Safety Data Sheet
according to WHS Regulations

Date of issue: 21.07.2025 Revision: 21.07.2025

*

1 Identification

· **Other means of identification**

· **Trade name: Opal™ Band™ Cement - Base**

· **Article number:** SDS 219-001.08R01, 71100, 500000, 500000-JP, 500087
· **Relevant identified uses of the substance or mixture and uses advised against** Professional Orthodontic Cement
· **Application of the substance / the mixture** Professional Orthodontic Cement

· **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
(800) 552-5512

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**

corrosion

Skin corrosion/irritation – Category 1A — H314 Causes severe skin burns and eye damage.

Skin sensitisation – Category 1 — H317 May cause an allergic skin reaction.
Specific target organ toxicity (single exposure) – Category 3 — H335 May cause respiratory irritation.

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** GHS05, GHS07
· **Signal word** Danger

· **Hazard-determining components of labelling:**
Trade Secret (≥5-<10 %)
Triethylene Glycol Dimethacrylate (≥1-<10 %)

(Contd. on page 2)

Safety Data Sheet
according to WHS Regulations

Date of issue: 21.07.2025 Revision: 21.07.2025

Trade name: Opal™ Band™ Cement - Base

(Contd. of page 1)

Methacrylic Acid (≥1-<3 %)
Diurethane Dimethacrylate (≥1-<10 %)

· **Hazard statements**
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.

· **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.*
P260	*Do not breathe dusts or mists.*
P303+P361+P353	*IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.*
P305+P351+P338	*IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*
P310	*Immediately call a POISON CENTER/doctor.*
P321	*Specific treatment (see on this label).*
P362+P364	*Take off contaminated clothing and wash it before reuse.*
P405	*Store locked up.*
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:**

20882-04-6	*Mono-2-(Methacryloyloxy) Ethyl Succinate* *Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319*	*<10%*
	Trade Secret *Skin corrosion/irritation – Category 1A, H314; Eye damage/irritation – Category 1, H318*	*≥5-<10%*
109-16-0	*Triethylene Glycol Dimethacrylate* *Skin sensitisation – Category 1, H317*	*≥1-<10%*
72869-86-4	*Diurethane Dimethacrylate* *Skin sensitisation – Category 1, H317*	*≥1-<10%*
79-41-4	*Methacrylic Acid* *Acute toxicity - dermal – Category 3, H311; Skin corrosion/irritation – Category 1A, H314; Eye damage/irritation – Category 1, H318; Acute toxicity - oral – Category 4, H302; Acute toxicity - inhalation – Category 4, H332; Specific target organ toxicity (single exposure) – Category 3, H335; Flammable liquids – Category 4, H227*	*≥1-<3%*
64-17-5	*Ethyl Alcohol* *Flammable liquids – Category 2, H225; Eye damage/irritation – Category 2A, H319*	*≥0.1-<1%*
94-36-0	*Benzoyl Peroxide* *Self-reactive substances and mixtures – Type B, H241; Organic peroxides – Type B, H241; Eye damage/irritation – Category 2A, H319; Skin sensitisation – Category 1, H317*	*≥0.1-<1%*

(Contd. on page 3)

Safety Data Sheet
according to WHS Regulations

Date of issue: 21.07.2025 Revision: 21.07.2025

Trade name: Opal™ Band™ Cement - Base

(Contd. of page 2)

· **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. Then consult a doctor.
· **After swallowing:** Drink plenty of water and provide fresh air. Call for a doctor immediately.
· **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:**
Carbon dioxide
Foam
Water spray
Use fire extinguishing methods suitable to surrounding conditions.
· **Special hazards arising from the substance or mixture**
During heating or in case of fire poisonous gases are produced.
· **Protective equipment:**
Wear fully protective suit.
Mouth respiratory protective device.

6 Accidental Release Measures

· **Personal precautions, protective equipment and emergency procedures**
Mount respiratory protective device.
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:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Use neutralising agent.
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.

(Contd. on page 4)

Safety Data Sheet
according to WHS Regulations

Date of issue: 21.07.2025 Revision: 21.07.2025

Trade name: Opal™ Band™ Cement - Base

(Contd. of page 3)

7 Handling and Storage

· **Handling:**
· **Precautions for safe handling:**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
· **Information about fire - and explosion protection:** Keep respiratory protective device available.
· **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:**
See product labelling.
Keep container tightly sealed.
· **Specific end use(s)** Professional Orthodontic Cement

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:**	
79-41-4 Methacrylic Acid	
WES	Long-term value: 70 mg/m³, 20 ppm
64-17-5 Ethyl Alcohol	
WES	Long-term value: 1880 mg/m³, 1000 ppm

· **Additional information:** The lists valid during the making were used as basis.
· **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.
Avoid contact with the eyes and skin.
· **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.

(Contd. on page 5)

Safety Data Sheet
according to WHS Regulations

Date of issue: 21.07.2025 Revision: 21.07.2025

Trade name: Opal™ Band™ Cement - Base

(Contd. of page 4)

· **Eye protection:**

Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and Chemical Properties

· **General Information**	
· **Appearance:**	
· **Form:**	Paste
· **Colour:**	Blue
· **Odour:**	Sweetish
· **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:**	>100 °C
· **Flammability**	Not applicable.
· **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 determined.
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
· **water:**	Not miscible or difficult to mix.
· **Partition coefficient: n-octanol/water:**	Not determined.
· **Viscosity:**	
· **Dynamic:**	Not determined.
· **Kinematic:**	Not determined.
· **Other information**	
· **Particle characteristics**	Not applicable.
· **Physical state**	Fluid

10 Stability and Reactivity

· **Reactivity** Polymerization occurs when exposed to amine catalysts, metal, or pressure.
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions:** No dangerous reactions known.
· **Conditions to avoid:** Pressure
· **Incompatible materials:**
Amine Catalysts

(Contd. on page 6)

Safety Data Sheet
according to WHS Regulations

Date of issue: 21.07.2025 Revision: 21.07.2025

Trade name: Opal™ Band™ Cement - Base

(Contd. of page 5)

Metals
· **Hazardous decomposition products:** Carbon dioxide

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)		
Oral	LD50	53,000 mg/kg
Dermal	LD50	25,000 mg/kg
Inhalative	LC50/4 h	355 mg/l

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)
72869-86-4 Diurethane Dimethacrylate		
Oral	LD50	>5,000 mg/kg (rat)
79-41-4 Methacrylic Acid		
Oral	LD50	1,250 mg/kg (mouse)
		1,060 mg/kg (rat)
		1,200 mg/kg (rabbit)
	LC50 Fish	86 mg/l (Fish)
Dermal	LD50	1,000 mg/kg (guinea pig)
		500 mg/kg (rabbit)
Inhalative	LC50/4 h	7.1 mg/l (rat)
64-17-5 Ethyl Alcohol		
Oral	LD50	5,600 mg/kg (guinea pig)
		3,400 mg/kg (mouse)
		7,060 mg/kg (rat)
	LC50 Fish	>10,000 mg/l (Fish)
Inhalative	LC50/4 h	39 mg/l (mouse)
		20,000 mg/l (rat)
94-36-0 Benzoyl Peroxide		
Oral	LD50	>5,000 mg/kg (rat)
	LC50 Fish	0.0602 mg/l (Fish) (Toxicity to fish)
Inhalative	LD50 Inhalation 4hrs	24.3 mg/l (rat) (Testing of Chemicals Acute Toxicity Inhalation)

· **Primary irritant effect:**
· **Skin corrosion/irritation** Causes severe skin burns and eye damage.
· **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**
Ethyl Alcohol, Silica Glass, Co-Cr-AL Spinel Blue Green are on the IARC list of carcinogens.
Based on available data, the classification criteria are not met.

(Contd. on page 7)

Safety Data Sheet
according to WHS Regulations

Date of issue: 21.07.2025 Revision: 21.07.2025

Trade name: Opal™ Band™ Cement - Base

(Contd. of page 6)

· **Reproductive toxicity**
Does not meet the classification criteria for this hazard class.
Based on available data, the classification criteria are not met.
· **STOT-single exposure**
Does not meet the classification criteria for this hazard class.
May cause respiratory irritation.
· **STOT-repeated exposure**
Does not meet the classification criteria for this hazard class.
Based on available data, the classification criteria are not met.
· **Aspiration hazard**
Does not meet the classification criteria for this hazard class.
Based on available data, the classification criteria are not met.

12 Ecological Information

· **Toxicity**

· **Aquatic toxicity:**	
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)
72869-86-4 Diurethane Dimethacrylate	
EC50	>0.6 mg/kg (Algae)
Biodegradability	28 days (Aerobic) (Biodegradability testing)
79-41-4 Methacrylic Acid	
EC50	17,000 mg/kg (Algae)
	<180 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
64-17-5 Ethyl Alcohol	
Algae Toxicity	1,000 mg/l (Algae)
94-36-0 Benzoyl Peroxide	
Algae Toxicity	0.0711 mg/l (Algae) (Toxicity to algae)
	0.11 mg/l (daphnia) (Toxicity to aquatic invertebrates)

· **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.
Must not reach sewage water or drainage ditch undiluted or unneutralised.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

(Contd. on page 8)

Safety Data Sheet
according to WHS Regulations

Date of issue: 21.07.2025 Revision: 21.07.2025

Trade name: Opal™ Band™ Cement - Base

(Contd. of page 7)

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
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
· **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**	
20882-04-6	Mono-2-(Methacryloyloxy) Ethyl Succinate
109-16-0	Triethylene Glycol Dimethacrylate
72869-86-4	Diurethane Dimethacrylate
	Trade Secret
79-41-4	Methacrylic Acid
64-17-5	Ethyl Alcohol
94-36-0	Benzoyl Peroxide
	Co-Cr-AL Spinel Blue Green
14808-60-7	Silica Glass
8013-76-1	Bitter almond oil

(Contd. on page 9)

Safety Data Sheet
according to WHS Regulations

Date of issue: 21.07.2025 Revision: 21.07.2025

Trade name: Opal™ Band™ Cement - Base

(Contd. of page 8)

128-37-0	Butylated Hydroxytoluene	

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

94-36-0	Benzoyl Peroxide	S2, S4, 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.

· **Relevant phrases from Section 3**
H225 Highly flammable liquid and vapour.
H227 Combustible liquid.
H241 Heating may cause a fire or explosion.
H302 Harmful if swallowed.
H311 Toxic in contact with skin.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
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
NIOSH: National Institute for Occupational Safety
Flammable liquids – Category 2: Flammable liquids – Category 2
Flammable liquids – Category 4: Flammable liquids – Category 4
Self-reactive substances and mixtures – Type B: Self-reactive substances and mixtures – Type B
Organic peroxides – Type B: Organic peroxides – Type B
Acute toxicity - oral – Category 4: Acute toxicity – Category 4
Acute toxicity - dermal – Category 3: Acute toxicity – Category 3
Skin corrosion/irritation – Category 1A: Skin corrosion/irritation – Category 1A
Skin corrosion/irritation – Category 2: Skin corrosion/irritation – Category 2
Eye damage/irritation – Category 1: Serious eye damage/eye irritation – Category 1
Eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A
Skin sensitisation – Category 1: Skin sensitisation – Category 1
Specific target organ toxicity (single exposure) – Category 3: Specific target organ toxicity (single exposure) – Category 3
· ***** Data compared to the previous version altered.**