



Safety Data Sheet

acc. to OSHA HCS

Printing date 01/27/2025

Reviewed on 01/27/2025

1 Identification

Product identifier

Trade name: Permaflo™ - Permaflo™ Pink - Permaflo™ Purple

Article number:

SDS 55-001.12R01, 94630, 76387, 94608, 72296, 94613, 10065, 94617, 76377, 94621, 94705, 94625, 94636

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

Information department: 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



GHS08 Health hazard

Toxic to Reproduction 1B H360 May damage fertility or the unborn child.



GHS07

Skin Irritation 2 H315 Causes skin irritation.
Eye Irritation 2A H319 Causes serious eye irritation.
Sensitization - Skin 1 H317 May cause an allergic skin reaction.

Label elements

- GHS label elements** Void
- Hazard pictograms** GHS07, GHS08
- Signal word** Danger

Health Hazard-determining components of labeling:

Triethylene Glycol Dimethacrylate
Ethyl-4-Dimethylamino Benzoate
2-Hydroxyethyl Methacrylate
Diurethane Dimethacrylate
Trade Secret
Irgacure 819

Hazard statements

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.

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H360 May damage fertility or the unborn child.

· **Precautionary statements**

- P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P261 Avoid breathing dust/fume/gas/mist/vapors/spray
 P264 Wash thoroughly after handling.
 P272 Contaminated work clothing must not be allowed out of the workplace.
 P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P302+P352 If on skin: Wash with plenty of water.
 P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P308+P313 IF exposed or concerned: Get medical advice/attention.
 P321 Specific treatment (see on this label).
 P362+P364 Take off contaminated clothing and wash it before reuse.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P337+P313 If eye irritation persists: Get medical advice/attention.
 P363 Wash contaminated clothing before reuse.
 P405 Store locked up.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **HMIS-ratings (scale 0 - 4)**



3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

109-16-0	Triethylene Glycol Dimethacrylate	>10-<30%
2530-85-0	Silane	>10-<30%
868-77-9	2-Hydroxyethyl Methacrylate	>1-<10%
72869-86-4	Diurethane Dimethacrylate	>1-<5%
13463-67-7	Titanium Dioxide	>1-<5%
	Trade Secret	<1%
10287-53-3	Ethyl-4-Dimethylamino Benzoate	≥0.1<1%
	Irgacure 819	<1%

· **Additional information:**

The specific chemical identity of composition is being withheld as a trade secret. The specific chemical identity is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of paragraph §1910.1200.

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4 First-aid measures

- **Description of 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.
- **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

- **Extinguishing media**
- **Suitable extinguishing agents:**
Water spray
Foam, dry chemical, carbon dioxide
Use fire fighting measures that suit the environment.
- **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 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

- **Handling:**
- **Precautions for safe handling**
Keep away from heat and direct sunlight.
Ensure good ventilation/exhaustion at the workplace.

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- Open and handle receptacle with care.
- Prevent formation of aerosols.
- **Information about protection against explosions and fires:** Keep respiratory protective device available.
- **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 receptacle tightly sealed.
- **Specific end use(s)** Professional dental restorative material

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
- The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.
- At this time, the other constituents have no known exposure limits.

13463-67-7 Titanium Dioxide

ACGIH TLV	Short-term value: 10* 5 mg/m ³
PEL	Long-term value: 15* mg/m ³ *total dust
REL	See Pocket Guide App. A
TLV	Long-term value: 0.2* 2.5** mg/m ³ resp. fraction, *nanoscale, **finescale, A3
TWA	Short-term value: 15* 5 mg/m ³

- **Additional information:** The lists that were valid during the creation 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.
- Store protective clothing separately.
- Avoid contact with the eyes and skin.
- **Breathing equipment:**
- In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Protection of hands:**



Protective gloves

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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 is based 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
Color:	Color Dependent
Odor:	Acrylic
Odor threshold:	Not determined.

· **pH-value:** Not applicable (non-aqueous)

· **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	213 °C

· **Flash point:** 106 °C

· **Flammability:** Not applicable.

· **Auto igniting:** 255 °C

· **Decomposition temperature:** Not determined.

· **Ignition temperature:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

· **Vapor pressure at 20 °C:** 0 hPa

Density:	Not determined
Relative density	Not determined
Vapor density	Not determined.
Evaporation rate	Not determined.

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- | | |
|---|--|
| · 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.
- **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**
 - 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:**

- **LD/LC50 values that are 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)

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)
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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)
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Dermal	LC50 Fish	19 mg/l (Fish)
Dermal	LD50	2,000 mg/kg (rabbit)
Inhalative	LC50/4 h	96 mg/l (rat)
Irgacure 819		
Oral	LD50	>2,000 mg/kg (rat)
	LC50 Fish	>0.09 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>2,000 mg/kg (rat)

· **Primary irritant effect:**

· **on the skin:** Irritant to skin and mucous membranes.

· **on the eye:** Irritating effect.

· **Sensitization:** Sensitization possible through skin contact.

· **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

	Co-Cr-AL Spinel Blue Green	2B
14808-60-7	Silica Glass	I

· **NTP (National Toxicology Program)**

14808-60-7	Silica Glass	K
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· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

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)
13463-67-7 Titanium Dioxide	
EC50	>100 mg/kg (Algae) >1,000 mg/kg (Fish)
Trade Secret	
EC50	42 mg/kg (Algae)
Irgacure 819	
EC50 (static)	>1.175 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
Aqua toxicity	≥0.008 mg/l (daphnia) (Daphnia Magna Reproduction Test)

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Toxicity to Aquatic Plants (static) >0.26 mg/l (Plant) (Toxicity to algae)

- **Persistence and degradability** No further relevant information available.
- **Behavior 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 (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 packagings:**
- **Recommendation:** *Disposal must be made according to official regulations.*

14 Transport information

- | | |
|--|-----------------|
| · UN-Number | |
| · DOT, ADN, IMDG, IATA | Not Regulated |
| · UN proper shipping name | |
| · DOT, ADN, IMDG, IATA | Not Regulated |
| · Transport hazard class(es) | |
| · DOT, ADN, IMDG, IATA | |
| · Class | Not Regulated |
| · Packing group | |
| · DOT, IMDG, IATA | Not Regulated |
| · Environmental hazards: | Not Applicable. |
| · Special precautions for user | Not Applicable |
| · Transport in bulk according to Annex II of MARPOL73/78 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**
No further relevant information available.

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· **Sara**· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

Trade Secret

Co-Cr-AL Spinel Blue Green

· **TSCA (Toxic Substances Control Act):**

109-16-0	Triethylene Glycol Dimethacrylate	ACTIVE
2530-85-0	Silane	ACTIVE
868-77-9	2-Hydroxyethyl Methacrylate	ACTIVE
72869-86-4	Diurethane Dimethacrylate	ACTIVE
13463-67-7	Titanium Dioxide	ACTIVE
	Trade Secret	ACTIVE
10287-53-3	Ethyl-4-Dimethylamino Benzoate	ACTIVE
	Irgacure 819	ACTIVE

· **Hazardous Air Pollutants**

Co-Cr-AL Spinel Blue Green

· **Proposition 65**· **Chemicals known to cause cancer:**

14808-60-7 Silica Glass

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)**

	Trade Secret	A4
14808-60-7	Silica Glass	A2

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

14808-60-7 Silica Glass

· **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.

· **Department issuing SDS:** Environmental, Health, and Safety· **Contact:** Customer Service· **Date of preparation / last revision** 01/27/2025 / -

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· Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
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
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Skin Irritation 2: Skin corrosion/irritation – Category 2
Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A
Sensitization - Skin 1: Skin sensitisation – Category 1
Toxic to Reproduction 1B: Reproductive toxicity – Category 1B

· * Data compared to the previous version altered.

US