



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

- **Product identifier**
- **Trade name:** **Tetric Ceram HB**
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation**
High-viscosity light-curing resin-based dental restorative material
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
*Ivoclar Vivadent AG
Bendererstrasse 2
FL-9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN*
-
- Tel: +423 235 35 35
Fax: +423 235 33 60*
- **Further information obtainable from:**
*Regulatory Affairs
msds@ivoclarvivadent.com*
- **Emergency telephone number:** +423 / 235 33 13

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
 *Xi; Sensitising*
R43: May cause sensitisation by skin contact.
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
-
- **Label elements**
- **Labelling according to EU guidelines:**
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 Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.
- **Code letter and hazard designation of product:**
 *Xi Irritant*
- **Hazard-determining components of labelling:**
*urethane dimethacrylate
decamethylene dimethacrylate*
- **Risk phrases:**
43 May cause sensitisation by skin contact.
- **Safety phrases:**
*24 Avoid contact with skin.
37 Wear suitable gloves.
60 This material and its container must be disposed of as hazardous waste.*
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.

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· **vPvB:** Not applicable.

3 Composition/information on ingredients

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

- **Dangerous components:**

CAS: 1565-94-2	Bis-GMA	☒ Xi R36/38	2.5-10%
CAS: 72869-86-4 EINECS: 276-957-5	urethane dimethacrylate	☒ Xi R36; ☒ Xi R43 R52/53	2.5-10%
CAS: 6701-13-9	decamethylene dimethacrylate	☒ Xi R36; ☒ Xi R43	2.5-10%

- **Additional information:** For the wording of the listed risk 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:** 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 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **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:** Pick up mechanically.
- **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.

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- For use in dentistry only.
- **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.
 - Protect from heat and direct sunlight.
 - 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.
 - Wash hands before breaks and at the end of work.
 - Avoid contact with the skin.
 - Keep away from foodstuffs, beverages and feed.
- **Respiratory protection:** Not required.
- **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.
- **Eye protection:** Safety glasses

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9 Physical and chemical properties

· 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/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not determined.
· Self-igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not applicable.
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with water:	Nearly insoluble.
· Segregation coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Other information	No further relevant information available.

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.

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11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization 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
- **Sensitisation** May cause sensitisation by skin contact.

12 Ecological information

- **Toxicity**
- **Acquatic 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 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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **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

- **Land transport ADR/RID (cross-border)**
- **ADR/RID class:** -
- **Maritime transport IMDG:**
- **IMDG Class:** -
- **Marine pollutant:** No
- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** -

- **Special precautions for user** Not applicable.

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· *Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.*

15 Regulatory information

- *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 the EC-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

R36 Irritating to eyes.

R36/38 Irritating to eyes and skin.

R43 May cause sensitisation by skin contact.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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