

**Safety Data Sheet**  
*acc. to OSHA HCS*

Printing date 07/09/2020

Reviewed on 04/23/2020

**1 Identification**

- **Product identifier**
- **Trade name:** Opal™ Bond™ MV
- **Article number:** 71025
- **Index number:** 368-001.05
- **Application of the substance / the mixture** Professional Orthodontic Adhesive
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ultradent Products Inc.  
505 W. Ultradent Drive (10200 S)  
South Jordan, UT 84095-3942  
USA  
onlineordersupport@ultradent.com
- **Information department:** Customer Service
- **Emergency telephone number:**  
CHEMTREC (NORTH AMERICA) : (800) 424-9300  
(INTERNATIONAL) : +(703) 527-3887

**2 Hazard(s) identification**

- **Classification of the substance or mixture**



*Skin Sens. 1 H317 May cause an allergic skin reaction.*

- **Label elements**
- **GHS label elements**  
*Medical Devices are exempt from the labeling requirements of the Globally Harmonized System (GHS).*
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard-determining components of labeling:**  
Diurethane Dimethacrylate  
Triethylene Glycol Dimethacrylate  
2-Hydroxyethyl Methacrylate
- **Hazard statements**  
*May cause an allergic skin reaction.*
- **Precautionary statements**  
*Avoid breathing dust/fume/gas/mist/vapors/spray*  
*Contaminated work clothing must not be allowed out of the workplace.*  
*Wear protective gloves.*  
*If on skin: Wash with plenty of water.*  
*If skin irritation or rash occurs: Get medical advice/attention.*  
*Specific treatment (see on this label).*  
*Wash contaminated clothing before reuse.*  
*Dispose of contents/container in accordance with local/regional/national/international regulations.*

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· **Classification system:**· **NFPA ratings (scale 0 - 4)**· **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

· **Other hazards**· **Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.

### 3 Composition/information on ingredients

· **Chemical characterization: Mixtures**· **Description:** Mixture of the substances listed below with nonhazardous additions.· **Dangerous components:**

72869-86-4	Diurethane Dimethacrylate	>2.5-≤10%
1344-28-1	Aluminium Oxide	>2.5-≤10%
14808-60-7	Silica Glass	>2.5-≤10%
109-16-0	Triethylene Glycol Dimethacrylate	≤2.5%
868-77-9	2-Hydroxyethyl Methacrylate	0-≤2.5%

### 4 First-aid measures

· **Description of first aid measures**· **General information:** Immediately remove any clothing soiled by the product.· **After inhalation:**

This product is a thick paste, therefore inhalation is extremely unlikely.

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· **After eye contact:** Rinse opened eye for several minutes under running water.· **After swallowing:** Do not induce vomiting. Seek medical help if necessary.· **Information for doctor:**· **Most important symptoms and effects, both acute and delayed** No further relevant information available.· **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

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## 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
Foam, dry chemical, carbon dioxide  
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:**  
Wear self-contained respiratory protective device.  
Wear fully protective suit.

## 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Dispose contaminated material as waste according to item 13.  
Ensure adequate ventilation.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.
- **Protective Action Criteria for Chemicals**

- **PAC-1:**

72869-86-4	Diurethane Dimethacrylate	120 mg/m <sup>3</sup>
1344-28-1	Aluminium Oxide	15 mg/m <sup>3</sup>
14808-60-7	Silica Glass	0.075 mg/m <sup>3</sup>
109-16-0	Triethylene Glycol Dimethacrylate	33 mg/m <sup>3</sup>
868-77-9	2-Hydroxyethyl Methacrylate	1.9 mg/m <sup>3</sup>

- **PAC-2:**

72869-86-4	Diurethane Dimethacrylate	1,300 mg/m <sup>3</sup>
1344-28-1	Aluminium Oxide	170 mg/m <sup>3</sup>
14808-60-7	Silica Glass	33 mg/m <sup>3</sup>
109-16-0	Triethylene Glycol Dimethacrylate	360 mg/m <sup>3</sup>
868-77-9	2-Hydroxyethyl Methacrylate	21 mg/m <sup>3</sup>

- **PAC-3:**

72869-86-4	Diurethane Dimethacrylate	7,900 mg/m <sup>3</sup>
1344-28-1	Aluminium Oxide	990 mg/m <sup>3</sup>
14808-60-7	Silica Glass	200 mg/m <sup>3</sup>
109-16-0	Triethylene Glycol Dimethacrylate	2,100 mg/m <sup>3</sup>
868-77-9	2-Hydroxyethyl Methacrylate	1,000 mg/m <sup>3</sup>

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## 7 Handling and storage

- **Handling:**
- **Precautions for safe handling** *Ensure good ventilation/exhaustion at the workplace.*
- **Information about protection against explosions and fires:** *No special measures required.*
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** *Store in a cool location.*
- **Information about storage in one common storage facility:** *Not required.*
- **Further information about storage conditions:**  
*Protect from exposure to the light.*  
*Protect from heat*  
*See product labelling.*
- **Specific end use(s)** *Professional Orthodontic Adhesive*

## 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** *No further data; see item 7.*
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**  
*The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.*  
*At this time, the other constituents have no known exposure limits.*

### 1344-28-1 Aluminium Oxide

PEL	Long-term value: 15*; 5** mg/m <sup>3</sup> *Total dust; ** Respirable fraction
REL	Long-term value: 10* 5** mg/m <sup>3</sup> as Al*Total dust**Respirable/pyro powd./welding f.
TLV	Long-term value: 1* mg/m <sup>3</sup> as Al; *as respirable fraction

### 14808-60-7 Silica Glass

PEL	Long-term value: 0.05* mg/m <sup>3</sup> *resp. dust; 30mg/m3/%SiO2+2
REL	Long-term value: 0.05* mg/m <sup>3</sup> *respirable dust; See Pocket Guide App. A
TLV	Long-term value: 0.025* mg/m <sup>3</sup> *as respirable fraction

- **Additional information:** *The lists that were valid during the creation were used as basis.*
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
*Avoid contact with the eyes and skin.*  
*Immediately remove all soiled and contaminated clothing.*  
*Wash hands before breaks and at the end of work.*
- **Breathing equipment:**  
*In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.*

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· **Protection of hands:**

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material is based on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:** Not required.· **Body protection:** Protective work clothing

## 9 Physical and chemical properties

· **Information on basic physical and chemical properties**· **General Information**· **Appearance:**

<b>Form:</b>	Paste
<b>Color:</b>	Whitish
<b>Odor:</b>	Acrylic
<b>Odor threshold:</b>	Not determined.

· **pH-value:** Not applicable (non-aqueous)· **Change in condition**

<b>Melting point/Melting range:</b>	Undetermined.
<b>Boiling point/Boiling range:</b>	Undetermined

· **Flash point:** Not applicable· **Flammability (solid, gaseous):** Not determined.· **Decomposition temperature:** Not determined.· **Auto igniting:** Product is not selfigniting.· **Danger of explosion:** Product does not present an explosion hazard.· **Explosion limits:**

<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.

· **Vapor pressure:** Not applicable.

<b>Density at 20 °C:</b>	2.03 g/cm <sup>3</sup>
<b>Relative density</b>	Not determined
<b>Vapor density</b>	Not applicable.
<b>Evaporation rate</b>	Not applicable.

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- |   |   |
|---|---|
| <b>· Solubility in / Miscibility with Water:</b>  | <i>Insoluble.</i>                                 |
| <b>· Partition coefficient (n-octanol/water):</b> | <i>Not determined.</i>                            |
| <b>· Viscosity:</b>                               |   |
| <b>Dynamic:</b>                                   | <i>Not applicable.</i>                            |
| <b>Kinematic:</b>                                 | <i>Not applicable.</i>                            |
| <b>· Solvent content:</b>                         |   |
| <b>VOC (EC)</b>                                   | <i>&lt;1 %</i>                                    |
| <b>Solids content:</b>                            | <i>&lt;100.0 %</i>                                |
| <b>· Other information</b>                        | <i>No further relevant information available.</i> |

## 10 Stability and reactivity

- **Reactivity Stable**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** *No decomposition if used according to specifications.*
- **Possibility of hazardous reactions** *No dangerous reactions known.*
- **Conditions to avoid**
  - Light*
  - Ignition sources*
  - Flames*
  - Heat*
- **Incompatible materials:** *No further relevant information available.*
- **Hazardous decomposition products:** *No dangerous decomposition products known.*

## 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

### ATE (Acute Toxicity Estimate)

Dermal	LD50	>166,627 mg/kg (mouse)
Inhalative	LC50/4 h	22.8-37.9 mg/l

### 72869-86-4 Diurethane Dimethacrylate

Oral	LD50	>5,000 mg/kg (rat)
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### 1344-28-1 Aluminium Oxide

Oral	LD50	>5,000 mg/kg (rat)
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### 109-16-0 Triethylene Glycol Dimethacrylate

Oral	LD50	>5,000 mg/kg (rat)
	LC50 Fish	16.4 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>2,000 mg/kg (mouse)

### 868-77-9 2-Hydroxyethyl Methacrylate

Oral	LD50	3,275 mg/kg (mouse)
		>5,000 mg/kg (rat)

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Dermal	LC50 Fish	>100 mg/l (Fish)
	LD50	>3,000 mg/kg (rabbit)
	LC50(Daphnia magna)	24.1 mg/l (daphnia)

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**  
The product shows the following dangers according to internally approved calculation methods for preparations:  
Irritant

- **Carcinogenic categories**

· <b>IARC (International Agency for Research on Cancer)</b>		
14808-60-7	Silica Glass	I
128-37-0	Butylated Hydroxytoluene	3
· <b>NTP (National Toxicology Program)</b>		
14808-60-7	Silica Glass	K
· <b>OSHA-Ca (Occupational Safety &amp; Health Administration)</b>		
None of the ingredients is listed.		

## 12 Ecological information

- **Toxicity**

· <b>Aquatic toxicity:</b>	
<b>72869-86-4 Diurethane Dimethacrylate</b>	
Biodegradability	28 days (Aerobic) (Biodegradability testing)
EC50	>0.6 mg/l (Algae) (Toxicity to algae)
	>1.2 mg/l (daphnia) (Toxicity to aquatic invertebrates)
<b>109-16-0 Triethylene Glycol Dimethacrylate</b>	
Biodegradability	28 days (Aerobic) (Biodegradability testing)
Aqua toxicity	32 mg/l (daphnia) (No Observed Effect Concentration)
EC50	>100 mg/l (Algae) (Toxicity to algae)
<b>868-77-9 2-Hydroxyethyl Methacrylate</b>	
EC50	345 mg/l (Algae)

- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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· **Other adverse effects** No further relevant information available.

## 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:** Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

## 14 Transport information

- |  |                 |
|--|-----------------|
| · <b>UN-Number</b>   |                 |
| · <b>DOT, ADN, IMDG, IATA</b>  | not regulated   |
| · <b>UN proper shipping name</b>   |                 |
| · <b>DOT, ADN, IMDG, IATA</b>  | not regulated   |
| · <b>Transport hazard class(es)</b>  |                 |
| · <b>DOT, ADN, IMDG, IATA</b>  |                 |
| · <b>Class</b>   | not regulated   |
| · <b>Packing group</b>   |                 |
| · <b>DOT, IMDG, IATA</b>   | not regulated   |
| · <b>Environmental hazards:</b>  | Not applicable. |
| · <b>Special precautions for user</b>  | Not applicable. |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>  | not regulated   |

## 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

### · **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

### · **Section 313 (Specific toxic chemical listings):**

1344-28-1 Aluminium Oxide

### · **TSCA (Toxic Substances Control Act):**

All components have the value ACTIVE.

### · **Hazardous Air Pollutants**

None of the ingredients is listed.

### · **Proposition 65**

### · **Chemicals known to cause cancer:**

14808-60-7 Silica Glass

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· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

1344-28-1	Aluminium Oxide	A4
14808-60-7	Silica Glass	A2
128-37-0	Butylated Hydroxytoluene	A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

14808-60-7	Silica Glass
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· **GHS label elements**

Medical Devices are exempt from the labeling requirements of the Globally Harmonized System (GHS).

· **Hazard pictograms** GHS07

· **Signal word** Warning

· **Hazard-determining components of labeling:**

Diurethane Dimethacrylate

Triethylene Glycol Dimethacrylate

2-Hydroxyethyl Methacrylate

· **Hazard statements**

May cause an allergic skin reaction.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapors/spray

Contaminated work clothing must not be allowed out of the workplace.

Wear protective gloves.

If on skin: Wash with plenty of water.

If skin irritation or rash occurs: Get medical advice/attention.

Specific treatment (see on this label).

Wash contaminated clothing before reuse.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Chemical safety assessment:**

Device is biocompatible when used as directed by dental professionals per ISO 10993-1

## 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Regulatory Affairs

· **Contact:** Customer Service

· **Date of preparation / last revision** 07/09/2020 / -

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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*EINECS: European Inventory of Existing Commercial Chemical Substances*  
*ELINCS: European List of Notified Chemical Substances*  
*CAS: Chemical Abstracts Service (division of the American Chemical Society)*  
*NFPA: National Fire Protection Association (USA)*  
*HMIS: Hazardous Materials Identification System (USA)*  
*VOC: Volatile Organic Compounds (USA, EU)*  
*LC50: Lethal concentration, 50 percent*  
*LD50: Lethal dose, 50 percent*  
*PBT: Persistent, Bioaccumulative and Toxic*  
*vPvB: very Persistent and very Bioaccumulative*  
*NIOSH: National Institute for Occupational Safety*  
*OSHA: Occupational Safety & Health*  
*TLV: Threshold Limit Value*  
*PEL: Permissible Exposure Limit*  
*REL: Recommended Exposure Limit*  
*Skin Sens. 1: Skin sensitisation – Category 1*

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