

Revision date: 14-09-2020

Material Safety data Sheet

(REACH Regulation No. 1907/2006 and CLP Regulation No. 1272/2008)

1. Identification du mélange et de l'entreprise

1.1 Product identifier

Product name: Healbond Max
Type of product Dental adhesives
Product No: BMX-10

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

Adhesives amelo-dentin, bi-component.

1.3 Details of the supplier of the safety data sheet:

Name: G-PHARMA

Address: 35, avenue du Gros Chêne - ZI des Bellevues

BP 50072 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: + 33 (0)1 45 42 59 59

2. Identification des dangers

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):

STOT SE 3: H335

2.1.2 Classification according to Directive 67/548 / EEC:

F: R11, Xi: R36, R37, R38, R43: Sens. cut.

2.1.3 Additional Information

The full wording of the hazard classes and categories, hazard statements H and R phrases is mentioned in section 16

2.2 Label elements

Labeling in accordance with Regulation (EC) No 1272/2008 (CLP)

Pictogram SGH02 SGH07





<u>Signal word</u> Attention

<u>Hazard statement</u> **H317**: May cause skin allergy

H225: Highly flammable liquid and vapor.

H315, H319, and H335: Causes skin irritation, severe eye irritation and may irritate the

respiratory tract.

Precautionary advices P260: Do not breathe dust / fume / gas / mist / vapors / spray,

P271: Use only outdoors or in a well-ventilated area

P280: Wear protective gloves / protective clothing / equipment, eye / face protection.

P314: Consult a physician if you feel unwell.

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

vPvP.



Healbond Max Revision date: 14-09-2020

3. Information sur les composants du mélange

3.1 Substances/mixtures

EC Designation: Not Applicable Classification according to Directive 93/42 / EEC: Class IIa

3.2 General information

Index CE CAS	Chemical name	% mass	Classification according to Directive 67/548 / EEC (DPD)	Classification according to Regulation (EC) No 1272/2008 (CLP)	Generic threshold value
Index : 607-134-00-4 CE : N/A CAS : N/A	Methacrylates	20-30	Xi : R36/37/38	H315 : irrit. Cut 2 H319: Irrit. Oc. 2 H335: STOT SE 3	≥ 1%
Index : 603-002-00-5 CE : 200-578-6 CAS : 64-17-5	Ethanol	40-60	F:R11	H225 : Liq. Inflam. 2	≥ 1%

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

4. Information sur les premiers secours

4.1 Description of first aid measures

General information: Consult a physician if symptoms appear which may be caused by the product.

Inhalation: Fresh air

Ingestion: Get medical advice / attention Skin contact: Wash with soap and water.

Eye contact: Rinse eyes for several minutes under running water and consult a physician.

4.2 Most important symptoms and effects, both acute and delayed: Not applicable

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. Mesures à prendre en cas d'incendie

5.1 Extinguishing media

CO2, Powder, Water spray

Use the proper method and means to control the fire.

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

5.3 Tips for firefighters

Wear self-contained breathing apparatus

6. Mesure à prendre en cas de dispersions accidentels

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. Manipulation et Stockage



Revision date: 14-09-2020

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.

<u>Information on fire and explosion protection:</u>

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.

7.3 Specific end uses:

Pas de renseignements importants disponibles.

8. Contrôle de l'exposition des travailleurs et protection individuelle

8.1 Control parameters

Composants avec des valeurs limites à surveiller dans l'espace de travail:

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

8.2 Equipement

Respiratory Protection & Ventilation:

Necessary, when aerosols.

Not required under normal conditions of use.

Personal protective equipment:

Precautionary measures are those normally observed when handling chemicals.

Keep away from food and drink. Avoid contact with eyes or skin.

Hand protection. Protective gloves. Eye protection: Safety glasses.

9. Propriétés physiques et chimiques

9.1 Information sur les propriétés physiques et chimique essentielles

Part 1 Part 2 Physical state: Liquid

Colours Incolore Odor Caractéristic

78°C Melting point

Not applicable Fusion point

Flash point 12°C

Flammability Yes

Ignition temperature 425°C

Solubility with organic solvents Ethanol

ca. 1.0 g/cm3 Not applicable Relative Density Apparent density ca. 0.8 g/cm3 neutre

PΗ ca. 3

Solubility in water soluble

3.5 % (Kühn-Birett) Lower Explosive limit Not applicable Upper explosion limit Not applicable 15 %

9.2 Other information

None

10. Stabilité et réactivité du produit

10.1 Reactivity: Not applicable

10.2 Chemical stability: Stable under storage conditions

10.3 Possibility of hazardous reactions: None 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: Not applicable.



Revision date: 14-09-2020

11. Informations toxicologiques

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 methacrylates 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. Informations écologiques

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:Not applicable12.3 Bioaccumulative potential:Not applicable12.4 Mobility in soil:None information12.5 Results of PBT and vPvB assessment:Not applicable12.6 Other adverse effects:Not applicable

13. Considérations relatives à l'élimination

13.1 Waste treatment methods

Product: Landfill or appropriate incineration is recommended in accordance with local, state,

and federal regulations.

Uncleaned packaging: Disposal must be made according to official regulations.

14. Informations relatives au transport

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. Informations relatives à la réglementation

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. Autres informations

N / A: Not applicable

LD50: Lethal Dose 50

STOT SE 3: Specific target organ toxicity - single exposure hazard class 3

Potential Hazard Symbol:

F: Flammable

Xi: irritant,

Risk Phrases R

R11: Harmful: danger of serious damage to health by prolonged exposure through inhalation

R36: Irritating to eyes.

R37: Irritating to respiratory system.

R38: Irritating to skin.

Hazard statements H

H225: Highly flammable liquid and vapor. H315, cat.2: H315 Causes skin irritation.



Revision date: 14-09-2020

H335: May cause respiratory irritation. H319: Causes serious eye irritation.

Precautionary advice (s) P

P260: Do not breathe dust / fume / gas / mist / vapors / spray,

P271: Use only outdoors or in a well-ventilated place,

P280: Wear protective gloves / protective clothing / equipment, eye / face protection,

P314: Consult a doctor if you feel unwell.

Some of the information presented above and the resulting conclusions may be from different sources of information directly derived from the tests performed on the product itself.

This information, used in this document, has been obtained from sources that we believe are credible (Example: Article 9 of Regulation (EC) 1272/2008). Moreover, this information is given without any implicit or explicit guarantee as to their evaluation. Conditions or methods of use, handling, storage and disposal are beyond our control and these operations may also be performed without prior consultation with G-PHARMA.

For these reasons, we assume no liability and disclaim any legal liability for any damages, losses or expenses that may arise before, during or after handling, storing, using or disposing of the product.

If the product is used as an ingredient in the manufacture of another product, or if it is used without following the recommendations given by G-PHARMA, the information contained in this MSDS may be inadequate: The user should study the recommendations for the product and decide for itself whether the intended use context is appropriate.