Safety data sheet
according to 1907/2006/EC, Article 31

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

· **1.1 Product identifier**

· **Trade name: Heliobond**

· **1.2 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

· **1.3 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

· **Further information obtainable from:**
Regulatory Affairs
sds@ivoclar.com
· **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

*
SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**
Skin Sens. 1 H317 May cause an allergic skin reaction.
Repr. 1B H360 May damage fertility or the unborn child.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Danger

· **Hazard-determining components of labelling:**
triethylene glycol dimethacrylate
ethyl p-dimethylaminobenzoate
· **Hazard statements**
H317 May cause an allergic skin reaction.
H360 May damage fertility or the unborn child.
· **Precautionary statements**
P201 Obtain special instructions before use.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves / eye protection / face protection.
P302+P352 IF ON SKIN: Wash with plenty of water.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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· **Additional information:**
Medical devices as defined in Regulation (EU) 2017/745 (MDR) 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 (GB CLP/GHS) if they are in the finished state and intented for the final user.
· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

*
SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**
· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**			
CAS: 36425-15-7 NLP: 500-089-0 Reg.nr.: 01-2119485287-26	Bis-GMA		50-100%
CAS: 109-16-0 EINECS: 203-652-6 Reg.nr.: 01-2119969287-21-XXXX	triethylene glycol dimethacrylate	Skin Sens. 1, H317	25-50%

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

*
SECTION 4: First aid measures

· **4.1 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. Then consult a doctor.
· **After swallowing:** If symptoms persist consult doctor.
· **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**
No further relevant information available.

SECTION 5: Firefighting measures

· **5.1 Extinguishing media**
· **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
· **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
· **5.3 Advice for firefighters**
· **Protective equipment:** No special measures required.

*
SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
· **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.

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· **6.4 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.

SECTION 7: Handling and storage

· **7.1 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.

· **7.2 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.
· **7.3 Specific end use(s)** No further relevant information available.

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SECTION 8: Exposure controls/personal protection

· **8.1 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.

· **8.2 Exposure controls**
· **Appropriate engineering controls** No further data; see section 7.
· **Individual protection measures, such as personal protective equipment**
· **General protective and hygienic measures:**
Usual hygienic measures for dental practice and dental laboratories.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Do not inhale gases / fumes / aerosols.
· **Respiratory protection:** Not required.
· **Hand protection**



Protective gloves (EN 374)

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

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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/face protection** Safety glasses

*
SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Colour:**	Yellowish
· **Odour:**	Characteristic
· **Odour threshold:**	Not determined.
· **Melting point/freezing point:**	Undetermined.
· **Boiling point or initial boiling point and boiling range**	Undetermined.
· **Flammability**	Not applicable.
· **Lower and upper explosion limit**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Flash point:**	Not applicable.
· **pH**	Not determined.
· **Viscosity:**	
· **Kinematic viscosity**	Not determined.
· **Dynamic:**	Not determined.
· **Solubility**	
· **water:**	Not miscible or difficult to mix.
· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Vapour pressure:**	Not determined.
· **Density and/or relative density**	
· **Density at 20 °C:**	1.14 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.

· **9.2 Other information**	
· **Appearance:**	
· **Form:**	Fluid
· **Important information on protection of health and environment, and on safety.**	
· **Ignition temperature:**	Product is not selfigniting.
· **Explosive properties:**	Product does not present an explosion hazard.
· **Solvent content:**	
· **Solids content:**	0.0 %
· **Change in condition**	
· **Evaporation rate**	Not determined.

· **Information with regard to physical hazard classes**	
· **Explosives**	Void
· **Flammable gases**	Void
· **Aerosols**	Void
· **Oxidising gases**	Void
· **Gases under pressure**	Void
· **Flammable liquids**	Void

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· **Flammable solids**	Void
· **Self-reactive substances and mixtures**	Void
· **Pyrophoric liquids**	Void
· **Pyrophoric solids**	Void
· **Self-heating substances and mixtures**	Void
· **Substances and mixtures, which emit flammable gases in contact with water**	Void
· **Oxidising liquids**	Void
· **Oxidising solids**	Void
· **Organic peroxides**	Void
· **Corrosive to metals**	Void
· **Desensitised explosives**	Void

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **10.2 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.
· **10.3 Possibility of hazardous reactions** No dangerous reactions known.
· **10.4 Conditions to avoid**
Protect from exposure to the light.
Keep away from heat and direct sunlight.
· **10.5 Incompatible materials:** No further relevant information available.
· **10.6 Hazardous decomposition products:** None under normal conditions of storage and use.

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SECTION 11: Toxicological information

· **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
· **Acute toxicity** Based on available data, the classification criteria are not met.
· **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
· **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
· **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
· **Carcinogenicity** Based on available data, the classification criteria are not met.
· **Reproductive toxicity**
May damage fertility or the unborn child.
· **STOT-single exposure** Based on available data, the classification criteria are not met.
· **STOT-repeated exposure** Based on available data, the classification criteria are not met.
· **Aspiration hazard** Based on available data, the classification criteria are not met.
· **11.2 Information on other hazards**

· **Endocrine disrupting properties**
None of the ingredients is listed.

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SECTION 12: Ecological information

· **12.1 Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **12.2 Persistence and degradability** No further relevant information available.

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· **12.3 Bioaccumulative potential** No further relevant information available.
· **12.4 Mobility in soil** No further relevant information available.
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
· **12.7 Other adverse effects**
· **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.

SECTION 13: Disposal considerations

· **13.1 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.

SECTION 14: Transport information

· **14.1 UN number or ID number** · **ADR/RID/ADN, ADN, IMDG, IATA**	Void
· **14.2 UN proper shipping name** · **ADR/RID/ADN, ADN, IMDG, IATA**	Void
· **14.3 Transport hazard class(es)** · **ADR/RID/ADN, ADN, IMDG, IATA** · **Class**	Void
· **14.4 Packing group** · **ADR/RID/ADN, IMDG, IATA**	Void
· **14.5 Environmental hazards:** · **Marine pollutant:**	No
· **14.6 Special precautions for user**	Not applicable.
· **14.7 Maritime transport in bulk according to IMO instruments**	Not applicable.
· **Transport/Additional information:**	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· **UN "Model Regulation":**	Void

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SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **National regulations:**
· **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).
· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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SECTION 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**
H317 May cause an allergic skin reaction.
· **Classification according to Regulation (EC) No 1272/2008**
The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.
· **Abbreviations and acronyms:**
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
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)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Skin Sens. 1: Skin sensitisation – Category 1
Repr. 1B: Reproductive toxicity – Category 1B
· *** Data compared to the previous version altered.**