

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

077126725

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

077126188 077126196 077126204 077126212 077126238 077126246 077126253 077126261 077126279 077126287  
077126295 077126303 077126311 077126329 077126337 077126345 077126352 077126360 077126378 077126386  
077126394 077126402 077126410 077126428 077126436 077126444 077126451 077126550 077126568 077126576  
077126584 077126592 077126600 077126618 077126626 077126634 077126642 077126659 077126667 077126675  
077126683 077126691 077126709 077126717 077126733 077126741 077126758 077126766 077126774 077142516  
077142540 077142557 077142565 077142573 077142599 077142607 077142615 077142623 077142631 077142649  
077142656 077142698 077142706 077142714 077142722 077142730 077142904 077142912 077142920 077142938  
077142946 077142953 077142961 077142979 077142987 077142995 077143001 077143019 077143027 077143035  
077143043 077143050 077143068 077143076 077143084 077143092 077143217 077143241 077143258 077143266  
077143274 077143282 077143290 077143308 077143316 077143324 077143332 077143340 077143357 077143365  
077143373 077143381 077143399 077143407 077143415 077143423 077143431 077143555



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

- **Product identifier**
- **Trade name:** ***Tetric EvoCeram***
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** *Light-curing resin-based dental restorative material*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
*Ivoclar Vivadent Inc.*  
*175 Pineview Drive, Amherst, N.Y. 14228*  
*USA*  
*Tel. +1 800 533 6825*  
*Fax +1 716 691 2285*
- 
- Ivoclar Vivadent Inc.*  
*2785 Skymark Avenue, Unit 1, Mississauga, Ontario L4W4Y3*  
*CANADA*  
*Tel. +1 800 263 8182*  
*Fax +1 905 238 5711*
- **Information department:** *Quality Assurance / Regulatory Affairs*
- **Emergency telephone number:**  
*24 Hour Emergency Assistance:*  
*Emergency-Call USA - Infotrac: 1-800-535-5053*  
*Emergency-Call Canada - Canutec: 1-613-996-6666*
- 
- General MSDS Assistance:*  
*US: 1-800-533-6825*  
*Canada: 1-800-263-8182*


## 2 Composition/information on ingredients

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

- **Dangerous components:**

72869-86-4	urethane dimethacrylate	 H319; H317; H402; H412	2.5-10%
1565-94-2	Bis-GMA	 H315; H319	2.5-10%

## 3 Hazards identification

- **Classification of the substance or mixture**
  - **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**  
 **Irritant**  
*May cause sensitisation by skin contact.*
  - **Classification system:**  
*The classification was made according to the latest editions of international substances lists, and expanded upon from 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.*

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USA

# Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 07/07/2011

Version number 5

Reviewed on 07/07/2011

Trade name: **Tetric EvoCeram**

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· **Code letter and hazard designation of product:**



Irritant

· **Hazard-determining components of labelling:**  
urethane dimethacrylate

· **Risk phrases:**

May cause sensitisation by skin contact.

· **Safety phrases:**

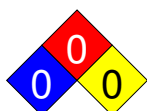
Avoid contact with skin.

Wear suitable gloves.

This material and its container must be disposed of as hazardous waste.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



HEALTH 0 Health = 0

FIRE 0 Fire = 0

REACTIVITY 0 Reactivity = 0

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

## 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:**

CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· **Advice for firefighters**

· **Protective equipment:** No special measures required.

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Trade name: **Tetric EvoCeram**

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### 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.  
For use in dentistry only.
- **Information about protection against explosions and fires:** 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 receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components 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 that were valid during the creation 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 eyes and skin.  
Keep away from foodstuffs, beverages and feed.
- **Breathing equipment:** 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

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**Trade name: Tetric EvoCeram**

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· **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

### 9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

**Form:** Pasty  
**Color:** According to product specification

· **Odor:** 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.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

**Lower:** Not determined.

**Upper:** Not determined.

· **Vapor pressure:** Not applicable.

· **Density at 20°C (68°F):** 2.1 g/cm<sup>3</sup> (17.525 lbs/gal)

· **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).

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Trade name: **Tetric EvoCeram**

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- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid**  
Keep away from heat and direct sunlight.  
Protect from exposure to the light.
- **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:**
- **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 internally approved calculation methods for preparations:  
Irritant

## 12 Ecological information

- **Toxicity**
- **Acquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior 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 (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 packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

## 14 Transport information

- **DOT regulations:**
- **Hazard class:** -

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- **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.
- **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**

- **Sara**

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

- **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

- **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **TLV (Threshold Limit Value established by ACGIH)**

13760-80-0 | ytterbium trifluoride

A4

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

- **Product related hazard informations:**

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/EWG usually if they are in the finished state and intended for the final user.

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**Trade name: Tetric EvoCeram**

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**· Hazard symbols:***Irritant***· Hazard-determining components of labelling:***urethane dimethacrylate***· Risk phrases:***May cause sensitisation by skin contact.***· Safety phrases:***Avoid contact with skin.**Wear suitable gloves.**This material and its container must be disposed of as hazardous waste.***· National regulations:****· Other regulations, limitations and prohibitive regulations***The product is a medical device according to the EC-directive 93/42/EEC.**This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.***· 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.*

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