according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 4/14/2006

SDS No : 45-001.5 **Date Revised :** 4/9/2014

Revision No: 5

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: Dental Restorative Material

1.3. Details of the supplier of the safety data sheet

Manufacturer Distributor

Ultradent Products, Inc.

505 W. 10200 S.

South Jordan, UT 84095

UP Dental GmbH

Am Westhover Berg 30

51149 Cologne Germany

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,R43

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : Xi



IIIIlaiil

R&S statement(s) : R36: Irritating to eyes.

R43: May cause sensitization by skin contact.

2.3. Other hazards

Immediate concerns : No Immediate Concerns

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

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



Date Issued : 4/14/2006

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Date Revised: 4/5/

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PermaFlo® DC Base

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 | < 15 | Xi; R36/37/38;R22 |

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: Hold eyelids apart and flush eyes with plenty of water for at least 15

minutes.

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.

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

Eyes : Causes eye irritation.

Skin
Ingestion
Inhalation
May cause sensitization to skin.
None expected for this product.
None expected for this product.

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 : Please see Fire Fighting Equipment under Section 5.3.

5.2. Special hazards arising from the substance or mixture

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

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



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Sensitivity to impact : Not Determined

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.

Fire fighting equipment: Foam, dry chemical, carbon dioxide (CO₂).

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: Not Applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling : Keep away from sources of ignition 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 : Not Determined

8.2. Exposure controls

Eye/face protection: Wear eye protection

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

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

levels.S38: In case of insufficient ventilation, wear suitable respiratory

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



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equipment.

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: Not Dete

products

: Not Determined

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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

according to Regulation (EC) No. 453/2010

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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 classified

14.3. Transport hazard class(es)

Primary hazard class/division: N/A **Hazard classification**: N/A

14.4. Packing group

14.5. Environmental hazards

Marine pollutant #1 : N/A

14.6. Special precautions for user

 ADR - road
 : N/A

 RID - rail
 : N/A

 IMDG - sea
 : N/A

 IATA - air
 : N/A

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

Transport in bulk : N/A

SECTION 15: Regulatory information

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

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



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

15.2. Chemical safety assessment

Chemical safety assessment

: Not Determined

Additional information

None of the ingredients are listed with: SARA Sect. 355 (extremely hazardous substances) or SARA Sect.313 (specific toxic chemical listings). Prop 65- Chemicals known to cause cancer. They are not listed in the Cancerogenity categories with the following agencies:

EPA, IARC, NTP, TLV, NIOSH-Ca, OSHA-Ca.

SECTION 16: Other information

Relevant R-phrases and/or Hstatements (number and full

text)

Prepared by

Revision summary
General statements

Manufacturer disclaimer

: R22: Harmful if swallowed.

R36/37/38: Irritating to eyes, respiratory system and skin.

R43: May cause sensitization by skin contact.

: Anu Kattoju

: This MSDS replaces the 4/9/2014 MSDS.

: N/A=Not Applicable

: 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.

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



Date Issued: 5/22/2006

SDS No: 52-001.4 **Date Revised** : 4/9/2014

Revision No: 4

PermaFlo® DC Catalyst Regular

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

1.1. Product identifier

Product code : RC/63698

Product name : PermaFlo® DC Catalyst Regular

Product description : Luting Cement Catalyst

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

Relevant identified uses : Dental Restorative Material

1.3. Details of the supplier of the safety data sheet

Manufacturer Distributor

Ultradent Products, Inc. UP Dental GmbH 505 W. 10200 S. Am Westhover Berg 30

South Jordan, UT 84095 51149 Cologne Germany

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,R43

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s)



R&S statement(s) : R36: Irritating to eyes.

R43: May cause sensitization by skin contact.

2.3. Other hazards

Immediate concerns : No Immediate Concerns

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

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



 $\textbf{Date Issued:}\ 5/22/2006$

SDS No : 52-001.4 **Date Revised :** 4/9/2014

Revision No: 4

PermaFlo® DC Catalyst Regular

3.2. Mixtures

| Chemical Name | CAS | EINECS No. | Wt.% | Classification according to Directive 67/548/EEC |
|-----------------------------------|-----------|------------|------|--|
| Bis GMA | 1565-94-2 | 216-367-7 | < 15 | Xi; R36/37/38;R22 |
| Triethylene Glycol Dimethacrylate | 109-16-0 | 203-652-6 | < 20 | Xi; R43 |

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: Hold eyelids apart and flush eyes with plenty of water for at least 15

minutes.

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.

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

Eyes : Causes eye irritation.

Skin : May cause sensitization to skin.

Ingestion : Substance maybe harmful if swallowed.

Inhalation: None expected for this product.

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 : Please see Fire Fighting Equipment under Section 5.3.

5.2. Special hazards arising from the substance or mixture

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

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



Date Issued : 5/22/2006

SDS No : 52-001.4 **Date Revised :** 4/9/2014

Revision No: 4

PermaFlo® DC Catalyst Regular

Sensitivity to impact : Not Determined

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.

Fire fighting equipment: Foam, dry chemical, carbon dioxide (CO₂).

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 : Not Applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling : Keep away from sources of ignition 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): 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 eye protection

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

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



Date Issued : 5/22/2006

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PermaFlo® DC Catalyst Regular

9.1. Information on basic physical and chemical properties

Physical state : Viscous substance

Colour : Beige
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 : None known.

10.5. Incompatible materials

Incompatible materials: None known.

10.6. Hazardous decomposition products

Hazardous decomposition: None known.

products

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD50: Not DeterminedOral LD50: Not DeterminedInhalation 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
48-hour EC₅₀
96-hour EC₅₀
Not Determined
Not Determined

12.2. Persistence and degradability

Persistence and degradability : Not Determined

according to Regulation (EC) No. 453/2010

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Date Issued : 5/22/2006 **SDS No :** 52-001.4

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PermaFlo® DC Catalyst Regular

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 classified

14.3. Transport hazard class(es)

Primary hazard class/division : N/A Hazard classification : N/A

14.4. Packing group

Packing group : N/A

14.5. Environmental hazards

Marine pollutant #1 : N/A

14.6. Special precautions for user

ADR - road : N/A
RID - rail : N/A
IMDG - sea : N/A
IATA - air : N/A

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

Transport in bulk : N/A

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

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



Date Issued: 5/22/2006

SDS No: 52-001.4 **Date Revised :** 4/9/2014

Revision No: 4

PermaFlo® DC Catalyst Regular

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 Hstatements (number and full

text)

Revision summary

Prepared by

General statements

Manufacturer disclaimer

: R22: Harmful if swallowed.

R36/37/38: Irritating to eyes, respiratory system and skin.

R43: May cause sensitization by skin contact.

: Anu Kattoju

: This MSDS replaces the 4/9/2014 MSDS.

: N/A=Not Applicable

: 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.