

Printing date 06/09/2025

Reviewed on 06/09/2025

1 Identification

- · Product identifier
- · Trade name: OpalTM BondTM MV
- Article number: SDS 368-001.06R01, 71025, 500066, 500067, 500067-JP, 500084, 50204, 1000283 • 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) : +1 (800) 424-9300 (INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) identification

· Classification of the substance or mixture



Toxic to Reproduction 1B H360 May damage fertility or the unborn child.



Sensitization - Skin 1 H317 May cause an allergic skin reaction.

- · Label elements
- GHS label elements Void
- · Hazard pictograms GHS07, GHS08
- · Signal word Danger
- Health Hazard-determining components of labeling: Diurethane Dimethacrylate Ethyl-4-Dimethylamino Benzoate Triethylene Glycol Dimethacrylate 2-Hydroxyethyl Methacrylate
- *Hazard statements* H317 May cause an allergic skin reaction.
- H360 May damage fertility or the unborn child.
- Precautionary statements
- *P201 Obtain special instructions before use.*
- P202 Do not handle until all safety precautions have been read and understood.
- P261 Avoid breathing dust/fume/gas/mist/vapors/spray
- *P272 Contaminated work clothing must not be allowed out of the workplace.*
- *P280 Wear protective gloves/protective clothing/eye protection/face protection.*
- P302+P352 If on skin: Wash with plenty of water.

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P308+P313 IF exposed or concerned: G	Get medical advice/attention.
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- *P321* Specific treatment (see on this label).
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- *P363 Wash contaminated clothing before reuse.*
- P405 Store locked up.
- *P501* Dispose of contents/container in accordance with local/regional/national/international regulations.

• Classification system:

· NFPA ratings (scale 0 - 4)



· HMIS-ratings (scale 0 - 4)

HEALTH 0	Health = 0
FIRE 0	Fire = 0
REACTIVITY 0	<i>Reactivity</i> $= 0$

3 Composition/information on ingredients

· Chemical characterization: Mixtures

• Description: Mixture of the substances listed below with nonhazardous additions.

· Dangerous	components:	
	Trade Secret	>2.5-≤10%
72869-86-4	Diurethane Dimethacrylate	>2.5-≤10%
14808-60-7	Silica Glass	>2.5-≤10%
2530-85-0	Silane	≥0-<10%
	Triethylene Glycol Dimethacrylate	≤2.5%
	2-Hydroxyethyl Methacrylate	≥0-≤2.5%
10287-53-3	Ethyl-4-Dimethylamino Benzoate	≥0.1-<25%

Additional information:

The specific chemical identity of composition is being withheld as a trade secret. The specific chemical identity is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of paragraph §1910.1200.

4 First-aid measures

· Description of first aid measures

- 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.

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• *Indication of any immediate medical attention and special treatment needed No further relevant information available.*

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 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. Open and handle receptacle with care.
- Information about protection against explosions and fires: Keep respiratory protective device available.
- · 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. Keep receptacle tightly sealed.
 Specific end use(s) Professional Orthodontic Adhesive

8 Exposure controls/personal protection

• Additional information about design of technical systems: No further data; see section 7.

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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.
Trade Secret
PEL Long-term value: 15*; 5** mg/m ³ *Total dust; ** Respirable fraction
REL Long-term value: 10* 5** mg/m ³ as Al*Total dust**Respirable/pyro powd./welding f.
TLV Long-term value: 1* mg/m ³
as Al; *as respirable fraction, A4
14808-60-7 Silica Glass
PEL Long-term value: 0.05* mg/m ³ *resp. dust; 30mg/m3/%SiO2+2
REL Long-term value: 0.05* mg/m ³
*respirable dust; See Pocket Guide App. A
TLV Long-term value: 0.025* mg/m ³
*respirable particulate matter, A2
• Additional information: The lists that were valid during the creation were used as basis.
 Exposure controls Personal protective equipment: General protective and hygienic measures: Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Store protective clothing separately. 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. Protection of hands:
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

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.

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· Body protection: Protective work clothing

9 Physical and chemical proper	rties	
· Information on basic physical and chemical properties		
· General Information		
· Appearance:		
Form:	Paste	
Color:	Whitish	
· Odor:	Acrylic	
· Odor threshold:	Not determined.	
· pH-value:	Not applicable (non-aqueous)	
· Change in condition		
Melting point/Melting range:	Undetermined.	
Boiling point/Boiling range:	Undetermined	
· Flash point:	Not applicable	
· Flammability:	Not determined.	
• Decomposition temperature:	Not determined.	
· Ignition temperature:	Product is not selfigniting.	
• Danger of explosion:	Product does not present an explosion hazard.	
· Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapor pressure:	Not applicable.	
· Density at 20 °C:	2.03 g/cm^3	
· Relative density	Not determined	
· Vapor density	Not applicable.	
· Evaporation rate	Not applicable.	
· Solubility in / Miscibility with		
Water:	Insoluble.	
· Partition coefficient (n-octanol/wat	'er): Not determined.	
· Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
• Other information	No further relevant information available.	

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

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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:

ATE (Act	ute Toxicity Estimate)	
Inhalative	e LC50/4 h	20.9-34.8 mg/l
Trade Se	cret	
Oral	LD50	>5,000 mg/kg (rat)
72869-86	-4 Diurethane Dimethaci	rylate
Oral	LD50	>5,000 mg/kg (rat)
109-16-0	Triethylene Glycol Dime	thacrylate
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 Methacr	ylate
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)
on the ski on the ey Sensitizat Additiond	i rritant effect: in: No irritant effect. e: No irritating effect. tion: Sensitization possibla al toxicological information act shows the following date	
-	enic categories	
,	ternational Agency for R	
	-7 Silica Glass	د ا
128-37	-0 Butylated Hydroxytolu	iene -
	tional Toxicology Progra	m)
	= 0.1. 01	K
	-7 Silica Glass	N

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12 Ecological inf	ormation		
· Toxicity			
• Aquatic toxicity:			
72869-86-4 Diur	ethane Dimethacrylate		
EC50	>0.6 mg/kg (Algae)		
Biodegradability	28 days (Aerobic) (Biodegradability testing)		
109-16-0 Triethy	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-Hydr	oxyethyl Methacrylate		
EC50	345 mg/kg (Algae)		
· Persistence and a	· Persistence and degradability No further relevant information available.		
	ronmental systems:		
	potential No further relevant information available.		
• Mobility in soil N	<i>Io further relevant information available.</i>		

- · 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.
- 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.

[•] **Recommendation:** Disposal must be made according to official regulations.

UN-Number		
DOT, ADN, IMDG, IATA	Not Regulated	
UN proper shipping name		
DOT, ADN, IMDG, IATA	Not Regulated	
Transport hazard class(es)		
DOT, ADN, IMDG, IATA		
Class	Not Regulated	

[·] Uncleaned packagings:

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· Packing group · DOT, IMDG, IATA	Not Regulated	
· Environmental hazards:	Not Applicable.	
· Special precautions for user	Not Applicable	
• Transport in bulk according to Annex MARPOL73/78 and the IBC Code	II of Not Applicable.	
· UN "Model Regulation":	Not Regulated	

15 Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture
No further relevant information available.
Sara
· Section 355 (extremely hazardous substances):

None of the ingredients is listed.

• Section 313 (Specific toxic chemical listings):

Trade Secret

• TSCA (Toxic Substances Control Act):

(,	
	Trade Secret	ACTIVE
72869-86-4	Diurethane Dimethacrylate	ACTIVE
14808-60-7	Silica Glass	ACTIVE
2530-85-0	Silane	ACTIVE
109-16-0	Triethylene Glycol Dimethacrylate	ACTIVE
		ACTIVE
10287-53-3	Ethyl-4-Dimethylamino Benzoate	ACTIVE

· Hazardous Air Pollutants

None of the ingredients is listed.

Proposition 65

• Chemicals known to cause cancer:

14808-60-7 Silica Glass

· 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.

· ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)

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14808-60-7 Silica Glass

128-37-0 Butylated Hydroxytoluene

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

14808-60-7 Silica Glass

· 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: Environmental, Health, and Safety

· Contact: Customer Service

· Date of preparation / last revision 06/09/2025 / -

· Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods DOT: US Department of Transportation 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) NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA) 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 Sensitization - Skin 1: Škin sensitisation – Category 1 Toxic to Reproduction 1B: Reproductive toxicity – Category 1B

• * Data compared to the previous version altered.

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