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

- **Product identifier**
- **Trade name:** ExciTE F

- **Relevant identified uses of the substance or mixture and uses advised against**
  - No further relevant information available.

- **Application of the substance / the preparation**
  - Dental adhesive with fluoride release

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

2 Hazards identification

- **Classification of the substance or mixture**

  - **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
    - Irritant
      - Irritating to eyes and skin. May cause sensitisation by skin contact.
    - Flammable.

  - **Information concerning particular hazards for human and environment:**
    - The product has to be labelled due to the calculation procedure of international guidelines.

  - **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:**
    - The product has been classified and marked in accordance with directives on hazardous materials.

(Contd. on page 2)
3 Composition/information on ingredients

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

- Dangerous components:

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Chemical Name</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1565-94-2</td>
<td>Bis-GMA</td>
<td>25-50%</td>
</tr>
<tr>
<td>64-17-5</td>
<td>ethanol</td>
<td>10-25%</td>
</tr>
<tr>
<td>868-77-9</td>
<td>2-hydroxyethyl methacrylate</td>
<td>10-25%</td>
</tr>
<tr>
<td>223681-84-3</td>
<td>phosphonic acid acrylate</td>
<td>10-25%</td>
</tr>
<tr>
<td>72869-86-4</td>
<td>urethane dimethacrylate</td>
<td>2.5-10%</td>
</tr>
<tr>
<td>7789-23-3</td>
<td>potassium fluoride</td>
<td>≤ 2.5%</td>
</tr>
</tbody>
</table>

(Contd. on page 3)
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: Immediately rinse with water.
- After eye contact:
  Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- After swallowing:
  Rinse out mouth and then drink plenty of water.
  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:
  CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- For safety reasons unsuitable extinguishing agents: Water with full jet
- Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters
  Protective equipment: No special measures required.
  Additional information Cool endangered receptacles with water spray.

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures
  Wear protective equipment. Keep unprotected persons away.
- Environmental precautions: Do not allow to enter sewers/surface or ground water.
- Methods and material for containment and cleaning up:
  Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
  Ensure adequate ventilation.
- 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.
  Ensure good ventilation/exhaustion at the workplace.
  Information about protection against explosions and fires:
  Keep ignition sources away - Do not smoke.
  Protect against electrostatic charges.
Trade name: **ExciTE F**

- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
  - **Requirements to be met by storerooms and receptacles:** No special requirements.
  - **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**

<table>
<thead>
<tr>
<th>Component</th>
<th>PEL</th>
<th>REL</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5 ethanol</td>
<td>1900 mg/m³, 1000 ppm</td>
<td>1900 mg/m³, 1000 ppm</td>
</tr>
<tr>
<td>TLV Short-term value</td>
<td>1880 mg/m³, 1000 ppm</td>
<td></td>
</tr>
</tbody>
</table>

- **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.
    - Keep away from foodstuffs, beverages and feed.
    - Immediately remove all soiled and contaminated clothing.
    - Wash hands before breaks and at the end of work.
    - Avoid contact with the eyes and skin.
    - Do not inhale gases / fumes / aerosols.
  - **Breathing equipment:**
    - In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Protection of hands:**
  - **Protective gloves**
    - After use of gloves apply skin-cleaning agents and skin cosmetics.
  - **Material of gloves**
    - Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
    - 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.
Trade name: **ExciTE F**

- **Eye protection:**
  - Tightly sealed goggles

### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  - **Appearance:**
    - **Form:** Fluid
    - **Color:** Colorless
    - **Odor:** Characteristic
    - **Odour threshold:** Not determined.
    - **pH-value (10 g/l) at 20 °C (68 °F):** 2.5
  - **Change in condition**
    - **Melting point/Melting range:** Undetermined.
    - **Boiling point/Boiling range:** Undetermined.
  - **Flash point:** 24 °C (75 °F)
  - **Ignition temperature:** 425 °C (797 °F)
  - **Auto igniting:** Product is not self-igniting.
  - **Danger of explosion:** Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
  - **Explosion limits:**
    - **Lower:** Not determined.
    - **Upper:** Not determined.
  - **Vapor pressure at 20 °C (68 °F):** 59 hPa (44 mm Hg)
  - **Density at 20 °C (68 °F):** 1.066 g/cm³ (8.896 lbs/gal)
  - **Relative density**
    - **Vapour density:** Not determined.
  - **Evaporation rate:** Not determined.
  - **Solubility in / Miscibility with**
    - **Water:** Partly miscible.
  - **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.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
Trade name: ExciTE F

- 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: Irritant to skin and mucous membranes.
      - 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
- 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.

### 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 2 (Self-assessment): hazardous for water
    - Do not allow product 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.
14 Transport information

- **UN-Number**
  - DOT
  - ADR, IMDG, IATA
  - UN1170
  - 1170

- **UN proper shipping name**
  - DOT, IATA
  - ETHANOL SOLUTION
  - ADR
  - 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
  - IMDG
  - ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

- **Transport hazard class(es)**
  - DOT
    - Class
    - Label
    - 3 Flammable liquids.
    - 3
  - ADR
    - Class
    - Label
    - 3 (F1) Flammable liquids
    - 3
  - IMDG, IATA
    - Class
    - Label
    - 3 Flammable liquids.
    - 3
  - Packing group
    - DOT, ADR, IMDG, IATA
    - III

- **Environmental hazards:**
  - Marine pollutant:
  - No

- **Special precautions for user**
  - Warning: Flammable liquids
  - Danger code (Kemler):
  - 30
  - EMS Number:
  - F-E,S-E

- **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):

  1565-94-2 Bis-GMA
  64-17-5 ethanol
  868-77-9 2-hydroxyethyl methacrylate
  72869-86-4 urethane dimethacrylate
  1830-78-0 glycerin-1,3-dimethacrylate
  7631-86-9 silicon dioxide, chemically prepared
  7789-23-3 potassium fluoride

- 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:
    64-17-5 ethanol

- Carcinogenic categories

  - EPA (Environmental Protection Agency)
    None of the ingredients is listed.

  - TLV (Threshold Limit Value established by ACGIH)
    64-17-5 ethanol A3
    7789-23-3 potassium fluoride 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:
The product has been classified and marked in accordance with directives on hazardous materials.

- Hazard symbols:

  Irritant
Hazard-determining components of labelling:
2-hydroxyethyl methacrylate
urethane dimethacrylate

Risk phrases:
Flammable.
Irritating to eyes and skin.
May cause sensitisation by skin contact.

Safety phrases:
Keep container tightly closed.
Keep away from sources of ignition - No smoking.
Do not breathe vapour/spray.
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.

* Data compared to the previous version altered.