

# SAFETY DATA SHEET

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

**ULTRADENT**  
PRODUCTS, INC.

Date Issued : 06/10/2011  
SDS No : 220-001.06  
Date Revised : 04/10/2018  
Revision No : 5

## Opal® Band™ Cement - Catalyst

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

#### 1.1. Product identifier

Product code : RY/71101  
Product name : Opal® Band™ Cement - Catalyst  
Product description : Catalyst for orthodontic cement

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

Relevant identified uses : Professional Orthodontic Cement

#### 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** : Eye Damage, Category 1  
Skin Sensitization, Category 1  
Acute Toxicity (Inhalation), Category 4

#### 2.2. Label elements

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

Hazard pictogram(s) :    
Exclamation mark      Corrosive

Signal Word : DANGER

Hazard statement(s) : H318: Causes serious eye damage.  
H317: May cause an allergic skin reaction.  
H332: Harmful if inhaled.

##### Precautionary statement(s)

Prevention : P280: Wear protective gloves/protective clothing/eye protection/face protection.

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P261: Avoid breathing vapours.  
P272: Contaminated work clothing should not be allowed out of the workplace.  
P271: Use only outdoors or in a well-ventilated area.  
P270: Do not eat, drink or smoke when using this product.  
P264: Wash hands thoroughly after handling.

### Response

: P310: Immediately call a POISON CENTER or doctor/physician.  
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P302+P352: IF ON SKIN: Wash with plenty of soap & water.  
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.  
P363: Wash contaminated clothing before reuse.  
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P312: Call a POISON CENTER or doctor/physician if you feel unwell.

### 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 Regulation(EC) No 1272/2008 [CLP]
Bis-GMA	1565-94-2	216-367-7	< 20	H315; H317; H319
Poly(ethylene glycol) diacrylate	26570-48-9	607-960-5	< 15	Skin Irr.,Cat. 2; Skin Sens.,Cat. 1; EYE DMG.,Cat. 1; H315; H317; H318
TEGDMA	109-16-0	203-652-6	< 10	Skin Sens.,Cat. 1B; H317

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

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

#### Following eyes

: Remove contact lenses, if present and easy to do. Flush eyes with plenty of water for at least 15 minutes, opening the eyelids fully. Seek immediate medical advice.

#### Following skin

: Remove contaminated clothing. Wash with soap and water. Get medical attention if irritation or sensitization develops or persists. Wash contaminated clothing before reuse.

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Following ingestion : No special measures required.  
 Following inhalation : Rest in the fresh air and seek medical advice if necessary.

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

Eyes : Causes eye irritation.  
 Skin : May cause skin irritation and sensitization.  
 Ingestion : None expected for this product.  
 Inhalation : May be harmful if inhaled.

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

Notes to physician : NAP

**SECTION 5: Fire fighting measures**

**5.1. Extinguishing media**

Extinguishing media : Water spray, fog, or mist, foam, dry chemical, carbon dioxide (CO<sub>2</sub>)

**5.2. Special hazards arising from the substance or mixture**

Hazardous combustion products : Carbon dioxide

**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 with cloth, soap and 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**

Handling : Stable when stored and handled under recommended conditions.  
 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 Orthodontic Cement

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**SECTION 8: Exposure controls / personal protection**

**8.1. Control parameters**

**Control parameters** : Contains no substances with occupational exposure limit values.

**8.2. Exposure controls**

**Eye/face protection** : Wear eye protection.

**Skin protection** : Wear suitable protective clothing and gloves.

**Respiratory protection** : 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** : Paste

**Appearance** : Medium viscosity

**Colour** : Yellow

**Odour** : Acrylic

**pH** : NAP (non-aqueous)

**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** : Visible light, ultraviolet light, and extreme heat

**10.5. Incompatible materials**

**Incompatible materials** : None known.

**10.6. Hazardous decomposition products**

**Hazardous decomposition products** : Carbon dioxide

**SECTION 11: Toxicological information**

**11.1. Information on toxicological effects**

**Acute**

**Dermal LD<sub>50</sub>** : > 3800 mg/kg Rabbit/Rat/Mouse

**Notes** : ~82% of the mixture consists of components of unknown toxicity (Dermal).

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<b>Oral LD<sub>50</sub></b>	: > 3500 mg/kg Rat OECD Test Guideline
<b>Notes</b>	: ~ 77% of the mixture consists of components of unknown toxicity (Oral).
<b>Inhalation LC<sub>50</sub></b>	: > 0.130 mg/L/4H Rat
<b>Notes</b>	: ~97% of the mixture consists of components of unknown toxicity (Inhalation). This substance is a paste so chance of inhalation is extremely low.
<b>Germ cell mutagenicity</b>	: The components in this product are not reported to produce mutagenic effects in humans.
<b>Carcinogenicity</b>	: None of the components of this material are listed by IARC, NTP, or CA Prop 65 as carcinogens.
<b>Reproductive toxicity</b>	: The components in this product are not reported to cause reproductive effects in humans.
<b>Other information</b>	: 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)**

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Hazard classification : NAP

**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 information** : European Substances of very high concern (SVHC) according to REACH, Article 57: Contains no SVHC Substances.  
CAN: All of the raw materials listed in Section 3 are on the Candian DSL list.

**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)** : EYE DMG., Cat. 1: Eye Damage, Category 1  
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.  
H318: Causes serious eye damage.  
H319: Causes serious eye irritation.

**Prepared by** : Anu Kattoju

**Revision summary** : This SDS replaces the 09/11/2017 SDS. Revised: **Section 1**: MSDS No.

**General statements** : NAP = Not Applicable  
NE = Not Established  
TLV = Threshold Limit Value  
PEL = Permittable exposure limits  
MAK = Maximum Workplace Concentration

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STEL = Short-term exposure limit  
STEV = Short-term exposure value  
TWA = Time Weighted Average  
PPE = Personal Protective Equipment

**Manufacturer disclaimer**

: FOR ORTHO 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.