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

*Printing date 25.03.2019* *Version number 7* *Revision: 24.01.2019*

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

· **1.1 Product identifier**

· **Trade name:** **Tetric EvoCeram**

· **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 resin-based dental restorative material*

· **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@ivoclarvivadent.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 Irrit. 2 H315 Causes skin irritation.*

*Eye Irrit. 2 H319 Causes serious eye irritation.*

*Skin Sens. 1 H317 May cause an allergic skin reaction.*

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

· **Hazard pictograms**

GHS07

· **Signal word** *Warning*

· **Hazard-determining components of labelling:**
*urethane dimethacrylate*
*Bis-GMA*
· **Hazard statements**
*H315 Causes skin irritation.*
*H319 Causes serious eye irritation.*
*H317 May cause an allergic skin reaction.*
· **Precautionary statements**

| | |
|---|---|
| *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.* |
| *P321* | *Specific treatment (see on this label).* |

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P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **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.

· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

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## SECTION 3: Composition/information on ingredients

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

· **Dangerous components:**

| | | |
|---|---|---|
| CAS: 72869-86-4<br>EINECS: 276-957-5 | urethane dimethacrylate<br>Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412 | ≥2.5-<10% |
| CAS: 36425-15-7<br>NLP: 500-089-0 | Bis-GMA<br>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 | ≥2.5-<10% |
| CAS: 13760-80-0<br>EINECS: 237-354-2 | ytterbium trifluoride<br>Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 | ≥2.5-<10% |
| CAS: 41637-38-1 | ethyoxylated bisphenol A dimethacrylate<br>Aquatic Chronic 4, H413 | 2.5-10% |

· **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:** 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.
· **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:**
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

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· **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** *Not required.*
· **6.2 Environmental precautions:** *Do not allow to enter sewers/ surface or ground water.*
· **6.3 Methods and material for containment and cleaning up:** *Pick up mechanically.*
· **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.*
· **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.*
*Protect from heat and direct sunlight.*
*Keep container tightly sealed.*
· **7.3 Specific end use(s)** *No further relevant information available.*

* 

## SECTION 8: Exposure controls/personal protection

· **Additional information about design of technical facilities:** *No further data; see item 7.*

· **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**
· **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.*
*Avoid contact with the eyes and skin.*
*Keep away from foodstuffs, beverages and feed.*
· **Respiratory protection:** *Not required.*
· **Protection of hands:**

*Protective gloves*

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*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*

## SECTION 9: Physical and chemical properties

| | |
|---|---|
| · **9.1 Information on basic physical and chemical properties** | |
| · **General Information** | |
| · **Appearance:** | |
| **Form:** | *Pasty* |
| **Colour:** | *According to product specification* |
| · **Odour:** | *Characteristic* |
| · **Odour threshold:** | *Not determined.* |
| · **pH-value:** | *Not applicable.* |
| · **Change in condition** | |
| **Melting point/freezing point:** | *Undetermined.* |
| **Initial boiling point and boiling range:** | *Undetermined.* |
| · **Flash point:** | *Not applicable.* |
| · **Flammability (solid, gas):** | *Not determined.* |
| · **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 applicable.* |
| · **Density at 20 °C:** | *2.1 g/cm³* |
| · **Relative density** | *Not determined.* |
| · **Vapour density** | *Not applicable.* |
| · **Evaporation rate** | *Not applicable.* |
| · **Solubility in / Miscibility with water:** | *Nearly insoluble.* |
| · **Partition coefficient: n-octanol/water:** | *Not determined.* |
| · **Viscosity:** | |
| **Dynamic:** | *Not applicable.* |
| **Kinematic:** | *Not applicable.* |

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· **9.2 Other information** *No further relevant information available.*

## 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**
*Keep away from heat and direct sunlight.*
*Protect from exposure to the light.*
· **10.5 Incompatible materials:** *No further relevant information available.*
· **10.6 Hazardous decomposition products:** *None under normal conditions of storage and use.*

* 

## SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity** *Based on available data, the classification criteria are not met.*
· **Skin corrosion/irritation**
*Causes skin irritation.*
· **Serious eye damage/irritation**
*Causes serious eye irritation.*
· **Respiratory or skin sensitisation**
*May cause an allergic skin reaction.*
· **Additional toxicological information:** *No further relevant information available.*
· **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** *Based on available data, the classification criteria are not met.*
· **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.*

## SECTION 12: Ecological information

· **12.1 Toxicity**
· **Aquatic toxicity:** *No further relevant information available.*
· **12.2 Persistence and degradability** *No further relevant information available.*
· **12.3 Bioaccumulative potential** *No further relevant information available.*
· **12.4 Mobility in soil** *No further relevant information available.*
· **Additional ecological information:**
· **General notes:**
*Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water*
*Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.*
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** *Not applicable.*
· **vPvB:** *Not applicable.*

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

## 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**<br>· **ADR/RID/ADN, ADN, IMDG, IATA** | *Void* |
| · **14.2 UN proper shipping name**<br>· **ADR/RID/ADN, ADN, IMDG, IATA** | *Void* |
| · **14.3 Transport hazard class(es)**<br>· **ADR/RID/ADN, ADN, IMDG, IATA**<br>· **Class** | *Void* |
| · **14.4 Packing group**<br>· **ADR/RID/ADN, IMDG, IATA** | *Void* |
| · **14.5 Environmental hazards:**<br>· **Marine pollutant:** | *No* |
| · **14.6 Special precautions for user** | *Not applicable.* |
| · **14.7 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* |

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## SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **REGULATION (EC) No 1907/2006 ANNEX XVII** *Conditions of restriction: 3*

· **National regulations:**
· **Other regulations, limitations and prohibitive regulations**
*The product is a medical device according to the Directive 93/42/EEC.*
· **15.2 Chemical safety assessment:** *A Chemical Safety Assessment has not been carried out.*

* 

## 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**
*H315 Causes skin irritation.*

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*H317 May cause an allergic skin reaction.*
*H319 Causes serious eye irritation.*
*H335 May cause respiratory irritation.*
*H412 Harmful to aquatic life with long lasting effects.*
*H413 May cause long lasting harmful effects to aquatic life.*

· **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*
*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 Irrit. 2: Skin corrosion/irritation – Category 2*
*Eye Irrit. 2: Serious eye damage/eye irritation – Category 2*
*Skin Sens. 1: Skin sensitisation – Category 1*
*STOT SE 3: Specific target organ toxicity (single exposure) – Category 3*
*Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3*
*Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4*

· **** Data compared to the previous version altered.***