

Safety Data Sheet according to WHS Regulations

Printing date 04.08.2023

Revision: 04.08.2023

1 Identification

- **Product identifier**
- **Trade name:** Permaflo™ - Permaflo™ Pink - Permaflo™ Purple
- **Article number:**
SDS 55-001.11R02, 10065, 72296, 76377, 76387, 94608, 94613, 94617, 94621, 94625, 94630, 94636, 94705
- **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

Ultradent Australia Pty Ltd.
Level 22/2 Market Street
Sydney NSW 2000
Australia
Email: info.anz@ultradent.com
Toll Free: 1-800-290929
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) Identification

- **Classification of the substance or mixture**



Skin Irrit. 2	H315 Causes skin irritation.
Serious eye damage/irritation – Category 2A	H319 Causes serious eye irritation.
Skin Sens. 1	H317 May cause an allergic skin reaction.

- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
Triethylene Glycol Dimethacrylate
2-Hydroxyethyl Methacrylate
Diurethane Dimethacrylate
- **Hazard statements**
H315 Causes skin irritation.

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H319 Causes serious eye irritation.

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 / eye protection / face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

3 Composition and Information on Ingredients

Chemical characterisation: Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:

109-16-0	Triethylene Glycol Dimethacrylate	>10-<30%
	⚠ Skin Sens. 1, H317	
2530-85-0	Silane	>10-<30%
	⚠ Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; STOT SE 3, H335	
868-77-9	2-Hydroxyethyl Methacrylate	>1-<10%
	⚠ Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; Skin Sens. 1, H317	
72869-86-4	Diurethane Dimethacrylate	>0.1-<5%
	⚠ Skin Sens. 1, H317	
13463-67-7	Titanium Dioxide	>0.1-<5%
	⚠ Carc. 2, H351	
	Trade Secret	<1%
	⚠ Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; Skin Sens. 1, H317; Flam. Liq. 4, H227	
162881-26-7	Organophosphine Oxide	<1%
	⚠ Skin Sens. 1, H317	

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

4 First Aid Measures

General information: Immediately remove any clothing soiled by the product.

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.

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- **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 Fire Fighting Measures

- **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.
- **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.
- **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.

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· **Specific end use(s)** Professional dental restorative material

8 Exposure controls and personal protection

· **Additional information about design of technical facilities:** No further data; see item 7.· **Ingredients with limit values that require monitoring at the workplace:**

13463-67-7 Titanium Dioxide

WES	Long-term value: 10 mg/m ³ inhalable dust
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· **Additional information:** The lists valid during the making were used as basis.· **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

· **General Information**· **Appearance:**· **Form:**

Gel

· **Colour:**

Color Dependent

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· 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:	213 °C
· Flash point:	106 °C
· 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:	Not determined.
· 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.
· Other information	No further relevant information available.

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:**
 - Light
 - Flames
 - Ignition sources
 - 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** Based on available data, the classification criteria are not met.

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)

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Dermal	LD50	>2,000 mg/kg (mouse)
868-77-9 2-Hydroxyethyl Methacrylate		
Oral	LD50	3,275 mg/kg (mouse) >5,000 mg/kg (rat)
	LC50 Fish	>100 mg/l (Fish)
Dermal	LD50	>3,000 mg/kg (rabbit)
	LC50(Daphnia magna)	24.1 mg/l (daphnia)
72869-86-4 Diurethane Dimethacrylate		
Oral	LD50	>5,000 mg/kg (rat)
13463-67-7 Titanium Dioxide		
Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)
Trade Secret		
Oral	LD50	1,550 mg/kg (rat)
	LC50 Fish	19 mg/l (Fish)
Dermal	LD50	2,000 mg/kg (rabbit)
Inhalative	LC50/4 h	96 mg/l (rat)
162881-26-7 Organophosphine Oxide		
Oral	LD50	>2,000 mg/kg (rat)
	LC50 Fish	>0.09 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>2,000 mg/kg (rat)

- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **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	
EC50	>100 mg/kg (Algae)
Biodegradability	28 days (Aerobic) (Biodegradability testing)
Aqua toxicity	32 mg/l (daphnia) (No Observed Effect Concentration)
868-77-9 2-Hydroxyethyl Methacrylate	
EC50	345 mg/kg (Algae)
72869-86-4 Diurethane Dimethacrylate	
EC50	>0.6 mg/kg (Algae)
Biodegradability	28 days (Aerobic) (Biodegradability testing)

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13463-67-7 Titanium Dioxide

EC50	>100 mg/kg (Algae)
	>1,000 mg/kg (Fish)

Trade Secret

EC50	42 mg/kg (Algae)
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162881-26-7 Organophosphine Oxide

EC50 (static)	>1.175 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
Aqua toxicity	≥0.008 mg/l (daphnia) (Daphnia Magna Reproduction Test)
Toxicity to Aquatic Plants (static)	>0.26 mg/l (Plant) (Toxicity to 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**
 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

- | | |
|--|-----------------|
| <ul style="list-style-type: none"> · UN-Number · ADG, ADN, IMDG, IATA | not regulated |
| <ul style="list-style-type: none"> · UN proper shipping name · ADG, ADN, IMDG, IATA | not regulated |
| <ul style="list-style-type: none"> · Transport hazard class(es) · ADG, ADN, IMDG, IATA · Class | not regulated |
| <ul style="list-style-type: none"> · Packing group · ADG, IMDG, IATA | not regulated |
| <ul style="list-style-type: none"> · Environmental hazards: | Not applicable. |
| <ul style="list-style-type: none"> · Special precautions for user | Not Applicable |

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- | | |
|---|-----------------|
| · 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**

· Australian Inventory of Industrial Chemicals

65997-17-3	Inorganic Glass
109-16-0	Triethylene Glycol Dimethacrylate
2530-85-0	Silane
868-77-9	2-Hydroxyethyl Methacrylate
	Trade Secret
72869-86-4	Diurethane Dimethacrylate
13463-67-7	Titanium Dioxide
10163-15-2	Sodium Monofluorophosphate
	Trade Secret
10287-53-3	Ethyl-4-Dimethylamino Benzoate
162881-26-7	Organophosphine Oxide
1332-37-2	Red Iron Oxide
68187-51-9	Zinc Ferrite Brown Spinel
51274-00-1	Yellow Iron Oxide
12737-27-8	Chromium Iron Oxide
	Co-Cr-AL Spinel Blue Green
10373-78-1	Camphorquinone
14808-60-7	Silica Glass

· Standard for the Uniform Scheduling of Medicines and Poisons

868-77-9	2-Hydroxyethyl Methacrylate	S5
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· Australia: Priority Existing Chemicals

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

H227 Combustible liquid.

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H315 Causes skin irritation.

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H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H351 Suspected of causing cancer.

· **Department issuing SDS:** Environmental, Health, and Safety

· **Contact:** Customer Service

· **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

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

Flam. Liq. 4: Flammable liquids – Category 4

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A

Skin Sens. 1: Skin sensitisation – Category 1

Carc. 2: Carcinogenicity – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· *** Data compared to the previous version altered.**

AU