1 Identification

- **Product identifier**
  - **Trade name:** Tetric EvoCeram

- **Application of the substance / the mixture** 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.
  1-6600 Dixie Road
  Mississauga, Ontario
  L5T 2Y2
  Canada
  Phone: +1 905 670 8499
  Fax: +1 905 670 3102

- **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 SDS Assistance:
    US: 1-800-533-6825
    Canada: 1-800-263-8182

2 Hazard identification

- **Classification of the substance or mixture**
  - Skin Irritation - Category 2  H315  Causes skin irritation.
  - Eye Irritation - Category 2A  H319  Causes serious eye irritation.
  - Skin Sensitizer - Category 1  H317  May cause an allergic skin reaction.

- **Label elements**
  - **GHS label elements**
    The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**
  - GHS07

- **Signal word** Warning

- **Hazard-determining components of labeling:**
  - urethane dimethacrylate
  - Bis-GMA

- **Hazard statements**
  - Causes skin irritation.
  - Causes serious eye irritation.

(Contd. on page 2)
Trade name: Tetric EvoCeram

May cause an allergic skin reaction.

**Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapours/spray.
Wash thoroughly after handling.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
If on skin: Wash with plenty of water.
Specific treatment (see on this label).
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Take off contaminated clothing and wash it before reuse.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
Dispose of contents/container in accordance with local/regional/national/international regulations.

**Additional information:**
Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

**Classification system:**

- **NFPA ratings (scale 0 - 4)**
  - Health = 2
  - Fire = 0
  - Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**
  - Health = 2
  - Fire = 0
  - Reactivity = 0

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**3 Composition/Information on ingredients**

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

  **Dangerous components:**
  - CAS: 72869-86-4 urethane dimethacrylate ≥50-<10% w/w *
  - CAS: 36425-15-7 Bis-GMA 3-7% w/w *
  - CAS: 13760-80-0 ytterbium trifluoride 1-5% w/w *

  * Actual concentration ranges are withheld as a trade secret.

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**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.

(Contd. on page 3)
5 Firefighting measures

- Extinguishing media
  - Suitable extinguishing agents: CO₂, extinguishing 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. 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 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.
  - 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
    - 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

9 Physical and chemical properties

- Information on basic physical and chemical properties
  - General Information
    - Appearance:
      - Form: Pasty
      - Color: According to product specification
      - Odor: Characteristic
      - Odor 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.
### 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**:
  - 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**:
    - **on the skin**: No irritant effect.
    - **on the eye**: Irritating effect.
  - **Sensitization**: Sensitization possible through skin contact.
  - **Additional toxicological information**: No further relevant information available.
- **Carcinogenic categories**
  - **NTP (National Toxicology Program)**: None of the ingredients is listed.

### 12 Ecological information

- **Toxicity**
  - **Aquatic 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.
Trade name: Tetric EvoCeram

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

- UN-Number
  - DOT/TDG, ADR, ADN, IMDG, IATA: Void
- UN proper shipping name
  - DOT/TDG, ADR, ADN, IMDG, IATA: Void
  - ADR: Void
- Transport hazard class(es)
  - DOT, ADR, ADN, IMDG, IATA: Void
  - Class: Void
- Packing group
  - DOT/TDG, ADR, IMDG, IATA: Void
- Environmental hazards:
  - Marine pollutant: No
- Special precautions for user: Not applicable.
- Transport in bulk according to Annex II of MARPOL 73/78 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

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.
Safety Data Sheet
according to HPR, Schedule 1

Printing date 07/22/2019
Version number 8
Reviewed on 06/03/2019

Trade name: Tetric EvoCeram

Section 313 (Specific toxic chemical listings):
None of the ingredients is listed.

TSCA (Toxic Substances Control Act):

<table>
<thead>
<tr>
<th>CAS</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>72869-86-4</td>
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</tr>
<tr>
<td>1565-94-2</td>
<td>Bis-GMA</td>
</tr>
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GHS label elements
The product is classified and labeled according to the Globally Harmonized System (GHS).

Hazard pictograms

GHS07

Signal word Warning

Hazard-determining components of labeling:
urethane dimethacrylate
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Hazard statements
Causes skin irritation.
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Precautionary statements
Avoid breathing dust/fume/gas/mist/vapours/spray.
Wash thoroughly after handling.
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If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
Dispose of contents/container in accordance with local/regional/national/international regulations.

National regulations:

Other regulations, limitations and prohibitive regulations
The product is a medical device according to the 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.

Date of the latest revision of the safety data sheet 07/22/2019 / 7

Abbreviations and acronyms:
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances

(Contd. on page 8)