

SAFETY DATA SHEET

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

ULTRADENT
PRODUCTS, INC.

Date Issued : 10/31/2006
SDS No : 67-001.7
Date Revised : 09/19/2016
Revision No : 6

Composite Wetting Resin

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

1.1. Product identifier

Product code : CW/13575
Product name : Composite Wetting Resin
Product description : Liquid resin for adaptation of composite restoration and preparation

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

Relevant identified uses : Professional Dental Composite Facilitating Agent

1.3. Details of the supplier of the safety data sheet

Manufacturer

Ultradent Products, Inc.
505 W. 10200 S.
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 Directive 1999/45/EC

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Danger symbols : Xi

R phrases : R36/38

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

Health : Skin Irritation, Category 2
Skin Sensitization, Category 1
Eye Irritation, Category 2

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : Xi



Irritant

R& statement(s) : R36/38: Irritating to eyes and skin.

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


SAFETY DATA SHEET

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

ULTRADENT
PRODUCTS, INC.

Date Issued : 10/31/2006
SDS No : 67-001.7
Date Revised : 09/19/2016
Revision No : 6

Composite Wetting Resin

Hazard pictogram(s)	:	 Exclamation mark
Signal Word	:	WARNING
Hazard statement(s)	:	H317: May cause an allergic skin reaction. H315: Causes skin irritation. H319: Causes serious eye irritation.
Precautionary statement(s)	:	
Prevention	:	P280: Wear protective gloves/protective clothing/eye protection/face protection.
Response	:	P305: IF IN EYES: P351: Rinse cautiously with water for several minutes. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P332+P313: If skin irritation occurs: Get medical advice/attention.
Storage	:	P273: Avoid release to the environment.
Disposal	:	P501: Dispose of in compliance with governmental regulation. (EC1975L0442-20/11/2003)

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 Directive 67/548/EEC	Classification according to Regulation(EC) No 1272/2008 [CLP]
Triethylene Glycol Dimethacrylate	109-16-0	203-652-6	< 20	Xi; R43	Skin Sens.,Cat. 1B; H317
Bis-GMA	1565-94-2	216-367-7	< 20	Xi; R22; R36/37/38	Skin Irr.,Cat. 2; Eye Irr.,Cat. 2B; Skin Sens.,Cat. 1; H315; H317; H319

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 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.

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



Date Issued : 10/31/2006
SDS No : 67-001.7
Date Revised : 09/19/2016
Revision No : 6

Composite Wetting Resin

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.

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

Eyes : May be mildly irritating to eyes.

Skin : May cause skin irritation and sensitization.

Ingestion : Maybe harmful if swallowed in large quantities.

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 : 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 : 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

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

Handling : Keep away from heat sources and direct sunlight.

Storage : See product labeling.

SAFETY DATA SHEET

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



Date Issued : 10/31/2006
SDS No : 67-001.7
Date Revised : 09/19/2016
Revision No : 6

Composite Wetting Resin

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 Facilitating Agent

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : None

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Low viscosity liquid

Colour : Slight yellow tint

Odour : Acrylic

pH : NAP (non-aqueous)

Specific gravity : 1.5 to 1.6

9.2. Other information

Percent volatile : Not Determined

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 exposure

10.5. Incompatible materials

Incompatible materials : Not Determined

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

SAFETY DATA SHEET

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



Date Issued : 10/31/2006
SDS No : 67-001.7
Date Revised : 09/19/2016
Revision No : 6

Composite Wetting Resin

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

- Dermal LD₅₀** : > 2000 mg/kg mouse/rat
- Notes** : ~81% of the mixture consists of components of unknown toxicity (dermal).
- Oral LD₅₀** : > 2500 mg/kg Rat/Mouse
- Notes** : ~62% 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 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** : Do not allow to enter sewers or drains that may lead to waterways.

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

SAFETY DATA SHEET

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



Date Issued : 10/31/2006
SDS No : 67-001.7
Date Revised : 09/19/2016
Revision No : 6

Composite Wetting Resin

14.4. Packing group

Packing group : NAP

14.5. Environmental hazards

Marine pollutant #1 : NAP

14.6. Special precautions for user

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 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 R-phrases and/or H-statements (number and full text) : R22: Harmful if swallowed.
R36/37/38: Irritating to eyes, respiratory system and skin.
R43: May cause sensitization by skin contact.
Eye Irr., Cat. 2B: Eye Irritation, Category 2B
Skin Irr., Cat. 2: Skin Irritation, Category 2
Skin Sens., Cat. 1B: Skin Sensitization, Category 1B
Skin Sens., Cat. 1: Skin Sensitization, Category 1
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 04/27/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 4:** INGESTION, INHALATION, SIGNS AND SYMPTOMS OF OVEREXPOSURE (INHALATION, SKIN). **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 7:** GENERAL PROCEDURES. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY . **Section 9:** COLOR, pH, PHYSICAL STATE, SPECIFIC GRAVITY. **Section 10:** CONDITIONS TO

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 10/31/2006

SDS No : 67-001.7

Date Revised : 09/19/2016

Revision No : 6

Composite Wetting Resin

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), VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 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
 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

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.