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

- **Product identifier**
  - **Trade name:** Permaflo™, Permaflo™ Pink, Permaflo™ Purple
  - **Article number:** 10065, 72296, 76377, 76387, 94608, 94613, 94617, 94621, 94625, 94630, 94636, 94705
  - **Index number:** SDS 55-001.11
  - **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@ultradent.com
    Emergency Phone: +49(0)2203-35-92-0
- **Further information obtainable from:**
  - **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**
  
  ![Alt text](image)

  GHS07

  Skin Irrit. 2  H315  Causes skin irritation.
  Eye Irrit. 2  H319  Causes serious eye irritation.
  Skin Sens. 1  H317  May cause an allergic skin reaction.

- **Hazard pictograms**
  GHS07

- **Signal word**
  Warning

- **Hazard-determining components of labelling:**
  Triethylene Glycol Dimethacrylate
  2-Hydroxyethyl Methacrylate

(Contd. on page 2)
49.4.3.1

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS</th>
<th>EINECS</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triethylene Glycol Dimethacrylate</td>
<td>109-16-0</td>
<td>203-652-6</td>
<td>&lt;30%</td>
</tr>
<tr>
<td>2-Hydroxyethyl Methacrylate</td>
<td>868-77-9</td>
<td>212-782-2</td>
<td>&lt;20%</td>
</tr>
<tr>
<td>Diurethane Dimethacrylate</td>
<td>72869-86-4</td>
<td>276-957-5</td>
<td>&lt;20%</td>
</tr>
<tr>
<td>Amine Methacrylate</td>
<td>162881-26-7</td>
<td>423-340-5</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Organophosphine Oxide</td>
<td>162657-95-6</td>
<td>423-340-5</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Sodium Monofluorophosphate</td>
<td>10163-15-2</td>
<td>233-433-0</td>
<td>0.3%</td>
</tr>
</tbody>
</table>

· Additional information: For the wording of the listed hazard phrases refer to section 16.
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 swallowed in large quantities seek medical attention.

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:
    Water spray
    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 self-contained respiratory protective device.
    Wear fully protective suit.

## 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:
    Keep away from heat and direct sunlight.
    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:
      See product labelling.
Store in a cool place.
Store in the dark.
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.

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

- **Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**
  Do not eat, drink, smoke or sniff while working.
  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.

- **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:**

  ![Tightly sealed goggles]

  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.
- **Ignition temperature:** 255 °C
- **Decomposition temperature:** Not determined.
- **Auto-ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**
  - Lower: Not determined.
  - Upper: Not determined.
- **Vapour pressure at 20 °C:** 0 hPa
- **Density at 20 °C:** 1.8-2 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 %
- **Other information**
  - No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
11 Toxicological information

- Information on toxicological effects
  - Acute toxicity Based on available data, the classification criteria are not met.

- LD/LC50 values relevant for classification:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Oral LD50</th>
<th>Oral LC50 Fish</th>
<th>Dermal LD50</th>
</tr>
</thead>
<tbody>
<tr>
<td>109-16-0 Triethylene Glycol Dimethacrylate</td>
<td>&gt;5,000 mg/kg (rat)</td>
<td>16.4 mg/l (Fish) (Toxicity to fish)</td>
<td>&gt;2,000 mg/kg (mouse)</td>
</tr>
<tr>
<td>868-77-9 2-Hydroxyethyl Methacrylate</td>
<td>3,275 mg/kg (mouse)</td>
<td>&gt;100 mg/l (Fish)</td>
<td>&gt;3,000 mg/kg (rabbit)</td>
</tr>
<tr>
<td>72869-86-4 Diurethane Dimethacrylate</td>
<td>&gt;5,000 mg/kg (rat)</td>
<td>24.1 mg/l (daphnia)</td>
<td></td>
</tr>
<tr>
<td>Amine Methacrylate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral LD50</td>
<td>1,350 mg/kg (rat)</td>
<td>19 mg/l (Fish)</td>
<td></td>
</tr>
<tr>
<td>LC50 Fish</td>
<td>2,000 mg/kg (rabbit)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal LD50</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhalative LC50/4 h</td>
<td>96 mg/l (rat)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>162881-26-7 Organophosphine Oxide</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral LD50</td>
<td>&gt;2,000 mg/kg (rat)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC50 Fish</td>
<td>&gt;0.09 mg/l (Fish) (Toxicity to fish)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal LD50</td>
<td>&gt;2,000 mg/kg (rat)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Primary irritant effect:
  - Skin corrosion/irritation
    Causes skin irritation.
  - Serious eye damage/irritation
    Causes serious eye irritation.
  - Respiratory or skin sensitisation
    May cause an allergic skin reaction.
  - CMR effects (carcinogenity, 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.
12 Ecological information

- Toxicity
  - Aquatic toxicity:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Biodegradability</th>
<th>Aqua toxicity</th>
<th>EC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>109-16-0 Triethylene Glycol Dimethacrylate</td>
<td>28 days (Aerobic) (Biodegradability testing)</td>
<td>32 mg/l (daphnia) (No Observed Effect Concentration)</td>
<td>&gt;100 mg/l (Algae) (Toxicity to algae)</td>
</tr>
<tr>
<td>868-77-9 2-Hydroxyethyl Methacrylate</td>
<td></td>
<td>345 mg/l (Algae)</td>
<td></td>
</tr>
<tr>
<td>72869-86-4 Diurethane Dimethacrylate</td>
<td>28 days (Aerobic) (Biodegradability testing)</td>
<td>&gt;0.6 mg/l (Algae) (Toxicity to algae)</td>
<td>&gt;1.2 mg/l (daphnia) (Toxicity to aquatic invertebrates)</td>
</tr>
<tr>
<td>Amine Methacrylate</td>
<td></td>
<td>EC50</td>
<td>42 mg/l (Algae)</td>
</tr>
<tr>
<td>162881-26-7 Organophosphate Oxide</td>
<td>EC50 (static)</td>
<td>&gt;1.75 mg/kg (daphnia) (Toxicity to aquatic invertebrates)</td>
<td>20.008 mg/l (daphnia) (Daphnia Magna Reproduction Test)</td>
</tr>
<tr>
<td></td>
<td>Aqua toxicity</td>
<td>&gt;0.026 mg/l (Plant) (Toxicity to algae)</td>
<td></td>
</tr>
</tbody>
</table>

- 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
  - Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- European waste catalogue
  - HP13 Sensitising

(Contd. on page 8)
49.4.3.1

· Uncleaned packaging:

· Recommendation: Disposal must be made according to official regulations.

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
  · 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

     H302 Harmful if swallowed.
     H312 Harmful in contact with skin.
     H315 Causes skin irritation.
     H317 May cause an allergic skin reaction.
     H319 Causes serious eye irritation.
     H413 May cause long lasting harmful effects to aquatic life.

· 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
  · EINECS: European Inventory of Existing Commercial Chemical Substances
Trade name: Permaflo™, Permaflo™ Pink, Permaflo™ Purple

ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
VOC: Volatile Organic Compounds (USA, EU)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 4: Acute toxicity – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4