

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 8/4/2006

SDS No : 55-001.6

Date Revised : 9/2/2014

Revision No : 6

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

Product code : JA/94705, JB/94608, JC/94617, JD/94621, JE/94625, JF/94630,
JG/94636, JV/76377, JW/76387

Product name : PermaFlo®

Product description : Light cure luting and flowable composite

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. 10200 S.
South Jordan, UT 84095

Distributor

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 Directive 1999/45/EC**

Danger symbols : Xi

R phrases : R36/38,R43

2.2. Label elements**Classification according to Directive 1999/45/EC**

Hazard pictogram(s) : Xi



Irritant

R&S statement(s) : R36/38: Irritating to eyes and skin.
R43: May cause sensitization by skin contact.

Classification according to Regulation (EC) No 1272/2008 [CLP]

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PRODUCTS, INC.

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Hazard pictogram(s)

:



Exclamation
mark

Signal Word

: WARNING

Hazard statement(s)

: H320: Causes eye irritation.
H315: Causes skin irritation.
H317: May cause an allergic skin reaction.

2.3. Other hazards

Immediate concerns

: No Immediate Concerns

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Directive 67/548/EEC
Triethylene Glycol Dimethacrylate	109-16-0	203-652-6	< 25	Xi; R43
Bis GMA	1565-94-2	216-367-7	< 10	Xi; R36/37/38;R22
Sodium Monofluorophosphate	10163-15-2	233-433-0	0.3	T; R22; R38

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes

: Flush eye with water for 15 minutes. Get medical attention.

Following skin

: Wash with soap and water. Get medical attention if irritation develops or persists.

Following ingestion

: If swallowed, rinse mouth with water, Do NOT Induce Vomiting. Give victim a glass of water or milk. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person.

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.

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

Eyes	: Irritating to eyes.
Skin	: May cause slight irritation.
Ingestion	: May be harmful if swallowed.
Inhalation	: Maybe harmful if inhaled.

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

Notes to physician	: Not Applicable
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SECTION 5: Fire fighting measures

5.1. Extinguishing media

Extinguishing media	: Please see Fire Fighting Equipment under Section 5.3.
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5.2. Special hazards arising from the substance or mixture

Explosion hazards	: Not Determined
Fire explosion	: Not Determined
Sensitive to static discharge	: Not Determined
Sensitivity to impact	: Not Determined

5.3. Advice for firefighters

Fire fighting procedures	: As in any fire, wear self-contained breathing apparatus pressure-demand, (MSHA/NIOSH approved or equivalent) and full protective gear.
Fire fighting equipment	: Water spray, fog, or mist, foam, dry chemical, carbon dioxide(CO ₂)

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General procedures	: Refer to Section 8 for Personal Protective Equipment.
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6.2. Environmental precautions

Water spill	: Do not allow to enter sewers or drains that may lead to waterways.
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6.3. Methods and material for containment and cleaning up

Small spill	: Clean up spills immediately, observing precautions in Protective Equipment section.
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6.4. Reference to other sections

Reference to other sections	: Not Applicable
Additional information	: Refer particularly to local circumstances and regulations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Storage	: See product labeling.
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7.2. Conditions for safe storage, including any incompatibilities

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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 : Not Determined

8.2. Exposure controls

Eye/face protection : Wear safety glasses with side shields (or goggles) and a face shield.

Skin protection : S36/37: Wear suitable protective clothing and gloves.

Respiratory protection : Good general ventilation should be sufficient to control airborne levels.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Viscous substance

Colour : Shade dependent.

Odour : Acrylic

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable : Yes

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

Hazardous polymerization : No

10.4. Conditions to avoid

Conditions to avoid : Not Determined

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

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PermaFlo®**Acute**

Dermal LD₅₀ : Not Determined
Oral LD₅₀ : Not Determined
Inhalation LC₅₀ : Not Determined

SECTION 12: Ecological information**12.1. Toxicity**

Aquatic toxicity (acute) : Do not allow to enter sewers or drains that may lead to waterways.
96-hour LC₅₀ : Not Determined
48-hour EC₅₀ : Not Determined
96-hour EC₅₀ : Not Determined

12.2. Persistence and degradability

Persistence and degradability : Not Determined

12.3. Bioaccumulative potential

Bioaccumulative potential : Not Determined

12.4. Mobility in soil

Mobility in soil : Not Determined

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Not Determined

12.6. Other adverse effects

Environmental data : No data 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 : N/A

14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : N/A

14.4. Packing group

Packing group : N/A

14.5. Environmental hazards

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Marine pollutant #1 : Not Dangerous Goods

14.6. Special precautions for user

ADR - road : Not Dangerous Goods

RID - rail : Not Dangerous Goods

IMDG - sea : Not Dangerous Goods

IATA - air : Not Dangerous Goods

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

Transport in bulk : Not Dangerous Goods

SECTION 15: Regulatory information

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

RoHS : Please refer to Medical Devices Directive 93/42/EEC

15.2. Chemical safety assessment

Chemical safety assessment : Not Determined

Additional information : This product is not considered dangerous for transportation

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R22: Harmful if swallowed.
 R36/37/38: Irritating to eyes, respiratory system and skin.
 R38: Irritating to skin.
 R43: May cause sensitization by skin contact.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 4/9/2014 SDS. Revised: **Section 1:** . **Section 2:** . **Section 14:** AIR (ICAO/IATA) (SPECIAL PROVISIONS), ROAD AND RAIL (ADR/RID) (PROPER SHIPPING NAME), VESSEL (IMO/IMDG) (SPECIAL PROVISIONS), ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS.

General statements : N/A=Not Applicable

Manufacturer disclaimer : FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material MSDS(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.