

# SAFETY DATA SHEET

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

**ULTRADENT**  
PRODUCTS, INC.

Date Issued : 07/18/2014  
SDS No : 368-001.03  
Date Revised : 03/12/2018  
Revision No : 2

## Opal® Bond™ MV

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

#### 1.1. Product identifier

Product code : OV/71025  
Product name : Opal® Bond™ MV  
Product description : Light-Cured Bonding Adhesive

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

Relevant identified uses : Professional Orthodontic Adhesive

#### 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 Irritation, Category 2  
Skin Irritation, Category 2

#### 2.2. Label elements

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

Hazard pictogram(s) :



Exclamation  
mark

**Signal Word** : WARNING

**Hazard statement(s)** : H319: Causes serious eye irritation.  
H315: Causes skin irritation.

##### Precautionary statement(s)

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

**Response** : P305: IF IN EYES:

# SAFETY DATA SHEET

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Orthodontic Use



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## Opal® Bond™ MV

P351: Rinse cautiously with water for several minutes.  
P313: Get medical advice/attention.  
P306+P360: IF ON CLOTHING: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.  
P332+P313: If skin irritation occurs: Get medical advice/attention.  
P363: Wash contaminated clothing before reuse.  
P301: IF SWALLOWED:  
P331: Do NOT induce vomiting.  
P330: Rinse mouth.  
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	< 35	H315; H317; H319
Bis EMA	41637-38-1	NAP	< 15	Skin Irr.,Cat. 2; Skin Sens.,Cat. 1; Eye Irr.,Cat. 2; STOT SE,CAT 3; H315; H317; H319; H335
Acetoacetoxyethyl Methacrylate	21282-97-3	244-311-1	< 20	Not classified
Aluminum Oxide	1344-28-1	215-691-6	< 10	Not Classified

For full text of H-statements: 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 immediately with plenty of water. Remove contaminated clothing. If irritation persists seek medical attention. Wash contaminated clothing before using them.  
**Following ingestion** : If swallowed Don't induce vomiting. Rinse mouth and seek medical advice if necessary.  
**Following inhalation** : No specific treatment is necessary since this material is not likely to be hazardous by inhalation.

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**Opal® Bond™ MV**

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

**Eyes** : Causes eye irritation.  
**Skin** : Causes skin irritation.  
**Ingestion** : May be harmful if swallowed.  
**Inhalation** : None expected for this product.

**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** : Foam, dry chemical, carbon dioxide (CO<sub>2</sub>).

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

**Hazardous combustion products** : 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.

**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** : Pick up wash liquid with additional absorbent and place in a disposable container.

**Large Spill** : Collect in tightly closed containers.

**6.4. Reference to other sections**

**Reference to other sections** : NAP

**SECTION 7: Handling and storage**

**7.1. Precautions for safe handling**

**Handling** : Use suitable protective equipment.

**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 Adhesive

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

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### 8.1. Control parameters

Control parameters : Aluminum Oxide CAS: 1344-28-1

Control Parameters	Exposure Limits
OSHA PEL Respirable fraction	5 mg/m <sup>3</sup>
OSHA PEL Total Dust	15 mg/m <sup>3</sup>
OSHA TWA Total Dust	10 mg/m <sup>3</sup>
OSHA TWA Respirable Fraction	5 mg/m <sup>3</sup>
OSHA TWA Respirable Fraction	1 mg/m <sup>3</sup>

### 8.2. Exposure controls

Eye/face protection : Wear eye protection.

Skin protection : Wear suitable protective clothing and gloves.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state : Paste  
Colour : White with slight to no yellowish tint  
Odour : Acrylic  
pH : NAP (non-aqueous)  
Specific gravity : 2.026

### 9.2. Other information

Additional information : No further relevant information available.

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Reactivity : Stable

### 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 : Heat, flames, ignition sources, direct light.

### 10.5. Incompatible materials

Incompatible materials : None known.

### 10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

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**Opal® Bond™ MV**

<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(I) The substance does not fulfill the PBT and vPvB criteria for screening assessment there is 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**

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**Opal® Bond™ MV**

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.  
All of the raw materials listed on the composition table are on the Canadian 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** : This product is not considered dangerous for transportation.

**SECTION 16: Other information**

**Relevant H-statements (number and full-text)** : Eye Irr., Cat. 2: Eye Irritation, Category 2  
Not Classified, : Not Classified,  
STOT SE, CAT 3: Target Organ Toxicity (Single exposure), Central Nervous System Category 3  
Skin Irr., Cat. 2: Skin Irritation, Category 2  
Skin Sens., Cat. 1: Skin Sensitization, Category 1  
H315: Causes skin irritation.  
H317: May cause an allergic skin reaction.  
H319: Causes serious eye irritation.  
H335: May cause respiratory irritation.

**Prepared by** : Anu Kattoju

**Revision summary** : This SDS replaces the 09/24/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 4:** NOTES TO PHYSICIAN. **Section 5:** EXTINGUISHING MEDIA, FIRE FIGHTING EQUIPMENT. **Section 6:** . **Section 8:** . **Section 9:** COMMENTS, ODOR, PERCENT VOLATILE, pH, SPECIFIC GRAVITY. **Section 11:** ACUTE, GENERAL COMMENTS, CARCINOGENICITY, GERM CELL MUTAGENICITY, REPRODUCTIVE TOXICITY. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) ( 48-HOUR EC<sub>50</sub>, 96-HOUR EC<sub>50</sub> ), SECTION 12: Ecological information. **Section 14:** ROAD AND RAIL (ADR/RID), VESSEL

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**Opal® Bond™ MV**

(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:** GENERAL COMMENTS, RoHS. **Section 16:** Revision Summary, 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 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.