1 Identification

- Product identifier
- Trade name: **Tetric EvoFlow**
- 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, flowable, resin-based dental restorative
- 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.
  Repr. 2  H361  Suspected of damaging fertility or the unborn child.

- Label elements
  - 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

(Contd. on page 2)
Safety Data Sheet
acc. to OSHA HCS

Trade name: Tetric EvoFlow

1,10-decandiol dimethacrylate

· Hazard statements
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
Suspected of damaging fertility or the unborn child.

· 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
  Health = 1

  FIRE
  Fire = 0

  REACTIVITY
  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:

<table>
<thead>
<tr>
<th>Substance ID</th>
<th>Substance Name</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1565-94-2</td>
<td>Bis-GMA</td>
<td>10-&lt;20%</td>
</tr>
<tr>
<td>72869-86-4</td>
<td>urethane dimethacrylate</td>
<td>10-&lt;20%</td>
</tr>
<tr>
<td>13760-80-0</td>
<td>ytterbium trifluoride</td>
<td>10-&lt;20%</td>
</tr>
<tr>
<td>6701-13-9</td>
<td>1,10-decandiol dimethacrylate</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td>75980-60-8</td>
<td>diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide</td>
<td>0.1-&lt;1%</td>
</tr>
</tbody>
</table>

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.
Trade name: **Tetric EvoFlow**

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.
**Trade name: Tetric EvoFlow**

- **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](image)

  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.
Safety Data Sheet
acc. to OSHA HCS

Trade name: Tetric EvoFlow

- Vapor pressure: Not applicable.
- Density at 20 °C (68 °F): 1.78 g/cm³ (14.854 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.
  Photoactive (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: 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: Void
  - 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 MARPOL73/78 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.
    - 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)
      T3760-80-0 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
      - GHS08
  - Signal word Warning
  - Hazard-determining components of labeling:
    - Bis-GMA
    - urethane dimethacrylate
    - 1,10-decandiol dimethacrylate
  - Hazard statements
    Causes skin irritation.
    Causes serious eye irritation.
    May cause an allergic skin reaction.
    Suspected of damaging fertility or the unborn child.
  - 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 / 4

· 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
  Repr. 2: Reproductive toxicity, Hazard Category 2

* Data compared to the previous version altered.