 : 204-881-4 CAS : 128-37-0	2,6-Di-tert-butyl-4- methylphenol	<0.2 %	H302: Acute Tox. 4 H315: Skin Irrit. 2 H319: Eye Irrit. 2 H361fd: Repr. 2 H370: STOT SE 1 H373: STOT RE 2 H400: Aquatic Acute 1 H410: Aquatic Chronic 1	≥ 1 % ≥ 1 % ≥ 1 % ≥ 0.1 % ≥ 1 % ≥ 1 % ≥ 0.1 % ≥ 0.1 %
CAS : 85590-00-7	Phosphate methacrylate	10-30%	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	40-60 %	H225 : Liq. Inflam. 2	≥ 1 %

Note: The full text of H statements and R phrases is listed in section 16.

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 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.
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
128-37-0	BHT	-	Dermal DNEL dermal 0.5 mg/kg bw/day (man) Inhalative DNEL inhalation 3.5 mg/m3 (man)

8.2 Equipment

Respiratory Protection & Ventilation: Necessary when aerosols.
Not required under normal conditions of use.

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 chimiques essentielles****Appearance**

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

Other properties

Odor Ester-like odor.
Odor threshold No data available.
pH 2-3
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/cm³.
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
Autoignition TemperatureNot determined.
Product is 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. BHT , orl-rat LD50:890 mg/kg skn-rat LD50:>2000 mg/kg ivn-mus LD50:180 mg/kg ipr-mus LD50:138 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.
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:	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 laws.**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**

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Abbreviations and acronyms:

N 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
 Repr. 2: Suspected of damaging fertility. Suspected of damaging the unborn child.
 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.