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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:** **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.

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

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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.

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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** · **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 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.

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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**
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.***