

Safety data sheet according to UK REACH

Printing date 19.06.2025

Version number 1

Revision: 19.06.2025

1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** Opal™ Bond™ MV
- **Article number:** SDS 368-001.06R01, 71025, 500066, 500067, 500067-JP, 500084, 50204, 1000283
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Orthodontic Adhesive
- **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

- EC Responsible Person
Ultradent Products GmbH
Am Westhover Berg 30
51149 Cologne Germany
Email: infoDE@ultradent.com
Office Phone: +49(0)2203-35-92-0
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : +1 (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



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

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
Diurethane Dimethacrylate
Triethylene Glycol Dimethacrylate
Organophosphine Oxide
2-Hydroxyethyl Methacrylate
- **Hazard statements**
H317 May cause an allergic skin reaction.
- **Precautionary statements**
P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.

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- P103 Read carefully and follow all instructions.
 P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P280 Wear protective gloves.
 P362+P364 Take off contaminated clothing and wash it before reuse.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P321 Specific treatment (see on this label).
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

3 Composition/information on ingredients

- **Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

	Trade Secret substance with a Community workplace exposure limit	>2.5-≤10%
CAS: 72869-86-4 EINECS: 276-957-5	Diurethane Dimethacrylate ⚠ Skin Sens. 1, H317; Aquatic Chronic 3, H412	>2.5-≤10%
CAS: 14808-60-7 EINECS: 238-878-4	Silica Glass ⚠ Acute Tox. 4, H332; Skin Irrit. 2, H315	>2.5-≤10%
CAS: 2530-85-0 EINECS: 219-785-8	Silane ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	≥0-<10%
CAS: 109-16-0 EINECS: 203-652-6	Triethylene Glycol Dimethacrylate ⚠ Skin Sens. 1, H317	≤2.5%
CAS: 868-77-9 EINECS: 212-782-2	2-Hydroxyethyl Methacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	≥0-≤2.5%
CAS: 10287-53-3 EINECS: 233-634-3	Ethyl-4-Dimethylamino Benzoate ⚠ Repr. 1B, H360; ⚠ Aquatic Chronic 2, H411	<0.25%
	Organophosphine Oxide ⚠ Skin Sens. 1A, H317; Aquatic Chronic 4, H413	<0.1%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

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:**
If skin irritation continues, consult a doctor.
Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** Do NOT induce vomiting.
- **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 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
Foam
Dry Chemical
Carbon dioxide
Use fire extinguishing methods suitable to surrounding conditions.
- **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** Not required.
- **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 section 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.

7 Handling and storage

- **Precautions for safe handling:** Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **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

- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**

Trade Secret

WEL	Long-term value: 10* 4** mg/m ³ *inhalable dust **respirable dust
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- **Additional information:** The lists valid during the making were used as basis.

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- **Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
- **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Hand protection**



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 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/face protection** Not required.
- **Body protection:** Protective work clothing

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Solid
- **Colour:** Whitish
- **Odour:** Acrylic
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** Undetermined.
- **Boiling point or initial boiling point and boiling range** Undetermined.
- **Flammability** Not determined.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** Not applicable.
- **Decomposition temperature:** Not determined.
- **pH** Not applicable (non-aqueous)
- **Viscosity:**
- **Kinematic viscosity** Not applicable.
- **Dynamic:** Not applicable.
- **Solubility**
- **water:** Insoluble.
- **Partition coefficient n-octanol/water (log value)** Not determined.

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· Vapour pressure:	<i>Not applicable.</i>
· Density and/or relative density	
· Density at 20 °C:	<i>2.03 g/cm³</i>
· Relative density	<i>Not determined.</i>
· Vapour density	<i>Not applicable.</i>
· Other information	
· Appearance:	
· Form:	<i>Paste</i>
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	<i>Product is not selfigniting.</i>
· Explosive properties:	<i>Product does not present an explosion hazard.</i>
· Change in condition	
· Evaporation rate	<i>Not applicable.</i>
· Information with regard to physical hazard classes	
· Explosives	<i>Void</i>
· Flammable gases	<i>Void</i>
· Aerosols	<i>Void</i>
· Oxidising gases	<i>Void</i>
· Gases under pressure	<i>Void</i>
· Flammable liquids	<i>Void</i>
· Flammable solids	<i>Void</i>
· Self-reactive substances and mixtures	<i>Void</i>
· Pyrophoric liquids	<i>Void</i>
· Pyrophoric solids	<i>Void</i>
· Self-heating substances and mixtures	<i>Void</i>
· Substances and mixtures, which emit flammable gases in contact with water	<i>Void</i>
· Oxidising liquids	<i>Void</i>
· Oxidising solids	<i>Void</i>
· Organic peroxides	<i>Void</i>
· Corrosive to metals	<i>Void</i>
· Desensitised explosives	<i>Void</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.*

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11 Toxicological information

- **Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

- **LD/LC50 values relevant for classification:**

ATE (Acute Toxicity Estimates)

Inhalative	LC50/4 h	20.9-34.8 mg/l
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Trade Secret

Oral	LD50	>5,000 mg/kg (rat)
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72869-86-4 Diurethane Dimethacrylate

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

Organophosphine Oxide

Oral	LD50	>2,000 mg/kg (rat)
	LC50 Fish	>0.09 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>2,000 mg/kg (rat)

- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **Information on other hazards**

- **Endocrine disrupting properties**

128-37-0	Butylated Hydroxytoluene	List II
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12 Ecological information

- **Toxicity**

- **Aquatic toxicity:**

72869-86-4 Diurethane Dimethacrylate

EC50	>0.6 mg/kg (Algae)
Biodegradability	28 days (Aerobic) (Biodegradability testing)

109-16-0 Triethylene Glycol Dimethacrylate

EC50	>100 mg/kg (Algae)
Biodegradability	28 days (Aerobic) (Biodegradability testing)
Aqua toxicity	32 mg/l (daphnia) (No Observed Effect Concentration)

868-77-9 2-Hydroxyethyl Methacrylate

EC50	345 mg/kg (Algae)
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Organophosphine Oxide

EC50 (static)	>1.175 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
Aqua toxicity	≥0.008 mg/l (daphnia) (Daphnia Magna Reproduction Test)
Toxicity to Aquatic Plants (static)	>0.26 mg/l (Plant) (Toxicity to algae)

- **Persistence and degradability** No further relevant information available.
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **Other adverse effects**
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (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.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Disposal should be in accordance with applicable regional, national and local laws and regulations.
Dispose of contents/container in accordance with international, federal, state, and local regulations.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|-----------------|
| · UN number or ID number | |
| · ADR, ADN, IMDG, IATA | not regulated |
| · UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | not regulated |
| · Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | not regulated |
| · Packing group | |
| · ADR, IMDG, IATA | not regulated |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not Applicable |
| · Maritime transport in bulk according to IMO instruments | Not applicable. |
| · UN "Model Regulation": | not regulated |

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15 Regulatory information

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

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

14808-60-7	Silica Glass
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· **Poisons Act**

· **Regulated explosives precursors**

None of the ingredients is listed.

· **Regulated poisons**

None of the ingredients is listed.

· **Reportable explosives precursors**

None of the ingredients is listed.

· **Reportable poisons**

None of the ingredients is listed.

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **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.

· **Relevant phrases from Section 3**

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H360 May damage fertility or the unborn child.

H411 Toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

H413 May cause long lasting harmful effects to aquatic life.

· **Department issuing SDS:** Environmental, Health, and Safety

· **Contact:** Customer Service

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

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

ATE: Acute toxicity estimate values

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

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Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1A: Skin sensitisation – Category 1A

Repr. 1B: Reproductive toxicity – Category 1B

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

*** Data compared to the previous version altered.**

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