

Safety Data Sheet

according to WHS Regulations

Printing date 03.08.2023

Revision: 03.08.2023

1 Identification

- **Product identifier**
- **Trade name:** *Opal™ Bond™ MV*
- **Article number:** SDS 368-001.05R02, 71025
- **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*
- Ultradent Australia Pty Ltd.
Level 22/2 Market Street
Sydney NSW 2000
Australia
Email: info.anz@ultradent.com
Toll Free: 1-800-290929*
- **Further information obtainable from:** *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** *Void*
- **Hazard pictograms** *GHS07*
- **Signal word** *Warning*
- **Hazard-determining components of labelling:**
*Diurethane Dimethacrylate
Triethylene Glycol Dimethacrylate*
- **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.
P103 Read label before use.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.*

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- 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 and Information on Ingredients

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

- **Dangerous components:**

72869-86-4	Diurethane Dimethacrylate	≥1-<10%
	⚠ Skin Sens. 1, H317	
	Trade Secret	<10%
14808-60-7	Silica Glass	≥0-<10%
	⚠ Acute Tox. 4, H332; Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319	
2530-85-0	Silane	≥0-<10%
	⚠ Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; STOT SE 3, H335	
109-16-0	Triethylene Glycol Dimethacrylate	≥1-<10%
	⚠ Skin Sens. 1, H317	
868-77-9	2-Hydroxyethyl Methacrylate	≥0.1-<1%
	⚠ Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; Skin Sens. 1, H317	

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

4 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.
- **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.

5 Fire Fighting Measures

- **Suitable extinguishing agents:**
 Foam
 Dry Chemical

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Carbon dioxide

Use fire extinguishing methods suitable to surrounding conditions.

· **Special hazards arising from the substance or mixture** No further relevant information available.· **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 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.

7 Handling and Storage

· **Handling:**· **Precautions for safe handling:** Ensure good ventilation/exhaustion at the workplace.· **Information about fire - and explosion protection:** No special measures required.· **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 and personal protection

· **Additional information about design of technical facilities:** No further data; see item 7.· **Ingredients with limit values that require monitoring at the workplace:****Trade Secret**WES Long-term value: 10 mg/m³
inhalable dust**14808-60-7 Silica Glass**WES Long-term value: 0.05 mg/m³
respirable dust· **Additional information:** The lists valid during the making were used as basis.· **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.

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· **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.

· **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 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

· **General Information**

· **Appearance:**

· **Form:**

Paste

· **Colour:**

Whitish

· **Odour:**

Acrylic

· **Odour threshold:**

Not determined.

· **pH-value:**

Not applicable (non-aqueous)

· **Change in condition**

· **Melting point/freezing point:**

Undetermined.

· **Initial boiling point and boiling range:**

Undetermined.

· **Flash point:**

Not applicable.

· **Flammability (solid, gas):**

Not determined.

· **Decomposition temperature:**

Not determined.

· **Auto-ignition temperature:**

Product is not selfigniting.

· **Explosive properties:**

Product does not present an explosion hazard.

· **Explosion limits:**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Vapour pressure:**

Not applicable.

· **Density at 20 °C:**

2.03 g/cm³

· **Relative density**

Not determined.

· **Vapour density**

Not applicable.

· **Evaporation rate**

Not applicable.

· **Solubility in / Miscibility with**

· **water:**

Insoluble.

· **Partition coefficient: n-octanol/water:**

Not determined.

· **Viscosity:**

· **Dynamic:**

Not applicable.

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| · Kinematic: | Not applicable. |
| · Other information | No further relevant information available. |

10 Stability and Reactivity

- **Reactivity Stable**
- **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** Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

Inhalative	LC50/4 h	22.8-37.9 mg/l
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72869-86-4 Diurethane Dimethacrylate

Oral	LD50	>5,000 mg/kg (rat)
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Trade Secret

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)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.

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· **Aspiration hazard** Based on available data, the classification criteria are not met.

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)

· **Persistence and degradability** No further relevant information available.· **Behaviour 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 (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.

· **Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.· **Other adverse effects** No further relevant information available.

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**· **ADG, ADN, IMDG, IATA**

not regulated

· **UN proper shipping name**· **ADG, ADN, IMDG, IATA**

not regulated

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· Transport hazard class(es)	
· ADG, ADN, IMDG, IATA	
· Class	not regulated
· Packing group	
· ADG, IMDG, IATA	not regulated
· Environmental hazards:	Not applicable.
· Special precautions for user	Not Applicable
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	not regulated

15 Regulatory information

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

· **Australian Inventory of Industrial Chemicals**

72869-86-4	Diurethane Dimethacrylate
	Trade Secret
14808-60-7	Silica Glass
21282-97-3	2-[(2-methyl-1-oxoallyl)oxy]ethylacetoacetate
41637-38-1	EOBPADMA
2530-85-0	Silane
109-16-0	Triethylene Glycol Dimethacrylate
868-77-9	2-Hydroxyethyl Methacrylate
10287-53-3	Ethyl-4-Dimethylamino Benzoate
128-37-0	Butylated Hydroxytoluene
10373-78-1	Camphorquinone
162881-26-7	Organophosphine Oxide

· **Standard for the Uniform Scheduling of Medicines and Poisons**

868-77-9	2-Hydroxyethyl Methacrylate	S5
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· **Australia: Priority Existing Chemicals**

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.

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*H319 Causes serious eye irritation.**H332 Harmful if inhaled.**H335 May cause respiratory irritation.*

- **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

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

Acute Tox. 4: Acute toxicity – Category 4

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

Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A

Skin Sens. 1: Skin sensitisation – Category 1

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

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

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