

**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 05/12/2006

SDS No : 48-001.8

Date Revised : 01/16/2017

Revision No : 8

**PermaFlo® Purple****SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

Product code : JR/94613  
 Product name : PermaFlo® Purple  
 Product description : Flowable Composite

**1.2. Relevant identified uses of the substance or mixture and uses advised against**

Relevant identified uses : Professional Dental Anatomical Indicating Composite

**1.3. Details of the supplier of the safety data sheet****Manufacturer**

Ultradent Products, Inc.  
 505 W. Ultradent Drive (10200 South)  
 South Jordan, UT 84095

**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

**1.4. Emergency telephone number**

CHEMTREC (NORTH AMERICA) : (800) 424 - 9300  
 (INTERNATIONAL) : +1(703) 527 - 3887

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Classification according to Regulation(EC) No 1272/2008 [CLP]**

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

**Health** : Skin Sensitization, Category 1B  
 Target Organ Toxicity (Single exposure), Category 3

**2.2. Label elements****Classification according to Regulation(EC) No 1272/2008 [CLP]**

Hazard pictogram(s) :



Exclamation  
mark

**Signal Word** : WARNING

**Hazard statement(s)** : H317: May cause an allergic skin reaction.  
 H335: May cause respiratory irritation.

**Precautionary statement(s)**

**Prevention** : P280: Wear protective gloves/protective clothing/eye protection/face protection.

**Response** : P305: IF IN EYES:

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P351: Rinse cautiously with water for several minutes.  
P337+P313: If eye irritation persists: Get medical advice/attention.  
P302+P352: IF ON SKIN: Wash with plenty of soap and water.  
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.  
P304+P341: IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

**Storage** : P273: Avoid release to the environment.  
**Disposal** : P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-21/11/2003)

### 2.3. Other hazards

Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

## SECTION 3: Composition / information on ingredients

### 3.1. Substances

Not Applicable

### 3.2. Mixtures

| Chemical Name                     | CAS        | EINECS No. | Wt.% | Classification according to Regulation(EC) No 1272/2008 [CLP] |
|-----------------------------------|------------|------------|------|---------------------------------------------------------------|
| Triethylene Glycol Dimethacrylate | 109-16-0   | 203-652-6  | ≤ 20 | Skin Sens.,Cat. 1B; H317                                      |
| Diurethane Dimethacrylate (DUDMA) | 72869-86-4 | 276-957-5  | < 5  | Skin Sens.,Cat. 1; H317                                       |
| Bis-GMA                           | 1565-94-2  | 216-367-7  | < 10 | H315; H317; H319                                              |
| Sodium Monofluorophosphate        | 10163-15-2 | 233-433-0  | 0.3  | Acute Tox. (O),Cat. 4; H302                                   |

For full text of H-statements: see SECTION 16.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

**Following eyes** : Flush eyes with water. Get medical attention if irritation develops or persists.  
**Following skin** : Wash with soap and water. Get medical attention if irritation develops or persists.  
**Following ingestion** : If swallowed in small quantity the product is harmless, otherwise consult a doctor.  
**Following inhalation** : No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

### 4.2. Most important symptoms and effects, both acute and delayed

**Eyes** : May cause mild irritation.  
**Skin** : May cause sensitization to skin.

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**Ingestion** : May be harmful if swallowed in large quantities.  
**Inhalation** : May be harmful if inhaled.

### 4.3. Indication of any immediate medical attention and special treatment needed

**Notes to physician** : Not Applicable

## SECTION 5: Fire fighting measures

### 5.1. Extinguishing media

**Extinguishing media** : Water spray, fog, or mist, foam, dry chemical, carbon dioxide (CO<sub>2</sub>)

### 5.2. Special hazards arising from the substance or mixture

**Hazardous combustion products** : None known.

### 5.3. Advice for firefighters

**Fire fighting procedures** : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

**General procedures** : Refer to Section 8 for Personal Protective Equipment.

### 6.2. Environmental precautions

**Water spill** : No specific hazards are encountered under normal product use.

### 6.3. Methods and material for containment and cleaning up

**Small Spill** : Wipe up small amounts with chemical resistant or damp rag which is washed with large amounts of water after each use. After cleaning, flush away traces with water.

**Large Spill** : Absorb with inert, damp non-combustible material, then flush area with water.

### 6.4. Reference to other sections

**Reference to other sections** : Not Applicable

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

**Handling** : Keep away from heat sources and direct sunlight.

**Storage** : See product labeling.

### 7.2. Conditions for safe storage, including any incompatibilities

**Shelf life** : See product labeling

### 7.3. Specific end use(s)

**Specific end use(s)** : Professional Dental Anatomical Indicating Composite

## SECTION 8: Exposure controls / personal protection

### 8.1. Control parameters

**Control parameters** : None

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### 8.2. Exposure controls

**Eye/face protection** : Wear eye protection .

**Skin protection** : Wear suitable protective clothing and gloves.

**Respiratory protection** : Good general ventilation should be sufficient to control airborne levels. In case of insufficient ventilation, wear suitable respiratory equipment.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

**Physical state** : Viscous substance

**Colour** : Purple

**Odour** : Acrylic

### 9.2. Other information

**Additional information** : No further relevant information available.

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

**Reactivity** : Polymerization occurs when exposed to visible light, ultraviolet light or extreme heat.

### 10.2. Chemical stability

**Chemical stability** : Stable when stored and handled under recommended conditions.

### 10.3. Possibility of hazardous reactions

**Hazardous polymerization** : None

### 10.4. Conditions to avoid

**Conditions to avoid** : Light, Heat

### 10.5. Incompatible materials

**Incompatible materials** : Not Determined

### 10.6. Hazardous decomposition products

**Hazardous decomposition products** : None known.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

#### Acute

**Dermal LD<sub>50</sub>** : > 2000 mg/kg Mouse/Rat

**Notes** : ~80% of the mixture consists of components of unknown toxicity (Dermal).

**Oral LD<sub>50</sub>** : > 4500 mg/kg Rat

**Notes** : ~73% of the mixture consists of components of unknown toxicity (Oral)

**Inhalation LC<sub>50</sub>** : Not able to calculate ATE mix (inhalation) due to lack of data on the components.

**Other information** : Device is biocompatible when used as directed by dental professionals per ISO

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10993-1.

### SECTION 12: Ecological information

#### 12.1. Toxicity

**Aquatic toxicity (acute)** : No specific hazards are encountered when product is used according to recommendations.

#### 12.2. Persistence and degradability

**Persistence and degradability** : Not classified

#### 12.3. Bioaccumulative potential

**Bioaccumulative potential** : Not classified

#### 12.4. Mobility in soil

**Mobility in soil** : Not Available

#### 12.5. Results of PBT and vPvB assessment

**Results of PBT and vPvB assessment** : Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

#### 12.6. Other adverse effects

**Environmental data** : No further relevant information available.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

**Disposal method** : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

### SECTION 14: Transport information

#### 14.1. UN number

**UN number** : NAP

#### 14.2. UN proper shipping name

**UN proper shipping name** : Not Dangerous Goods

#### 14.3. Transport hazard class(es)

**Hazard classification** : NAP

#### 14.4. Packing group

**Packing group** : NAP

#### 14.5. Environmental hazards

**Marine pollutant #1** : NAP

#### 14.6. Special precautions for user

**ADR - road** : NAP

**RID - rail** : NAP

**IMDG - sea** : NAP

**IATA - air** : NAP

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### 14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk : NAP

### SECTION 15: Regulatory information

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

**General information** : Substances of very high concern (SVHC) according to REACH, Article 57:  
Contains no SVHC substances.

**General comments** : Please refer to Medical Devices Directive 93/42/EEC.

#### 15.2. Chemical safety assessment

**Chemical safety assessment** : See Section 11

**Additional information** : This product is not considered dangerous for transportation.

### SECTION 16: Other information

**Relevant H-statements (number and full text)** : Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4  
Skin Sens., Cat. 1B: Skin Sensitization, Category 1B  
Skin Sens., Cat. 1: Skin Sensitization, Category 1  
H302: Harmful if swallowed.  
H315: Causes skin irritation.  
H317: May cause an allergic skin reaction.  
H319: Causes serious eye irritation.

**Prepared by** : Anu Kattoju

**Revision summary** : This SDS replaces the 07/14/2015 SDS. Revised: **Section 1:** MSDS  
No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3.  
Other hazards. **Section 4:** EYES, SIGNS AND SYMPTOMS OF  
OVEREXPOSURE - INHALATION. **Section 5:** EXPLOSION HAZARDS,  
EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT,  
SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:**  
WATER SPILL. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT -  
RESPIRATORY. **Section 9:** COMMENTS, PERCENT VOLATILE. **Section**  
**10:** CONDITIONS TO AVOID, STABLE. **Section 11:** ACUTE ( DERMAL LD<sub>50</sub>  
(rabbit), DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), ORAL LD<sub>50</sub> (rat),  
INHALATION LC<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat)  
ACUTE, GENERAL COMMENTS. **Section 12:** CHEMICAL FATE  
INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA,  
BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE),  
AQUATIC TOXICITY (ACUTE) ( 48-HOUR EC<sub>50</sub>, 96-HOUR EC<sub>50</sub> ), SECTION  
12: Ecological information. **Section 14:** ROAD AND RAIL (ADR/RID), VESSEL  
(IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) -  
SPECIAL PROVISIONS SECTION 14: Transport information, UN number,  
Packing group, ADR - road, IMDG - sea, IATA - air. **Section 15:** COMMENTS,  
GENERAL COMMENTS, RoHS. **Section 16:** GENERAL STATEMENTS.

**General statements** : NAP = Not Applicable  
NE = Not Established  
TLV = Threshold Limit Value

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PEL = Permittable exposure limits  
MAK = Maximum Workplace Concentration  
STEL = Short-term exposure limit  
STEV = Short-term exposure value  
TWA = Time Weighted Average  
PPE = Personal Protective Equipment  
AMU = Atomic Mass Unit

**Manufacturer disclaimer**

: FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.