

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 09/27/2007

SDS No : 183-001.4

Date Revised : 01/16/2017

Revision No : 3

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

Product code : JX/10065
 Product name : PermaFlo® Pink
 Product description : Flowable Composite

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

Relevant identified uses : Professional Dental Composite for Masking Gingival Recession

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 (CO₂)

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 Composite for Masking Gingival Recession

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 : Pink

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 LD₅₀ : > 2000 mg/kg Mouse/Rat

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

Oral LD₅₀ : > 4500 mg/kg Rat

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

Inhalation LC₅₀ : 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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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 : N/A

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 05/01/2015 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. **Section 11:** ACUTE (DERMAL LD₅₀ (rabbit),
DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), ORAL LD₅₀ (rat), INHALATION
LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat) ACUTE,
GENERAL COMMENTS. **Section 12:** CHEMICAL FATE INFORMATION,
DISTRIBUTION, ENVIRONMENTAL DATA,
BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE),
AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), SECTION
12: Ecological information. **Section 14:** ROAD AND RAIL (ADR/RID), 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.