

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



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 (CO₂).

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 ₅₀	: > 9000 mg/kg Mouse/Rabbit/Hamster
Notes	: ~72% of the mixture consists of components of unknown toxicity (Dermal).
Oral LD ₅₀	: > 4900 mg/kg Rat
Notes	: ~75% of the mixture consists of components of unknown toxicity (Oral)
Inhalation LC ₅₀	: > 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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Carcinogenicity	: None of the components of this material are listed by IARC, NTP, or CA Prop 65 as carcinogens.
Reproductive toxicity	: The components in this product are not reported to cause reproductive effects in humans.
Other information	: 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 LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (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 EC₅₀, 96-HOUR EC₅₀), 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.