

# SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010  
Dental Use

**ULTRADENT**  
PRODUCTS, INC.

Date Issued : 04/14/2006  
SDS No : 45-001.8  
Date Revised : 04/20/2017  
Revision No : 8

## PermaFlo® DC - Base

### SECTION 1 : Identification of the substance/preparation and of the company/undertaking

#### 1.1. Product identifier

**Product code** : RD/63594, RE/63593, RO/63544,RX/63592  
**Product name** : PermaFlo® DC - Base  
**Product description** : Dual Cure Composite Luting / Restorative Resin

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

**Relevant identified uses** : Professional Dental Restorative Material

#### 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 1

#### 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** : P261: Avoid breathing dust/fumes/gas/mist/vapours/spray.  
P272: Contaminated work clothing should not be allowed out of the workplace.  
P280: Wear protective gloves/protective clothing/eye protection/face protection.

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**Response** : P302+P352: IF ON SKIN: Wash with plenty of soap and water.  
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.  
P363: Wash contaminated clothing before reuse.

**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]
TEGDMA	109-16-0	203-652-6	≤ 20	Skin Sens.,Cat. 1B; H317
Bis-GMA	1565-94-2	216-367-7	< 10	H315; H317; H319

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 for 5 minutes. 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** : No special measures required.

**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 irritation.

**Skin** : May cause skin irritation and sensitization.

**Ingestion** : None expected for this product.

**Inhalation** : None expected for this product.

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

**Notes to physician** : NAP

## SECTION 5: Fire fighting measures

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**5.1. Extinguishing media**

**Extinguishing media** : Foam, dry chemical, carbon dioxide (CO<sub>2</sub>).

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

**Hazardous combustion products** : Information not available

**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** : Do not allow to enter sewers or drains that may lead to waterways.

**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** : NAP

**SECTION 7: Handling and storage**

**7.1. Precautions for safe handling**

**General procedures** : Avoid contact with eyes, skin and clothing.

**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 Restorative Material

**SECTION 8: Exposure controls / personal protection**

**8.1. Control parameters**

**Control parameters** : None Required

**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.

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### SECTION 9: Physical and chemical properties

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

Physical state	: Viscous substance
Appearance	: Opaque high viscosity material
Colour	: Shade dependent.
Odour	: Acrylic
pH	: NAP (non-aqueous)
Specific gravity	: 1.8 - 2.1

#### 9.2. Other information

Additional information	: No further relevant information available
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### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

Reactivity	: Polymerization occurs when exposed to visible light, ultraviolet light or extreme heat.
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#### 10.2. Chemical stability

Chemical stability	: Stable when stored and handled under recommended conditions.
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#### 10.3. Possibility of hazardous reactions

Hazardous polymerization	: None
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#### 10.4. Conditions to avoid

Conditions to avoid	: Visible light, ultraviolet light, and extreme heat
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#### 10.5. Incompatible materials

Incompatible materials	: None known.
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#### 10.6. Hazardous decomposition products

Hazardous decomposition products	: None known.
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### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

##### Acute

Dermal LD <sub>50</sub>	: > 9000 mg/kg Mouse/Rabbit/Hamster
Notes	: ~72% of the mixture consists of components of unknown toxicity (Dermal).
Oral LD <sub>50</sub>	: > 4900 mg/kg Rat
Notes	: ~75% of the mixture consists of components of unknown toxicity (Oral)
Inhalation LC <sub>50</sub>	: > 0.3 mg/L/4H Rat
Notes	: ~34% of the mixture consists of components of unknown toxicity (inhalation). This substance is a viscous gel, therefore chance of inhalation is extremely low.
Germ cell mutagenicity	: The components in this product are not reported to produce mutagenic effects in humans.

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<b>Carcinogenicity</b>	: None of the components of this material are listed by IARC, NTP, or CA Prop 65 as carcinogens.
<b>Reproductive toxicity</b>	: The components in this product are not reported to cause reproductive effects in humans.
<b>Other information</b>	: Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

**SECTION 12: Ecological information**

**12.1. Toxicity**

**Aquatic toxicity (acute)** : Do not allow to enter sewers or drains that may lead to waterways.

**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**

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ADR - road : NAP  
RID - rail : NAP  
IMDG - sea : NAP  
IATA - air : NAP

### 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** : None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.  
This product is not considered dangerous for transportation.

## SECTION 16: Other information

**Relevant H-statements (number and full text)** : Skin Sens., Cat. 1B: Skin Sensitization, Category 1B  
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 09/03/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 3:** Wt.%. **Section 4:** EYES, INGESTION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE ( SKIN ). **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** . **Section 7:** GENERAL PROCEDURES. **Section 8:** . **Section 9:** APPEARANCE, COMMENTS, PERCENT VOLATILE, pH, SPECIFIC GRAVITY. **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), INHALATION LC<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat) ACUTE, GENERAL COMMENTS, CARCINOGENICITY, GERM CELL MUTAGENICITY, REPRODUCTIVE TOXICITY. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, 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

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POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS  
 SECTION 14: Transport information, UN number, Primary hazard class/division,  
 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  
 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.