

Safety Data Sheet
in accordance with HSNO

Printing date 11.12.2019


Version number 8

Revision: 11.12.2019

1 Identification of the substance or mixture and of the supplier

- **Product identifier**
- **Trade name:** ***Heliobond***
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Light-curing primer agent
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent AG
Bendererstrasse 2
9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN
Tel: +423 235 35 35 / Fax: +423 235 33 60
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- **Importer:**
Ivoclar Vivadent Ltd
12 Omega St, Rosedale, Auckland
New Zealand
Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclarvivadent.com
- **Emergency telephone number:** 0800 764 766 (National Poison Centre - 24 hours / 7 days)

2 Hazards identification

- **Classification of the substance or mixture**
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2A H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
STOT SE 3 H335 May cause respiratory irritation.
- **Label elements**
- **GHS label elements**
The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**
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GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
Bis-GMA
triethylene glycol dimethacrylate
- **Hazard statements**
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
May cause respiratory irritation.

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- **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If skin irritation or rash occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Wash contaminated clothing before reuse.

- **Additional information:**

Medical devices as defined in Directive 93/42/EEC 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.

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

3 Composition/Information on ingredients

- **Chemical characterisation: Mixtures**

- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 36425-15-7	Bis-GMA	50-100%
NLP: 500-089-0	Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Skin Sens. 1, H317	
CAS: 109-16-0	triethylene glycol dimethacrylate	25-50%
EINECS: 203-652-6	Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Skin Sens. 1, H317; STOT SE 3, H335	

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- **Description of first aid measures**

- **After inhalation:**

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

- **After skin contact:** Immediately rinse with water.

- **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- **After swallowing:** If symptoms persist consult doctor.

- **Information for doctor:**

- **Most important symptoms and effects, both acute and delayed** No further relevant information available.

- **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

5 Fire fighting measures

- **Extinguishing media**

- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.

- **Special hazards arising from the substance or mixture** No further relevant information available.

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- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Protect from exposure to the light.
Keep container tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Usual hygienic measures for dental practice and dental laboratories.
Wash hands before breaks and at the end of work.
Do not inhale gases / fumes / aerosols.
Avoid contact with the eyes and skin.
Keep away from foodstuffs, beverages and feed.
- **Respiratory protection:** Not required.

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· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Not suitable are gloves made of the following materials:**

Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

· **Eye protection:** Safety glasses

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· Form:	Fluid
· Colour:	Yellowish
· Odour:	Characteristic
· Odour threshold:	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· Melting point/freezing point:	Undetermined.
· Initial boiling point and boiling range:	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gas):** Not applicable.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

· **Explosion limits:**

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapour pressure:** Not determined.

· Density at 20 °C:	1.14 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.

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| · Solubility in / Miscibility with water: | <i>Not miscible or difficult to mix.</i> |
| · Partition coefficient: n-octanol/water: | <i>Not determined.</i> |
| · Viscosity: | |
| Dynamic: | <i>Not determined.</i> |
| Kinematic: | <i>Not determined.</i> |
| · Other information | <i>No further relevant information available.</i> |

10 Stability and reactivity

- **Reactivity** *No further relevant information available.*
- **Chemical stability**
Stable under normal handling and storage conditions.
Photoreactive (Danger of polymerization).
- **Thermal decomposition / conditions to be avoided:** *No decomposition if used according to specifications.*
- **Possibility of hazardous reactions** *No dangerous reactions known.*
- **Conditions to avoid**
Protect from exposure to the light.
Keep away from heat and direct sunlight.
- **Incompatible materials:** *No further relevant information available.*
- **Hazardous decomposition products:** *None under normal conditions of storage and use.*

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity**
- **Skin corrosion/irritation** *Irritant to skin and mucous membranes.*
- **Serious eye damage/irritation** *Irritating effect.*
- **Respiratory or skin sensitisation** *Sensitisation possible through skin contact.*
- **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Irritant

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** *No further relevant information available.*
- **Persistence and degradability** *No further relevant information available.*
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** *No further relevant information available.*
- **Mobility in soil** *No further relevant information available.*
- **Additional ecological information:**
- **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

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· **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|---|--|
| · UN-Number | Void |
| · ADR/RID/ADN, ADN, IMDG, IATA | Void |
| · UN proper shipping name | Void |
| · ADR/RID/ADN, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | Void |
| · ADR/RID/ADN, ADN, IMDG, IATA | Void |
| · Class | Void |
| · Packing group | Void |
| · ADR/RID/ADN, IMDG, IATA | Void |
| · Environmental hazards: | No |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · Transport/Additional information: | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · UN "Model Regulation": | Void |

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**· **New Zealand Inventory of Chemicals**

All ingredients are listed.

· **HSNO Approval numbers**

CAS: 109-16-0 | triethylene glycol dimethacrylate

HSR003763

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**

GHS07

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- **Signal word** *Warning*
- **Hazard-determining components of labelling:**
Bis-GMA
triethylene glycol dimethacrylate
- **Hazard statements**
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
May cause respiratory irritation.
- **Precautionary statements**
Wear protective gloves/protective clothing/eye protection/face protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
Wash contaminated clothing before reuse.
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** *None of the ingredients is listed.*
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to the Directive 93/42/EEC.
- **Chemical safety assessment:** *A Chemical Safety Assessment has not been carried out.*

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
- **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
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)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
Skin Sens. 1: Skin sensitisation – Category 1
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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