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

· Product identifier
  · Trade name: Permaflo™ DC Catalyst
  · Article number: 63698
  · Index number: SDS 52-001.07
· 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

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
    Amine Methacrylate
  · Hazard statements
    H332 Harmful if inhaled.
Trade name: Permaflo™ DC Catalyst

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:**
  - CAS: 109-16-0 Triethylene Glycol Dimethacrylate
    - Skin Sens. 1, H317
    - >10-% ≤25%
    - EINECS: 203-652-6
  - CAS: 75980-60-8 Diphenyl (2,4,6- trimethylbenzoyl) phosphine oxide
    - Repr. 2, H361f
    - ≤2.5%
    - EINECS: 278-355-8
  - Amine Methacrylate
    - Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317
    - ≤1%
    - EINECS: 278-355-8

- **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.
  - 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:**
  - If skin irritation continues, consult a doctor.
  - Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:**
  - Rinse opened eye for several minutes under running water.
- **After swallowing:**
  - If symptoms persist consult doctor.
- **Information for doctor:**
  - **Most important symptoms and effects, both acute and delayed** No further relevant information available.
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- Indication of any immediate medical attention and special treatment needed
  No further relevant information available.

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
  Ensure adequate ventilation
- 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:
  See product labelling.
  Keep container tightly sealed.
- Specific end use(s)
  No further relevant information available.

8 Exposure controls/personal protection

- Additional information about design of technical facilities:
  No further data; see item 7.
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- 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:
      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: Structurally viscous
      - Colour: Beige
      - 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: >150 °C

- Flammability (solid, gas): Not applicable.

- Decomposition temperature: Not determined.
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- 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: Not determined.
  - Density at 20 °C: 1.9-2.0 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 %
- Other information: No further relevant information available.

10 Stability and reactivity

- Reactivity: Polymerization occurs when exposed to visible light, ultraviolet light or extreme heat.
- 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 ≥2.78-<5.56 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)
    - Amine Methacrylate
      - Oral LD50 1,550 mg/kg (rat)
Safety data sheet
according to 1907/2006/EC, Article 31

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- 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) |
  - Amine Methacrylate
    | EC50             | 42 mg/l (Algae) |
    - 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
  - HP 13 Sensitising
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- 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.

- **Stowage Category**
  - E

- **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**
  - 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.
  - H361f Suspected of damaging fertility.

- **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
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
Repr. 2: Reproductive toxicity – Category 2