Safety Data Sheet
according to WHS Regulations

Date of issue: 19.06.2025 Revision: 19.06.2025

*
1 Identification

· **Other means of identification**

· **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

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) : +1 (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) Identification

· **Classification of the substance or mixture**

Skin sensitisation – Category 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 (>2.5-≤10 %)
Triethylene Glycol Dimethacrylate (≤2.5 %)
· **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.
P280 Wear protective gloves.

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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:**

	Trade Secret	>2.5-≤10%
72869-86-4	Diurethane Dimethacrylate Skin sensitisation – Category 1, H317	>2.5-≤10%
14808-60-7	Silica Glass Acute toxicity - inhalation – Category 4, H332; Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319	>2.5-≤10%
2530-85-0	Silane Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319; Specific target organ toxicity (single exposure) – Category 3, H335	≥0-<10%
109-16-0	Triethylene Glycol Dimethacrylate Skin sensitisation – Category 1, H317	≤2.5%
868-77-9	2-Hydroxyethyl Methacrylate Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319; Skin sensitisation – Category 1, H317	≥0-≤2.5%
10287-53-3	Ethyl-4-Dimethylamino Benzoate Reproductive toxicity – Category 1B, H360	<0.3%

· **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

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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.
· **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

· **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

· **Appropriate engineering controls** No further data; see section 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**	Not determined.
· **Decomposition temperature:**	Not determined.
· **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**	
· **Particle characteristics**	Not determined.
· **Physical state**	Solid

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	20.9-34.8 mg/l

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

· **Primary irritant effect:**
· **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.

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· **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.
· **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**

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**	
14808-60-7	Silica Glass

· **Australian Inventory of Industrial Chemicals**	
	Trade Secret
72869-86-4	Diurethane Dimethacrylate
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
	Organophosphine Oxide

· **Standard for the Uniform Scheduling of Medicines and Poisons**		
868-77-9	2-Hydroxyethyl Methacrylate	S5

· **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.

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· **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.

· **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
NIOSH: National Institute for Occupational Safety
Acute toxicity - inhalation – Category 4: Acute toxicity – Category 4
Skin corrosion/irritation – Category 2: Skin corrosion/irritation – Category 2
Eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A
Skin sensitisation – Category 1: Skin sensitisation – Category 1
Reproductive toxicity – Category 1B: Reproductive toxicity – Category 1B
Specific target organ toxicity (single exposure) – Category 3: Specific target organ toxicity (single exposure) – Category 3
· *** Data compared to the previous version altered.**