1 Identification

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

- **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

- **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(s) identification

- **Classification of the substance or mixture**
  - **Skin Irrit. 2 H315** Causes skin irritation.
  - **Eye Irrit. 2A H319** Causes serious eye irritation.
  - **Skin Sens. 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:**
  - Bis-GMA
  - urethane dimethacrylate

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

- **Hazard statements**
  - Causes skin irritation.
  - Causes serious eye irritation.
  - May cause an allergic skin reaction.

- **Precautionary statements**
  - Wear protective gloves/protective clothing/eye protection/face protection.
  - Wash contaminated clothing before reuse.
  - If skin irritation or rash occurs: Get medical advice/attention.
  - If eye irritation persists: Get medical advice/attention.

- **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 = 1
    - Fire = 0
    - Reactivity = 0
  - **HMIS-ratings (scale 0 - 4)**
    - Health = 1
    - Fire = 0
    - Reactivity = 0

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

### 3 Composition/information on ingredients

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

- **Dangerous components:**
  - 1565-94-2 Bis-GMA 2.5-%<10%
  - 72869-86-4 urethane dimethacrylate 2.5-%<10%
  - 13760-80-0 ytterbium trifluoride 2.5-%<10%
  - 41637-38-1 ethyoxylated bisphenol A dimethacrylate 2.5-%<10%

### 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.
Trade name: Tetric EvoCeram Bulk Fill

5 Fire-fighting 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.
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 determined.
- **Change in condition**
  - **Melting point/Melting range:** Undetermined.
  - **Boiling point/Boiling range:** Undetermined.
- **Flash point:** Not applicable.
- **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 determined.
- **Density at 20 °C (68 °F):** 2.064 g/cm³ (17.224 lbs/gal)
Safety Data Sheet
acc. to OSHA HCS

Trade name: Tetric EvoCeram Bulk Fill

- Relative density: Not determined.
- Vapour density: Not determined.
- Evaporation rate: Not determined.

- Solubility in / Miscibility with Water: Nearly insoluble.
- Partition coefficient (n-octanol/water): Not determined.
- Viscosity:
  - Dynamic: Not determined.
  - Kinematic: Not determined.
- 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.

11 Toxicological information
- Information on toxicological effects
  - Acute toxicity:
  - Primary irritant effect:
    - on the skin: No irritant effect.
    - on the eye: No 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.
  - OSHA-Ca (Occupational Safety & Health Administration): 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.

(Contd. on page 6)
13 Disposal considerations

- 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.

14 Transport information

- UN-Number: Void
  - DOT, ADR, ADN, IMDG, IATA
- UN proper shipping name: Void
  - DOT, ADR, ADN, IMDG, IATA
- Transport hazard class(es)
  - DOT, ADR, ADN, IMDG, IATA: Void
  - Class: Void
- Packing group: Void
  - DOT, ADR, IMDG, IATA
- 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": -

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.

(Contd. on page 7)
### 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.
- **TLV (Threshold Limit Value established by ACGIH)**
  13760-80-0 ytterbium trifluoride
- **NIOSH-Ca (National Institute for Occupational Safety and Health)**
  None of the ingredients is listed.

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

### Hazard pictograms
- **Signal word** Warning

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

### Hazard statements
- Causes skin irritation.
- Causes serious eye irritation.
- May cause an allergic skin reaction.

### Precautionary statements
- **Wear protective gloves/protective clothing/eye protection/face protection.**
- Wash contaminated clothing before reuse.
- If skin irritation or rash occurs: Get medical advice/attention.
- If eye irritation persists: Get medical advice/attention.

### 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.
Trade name: Tetric EvoCeram Bulk Fill

- 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 preparation / last revision 04/20/2015 / 1
- 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
  - DOT: US Department of Transportation
  - IATA: International Air Transport Association
  - ACGIH: American Conference of Governmental Industrial Hygienists
  - 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)
  - NFPA: National Fire Protection Association (USA)
  - HMIS: Hazardous Materials Identification System (USA)
  - Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
  - Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A
  - Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
- * Data compared to the previous version altered.