1 Identification

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

- **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 6925
      - 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
  - triethylene glycol dimethacrylate

(Contd. on page 2)
Trade name: Tetric

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:
- 13760-80-0 ytterbium trifluoride 10-<20%
- 1565-94-2 Bis-GMA 2.5-<10%
- 72869-86-4 urethane dimethacrylate 2.5-<10%
- 109-16-0 triethylene glycol 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.
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.
40.1.5 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.
- 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.
- 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.
Trade name: Tetric

40.1.5

- Vapor pressure: Not applicable.
- Density at 20 °C (68 °F): 2.26 g/cm³ (18.86 lbs/gal)
- 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.
- 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.
  Photo reactive (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:
    - Primary irritant effect:
      - 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
  IARC (International Agency for Research on Cancer)
  7631-86-9 silicon dioxide, chemically prepared 3
  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.

- 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

- UN-Number
  - DOT, ADR, ADN, IMDG, IATA: Void

- UN proper shipping name
  - DOT, ADR, ADN, IMDG, IATA: Void

- Transport hazard class(es)
  - DOT, ADR, ADN, IMDG, IATA
    - Class: Void

- Packing group
  - DOT, 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: 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.
    - 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 A4
    - 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
      GHS07
  - Signal word Warning
  - Hazard-determining components of labeling:
    Bis-GMA
    urethane dimethacrylate
    triethylene glycol 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.
- 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 / 5
- 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.