

Safety data sheet according to UK REACH

Printing date 20.06.2025

Version number 1

Revision: 20.06.2025

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

- **Product identifier**
- **Trade name:** Permaflo™ DC Base
- **Article number:** SDS 45-001.11R01, 63544, 63592, 63593, 63594, 5915, 5914, 1006455, 5912, 5913, 1006453
- **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@ultradent.com
- **EC Responsible Person**
Ultradent Products GmbH
Am Westhover Berg 30
51149 Cologne Germany
Email: infoDE@ultradent.com
Office Phone: +49(0)2203-35-92-0
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : +1 (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

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



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** Void
- **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.

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- P103 Read carefully and follow all instructions.
 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.

3 Composition/information on ingredients

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

- **Dangerous components:**

CAS: 109-16-0	Triethylene Glycol Dimethacrylate	≥1-≤25%
EINECS: 203-652-6	⚠ Skin Sens. 1, H317	
CAS: 94-36-0	Benzoyl Peroxide	≤2.5%
EINECS: 202-327-6	⚠ Org. Perox. B, H241; ⚠ Aquatic Chronic 1, H410; ⚠ Eye Irrit. 2, H319; Skin Sens. 1, H317	

- **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.
 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.
- **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:**
 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.

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- **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 section 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

- **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

- **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**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as 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.

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- **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.

- **Hand protection**



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/face protection** Goggles recommended during refilling

- **Body protection:** Protective work clothing

9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Physical state**

Fluid

- **Colour:**

According to product specification

- **Odour:**

Acrylic

- **Odour threshold:**

Not determined.

- **Melting point/freezing point:**

Undetermined.

- **Boiling point or initial boiling point and boiling range**

Undetermined.

- **Flammability**

Not applicable.

- **Lower and upper explosion limit**

- **Lower:**

Not determined.

- **Upper:**

Not determined.

- **Flash point:**

Not applicable.

- **Decomposition temperature:**

Not determined.

- **pH**

Not applicable (non-aqueous)

- **Viscosity:**

- **Kinematic viscosity**

Not determined.

- **Dynamic:**

Not determined.

- **Solubility**

- **water:**

Not miscible or difficult to mix.

- **Partition coefficient n-octanol/water (log value)**

Not determined.

- **Vapour pressure:**

Not determined.

- **Density and/or relative density**

- **Density at 20 °C:**

1.8-2.1 g/cm³

- **Relative density**

Not determined.

- **Vapour density**

Not determined.

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- **Other information**
- **Appearance:**
- **Form:** Gel
- **Important information on protection of health and environment, and on safety.**
- **Ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Change in condition**
- **Evaporation rate** Not determined.
- **Information with regard to physical hazard classes**
- **Explosives** Void
- **Flammable gases** Void
- **Aerosols** Void
- **Oxidising gases** Void
- **Gases under pressure** Void
- **Flammable liquids** Void
- **Flammable solids** Void
- **Self-reactive substances and mixtures** Void
- **Pyrophoric liquids** Void
- **Pyrophoric solids** Void
- **Self-heating substances and mixtures** Void
- **Substances and mixtures, which emit flammable gases in contact with water** Void
- **Oxidising liquids** Void
- **Oxidising solids** Void
- **Organic peroxides** Void
- **Corrosive to metals** Void
- **Desensitised explosives** Void

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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Harmful if inhaled.

· LD/LC50 values relevant for classification:

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)

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94-36-0 Benzoyl Peroxide

Oral	LD50	>5,000 mg/kg (rat)
	LC50 Fish	0.0602 mg/l (Fish) (Toxicity to fish)
Inhalative	LD50 Inhalation 4hrs	24.3 mg/l (rat) (Testing of Chemicals Acute Toxicity Inhalation)

· **Respiratory or skin sensitisation** May cause an allergic skin reaction.· **Information on other hazards**· **Endocrine disrupting properties**

128-37-0 Butylated Hydroxytoluene

List II

12 Ecological information· **Toxicity**· **Aquatic toxicity:****109-16-0 Triethylene Glycol Dimethacrylate**

EC50	>100 mg/kg (Algae)
Biodegradability	28 days (Aerobic) (Biodegradability testing)
Aqua toxicity	32 mg/l (daphnia) (No Observed Effect Concentration)

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.· **Bioaccumulative potential** No further relevant information available.· **Mobility in soil** No further relevant information available.· **Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.· **Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.· **Other adverse effects**· **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.

13 Disposal considerations· **Waste treatment methods**· **Recommendation**

Dispose of contents/container in accordance with international, federal, state, and local regulations.

· **Uncleaned packaging:**· **Recommendation:** Disposal must be made according to official regulations.**14 Transport information**· **UN number or ID number**· **ADR, ADN, IMDG, IATA**

not regulated

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- | | |
|--|-----------------|
| · UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | not regulated |
| · Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | not regulated |
| · Packing group | |
| · ADR, IMDG, IATA | not regulated |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not Applicable |
| · Maritime transport in bulk according to IMO instruments | Not applicable. |
| · UN "Model Regulation": | not regulated |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

14808-60-7 Silica Glass

- **Poisons Act**

- **Regulated explosives precursors**

None of the ingredients is listed.

- **Regulated poisons**

None of the ingredients is listed.

- **Reportable explosives precursors**

None of the ingredients is listed.

- **Reportable poisons**

None of the ingredients is listed.

- **Directive 2012/18/EU**

- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

- **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 from Section 3**

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:** Environmental, Health, and Safety

- **Contact:** Customer Service

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· Abbreviations and acronyms:

ADR: Accord relatif au transport international 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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

ATE: Acute toxicity estimate values

Org. Perox. B: Organic peroxides – Type B

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

· * Data compared to the previous version altered.

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