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

- Product identifier
  - Trade name: Permaflo™ DC Base
  - Article number: 63593, 63594, 63544, 63592
  - Index number: SDS 45-001.09
- Relevant identified uses of the substance or mixture and uses advised against
  Professional Dental Restorative Material
- Application of the substance / the mixture Professional Dental Restorative Material
- Details of the supplier of the safety data sheet
  - Manufacturer/Supplier:
    Ultradent Products Inc.
    505 W. Ultradent Drive (10200 S)
    South Jordan, UT 84095-3942
    USA
    onlineordersupport@utradent.com

  EC Responsible Person
  Ultradent Products GmbH
  Am Westhover Berg 30
  51149 Cologne Germany
  Email: infoDe@utradent.com
  Emergency Phone: +49(0)2203-35-92-0

- Further information obtainable from: Customer Service
- Emergency telephone number:
  CHEMTREC (NORTH AMERICA) : (800) 424-9300
  (INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

- Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008

  GHS07

  Acute Tox. 4  H332  Harmful if inhaled.
  Skin Sens. 1  H317  May cause an allergic skin reaction.

- Label elements
  - Labelling according to Regulation (EC) No 1272/2008
    The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.

- Hazard pictograms GHS07
- Signal word Warning

- Hazard-determining components of labelling:
  Triethylene Glycol Dimethacrylate
  Benzoyl Peroxide

- Hazard statements
  H332 Harmful if inhaled.
H317 May cause an allergic skin reaction.

**Precautionary statements**

- **P101** If medical advice is needed, have product container or label at hand.
- **P102** Keep out of reach of children.
- **P103** Read label before use.
- **P261** Avoid breathing dust/fume/gas/mist/vapours/spray.
- **P280** Wear protective gloves.
- **P304+P340 IF INHALED:** Remove person to fresh air and keep comfortable for breathing.
- **P312** Call a POISON CENTER/doctor if you feel unwell.
- **P321** Specific treatment (see on this label).
- **P501** Dispose of contents/container in accordance with local/regional/national/international regulations.

**Other hazards**

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

### 3 Composition/information on ingredients

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

**Dangerous components:**

<table>
<thead>
<tr>
<th>CAS</th>
<th>EINECS</th>
<th>Chemical Name</th>
<th>Skin Sens.</th>
<th>Org. Perox.</th>
<th>Aquatic Chronic</th>
<th>Eye Irrit.</th>
<th>PBT:</th>
<th>vPvB:</th>
</tr>
</thead>
<tbody>
<tr>
<td>109-16-0</td>
<td>203-652-6</td>
<td>Triethylene Glycol Dimethacrylate</td>
<td>&gt;10-≤25%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>94-36-0</td>
<td>202-327-6</td>
<td>Benzoyl Peroxide</td>
<td>≤2.5%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 4 First aid measures

- **Description of first aid measures**

**General information:**

Immediately remove any clothing soiled by the product.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

**After inhalation:**

This product is a viscous gel, therefore chance of inhalation is extremely low.

Seek medical treatment in case of complaints.

**After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

**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.
- **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

(Contd. on page 3)
5 Firefighting measures

· Extinguishing media

· Suitable extinguishing agents:
  Foam, dry chemical, carbon dioxide
  Use fire extinguishing methods suitable to surrounding conditions.

· Special hazards arising from the substance or mixture No further relevant information available.

· Advice for firefighters:
  · Protective equipment:
    Wear fully protective suit.
    Mouth respiratory protective device.

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:
  Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
  Dispose contaminated material as waste according to item 13.
  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:
    Ensure good ventilation/exhaustion at the workplace.
    Prevent formation of aerosols.
  · Information about fire - and explosion protection: No special measures required.

· 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 heat
    See product labelling.
    Protect from exposure to the light.
    Keep container tightly sealed.

· Specific end use(s) Professional Dental Restorative Material

8 Exposure controls/personal protection

· Additional information about design of technical facilities: No further data; see item 7.

· Control parameters
  · Ingredients 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.
Trade name: Permaflo™ DC Base

Additional information: The lists valid during the making were used as basis.

Exposure controls

Personal protective equipment:

General protective and hygienic measures:
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.

Respiratory protection:
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

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 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 breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection: Goggles recommended during refilling

Body protection: Protective work clothing

9 Physical and chemical properties

Information on basic physical and chemical properties

General Information

Appearance:

Form: Gel
Colour: According to product specification
Odour: Acrylic
Odour threshold: Not determined.

pH-value: Not applicable (non-aqueous)

Change in condition
Melting point/freezing point: Undetermined.
Initial boiling point and boiling range: Undetermined.

Flash point: Not applicable.

Flammability (solid, gas): Not applicable.

Decomposition temperature: Not determined.

Auto-ignition temperature: Product is not selfigniting.

Explosive properties: Product does not present an explosion hazard.
49.4.3.1 · Explosion limits:
  Lower: Not determined.
  Upper: Not determined.

· Vapour pressure: Not determined.

· Density at 20 °C: 1.8-2.1 g/cm³
  · Relative density Not determined.
  · Vapour density Not determined.
  · Evaporation rate Not determined.

· Solubility in / Miscibility with water: Not miscible or difficult to mix.

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:
  · Dynamic: Not determined.
  · Kinematic: Not determined.

· Solvent content:
  · VOC (EC) 0.00 %
  · Solids content: <80.0 %

· Other information No further relevant information available.

10 Stability and reactivity

· Reactivity Polymerization occurs when exposed to amine catalysts, metal, or pressure.
· Chemical stability
· Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
· Possibility of hazardous reactions: No dangerous reactions known.
· Conditions to avoid: Visible light, ultraviolet light, and extreme heat
· Incompatible materials: No further relevant information available.
· Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

· Information on toxicological effects
· Acute toxicity Harmful if inhaled.

· LD/LC50 values relevant for classification:

  ATE (Acute Toxicity Estimates)
  Inhalative LC50/4 h ≥4.21-<8.42 mg/l (rat)

  109-16-0 Triethylene Glycol Dimethacrylate
  Oral LD50 >5,000 mg/kg (rat)
  LC50 Fish 16.4 mg/l (Fish) (Toxicity to fish)
  Dermal LD50 >2,000 mg/kg (mouse)

  94-36-0 Benzoyl Peroxide
  Oral LD50 >5,000 mg/kg (rat)
  LC50 Fish 0.0602 mg/l (Fish) (Toxicity to fish)

(Contd. on page 6)
Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: Permaflo™ DC Base

Inhalative LD50 Inhalation 4hrs 24.3 mg/l (rat) (Testing of Chemicals Acute Toxicity Inhalation)

- Primary irritant effect:
  - Skin corrosion/irritation Based on available data, the classification criteria are not met.
  - Serious eye damage/irritation Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation
  May cause an allergic skin reaction.
- CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)
  - Germ cell mutagenicity Based on available data, the classification criteria are not met.
  - Carcinogenicity Based on available data, the classification criteria are not met.
  - Reproductive toxicity Based on available data, the classification criteria are not met.
- STOT-single exposure Based on available data, the classification criteria are not met.
- STOT-repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.

12 Ecological information

- Toxicity
  - Aquatic toxicity:

109-16-0 Triethylene Glycol Dimethacrylate
  - Biodegradability 28 days (Aerobic) (Biodegradability testing)
  - Aqua toxicity 32 mg/l (daphnia) (No Observed Effect Concentration)
  - EC50 >100 mg/l (Algae) (Toxicity to algae)

94-36-0 Benzoyl Peroxide
  - Algae Toxicity 0.0711 mg/l (Algae) (Toxicity to algae)
  - 0.11 mg/l (daphnia) (Toxicity to aquatic invertebrates)

- Persistence and degradability No further relevant information available.
- Behaviour 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 (German Regulation) (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 Do not allow product to reach sewage system.
- European waste catalogue
  HP13 Sensitising
Trade name: Permaflo™ DC Base

14 Transport information

- **UN-Number**
  - **ADR, ADN, IMDG, IATA**: not regulated

- **UN proper shipping name**
  - **ADR, ADN, IMDG, IATA**: not regulated

- **Transport hazard class(es)**
  - **ADR, ADN, IMDG, IATA**: not regulated

- **Packing group**
  - **ADR, IMDG, IATA**: not regulated

- **Environmental hazards**: Not applicable.

- **Special precautions for user**: Not applicable.

- **Transport in bulk according to Annex II of Marpol and the IBC Code**: Not applicable.

- **UN "Model Regulation"**: not regulated

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - **Directive 2012/18/EU**
  - **Named dangerous substances - ANNEX I**: None of the ingredients is listed.
  - **REGULATION (EC) No 1907/2006 ANNEX XVII**: Conditions of restriction: 3

- **Chemical safety assessment**
  Device is biocompatible when used as directed by dental professionals per ISO 10993-1

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.

- **Relevant phrases**
  H241 Heating may cause a fire or explosion.
  H317 May cause an allergic skin reaction.
  H319 Causes serious eye irritation.
  H410 Very toxic to aquatic life with long lasting effects.

- **Department issuing SDS**: Regulatory Affairs
- **Contact**: Customer Service

**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
- IATA: International Air Transport Association
- GHS: Globally Harmonised System of Classification and Labelling of Chemicals (Contd. on page 8)
Trade name: Permaflo™ DC Base

| Acute Tox. 4: Acute toxicity – Category 4 |
| Eye Irrit. 2: Serious eye damage/eye irritation – Category 2 |
| Skin Sens. 1: Skin sensitisation – Category 1 |
| Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1 |