

Printing date 07/14/2025 Reviewed on 07/14/2025

### 1 Identification

- · Product identifier
- · Trade name: Opal<sup>TM</sup> Band<sup>TM</sup> Cement Catalyst
- · Article number: SDS 220-001.09R01, 71101, 500000, 500087, 500000-JP
- · 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

on line order support@ultradent.com

(800) 552-5512

- · 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



GHS08 Health hazard

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



GHS05 Corrosion

Eye Damage 1 H318 Causes serious eye damage.



GHS07

Acute Toxicity - Inhalation 4 H332 Harmful if inhaled.
Skin Irritation 2 H315 Causes skin irritation.

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

- · Label elements
- · GHS label elements Void
- · Hazard pictograms GHS05, GHS07, GHS08
- · Signal word Danger
- · Health Hazard-determining components of labeling:

Poly(ethylene glycol) Diacrylate Ethyl-4-Dimethylamino Benzoate Triethylene Glycol Dimethacrylate Diurethane Dimethacrylate Organophosphine Oxide

(Contd. on page 2)

Reviewed on 07/14/2025 Printing date 07/14/2025

### Trade name: Opal<sup>TM</sup> Band<sup>TM</sup> Cement - Catalyst

(Contd. of page 1)

#### · Hazard statements

H332 Harmful if inhaled.

H315 Causes skin irritation.

H318 Causes serious eye damage.

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

P264 Wash thoroughly after handling.

Use only outdoors or in a well-ventilated area. P271

Contaminated work clothing must not be allowed out of the workplace. P272 P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 If on skin: Wash with plenty of water.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

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.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P321 Specific treatment (see on this label).

P362+P364 Take off contaminated clothing and wash it before reuse. If skin irritation or rash occurs: Get medical advice/attention. P333+P313

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)



Health = 3Fire = 0Reactivity = 0

### · HMIS-ratings (scale 0 - 4)



Health = \*3Fire = 0

REACTIVITY 0

Reactivity = 0

# 3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- · Description: Mixture of the substances listed below with nonhazardous additions.

· Dangerous	components:	
26570-48-9	Poly(ethylene glycol) Diacrylate	>10-≤25%
109-16-0	Triethylene Glycol Dimethacrylate	1-10%
72869-86-4	Diurethane Dimethacrylate	1-10%
	Trade Secret	1-10%
10287-53-3	Ethyl-4-Dimethylamino Benzoate	≥0.1-<1%
	Organophosphine Oxide	≥0.1-<1%
	(C	ontd. on page 3)

Printing date 07/14/2025 Reviewed on 07/14/2025

Trade name: Opal<sup>TM</sup> Band<sup>TM</sup> Cement - Catalyst

(Contd. of page 2)

### · 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
- · General information:

Immediately remove any clothing soiled by the product.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· 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: If swallowed in large quantities seek medical attention.
- 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

- · Extinguishing media
- · Suitable extinguishing agents: 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 fully protective suit.

Mouth respiratory protective device.

### 6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

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 neutralizing 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.

(Contd. on page 4)

Printing date 07/14/2025 Reviewed on 07/14/2025

Trade name: Opal<sup>TM</sup> Band<sup>TM</sup> Cement - Catalyst

(Contd. of page 3)

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.

Prevent formation of aerosols.

- · 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.

See product labelling.

Keep receptacle tightly sealed.

· Specific end use(s) Professional Orthodontic Cement

### 8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see section 7.
- · Control parameters
- · Components with limit values that require monitoring at the workplace:

The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

At this time, the other constituents have no known exposure limits.

#### Trade Secret

TWA Short-term value: 0.8 mg/m³

- · 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.

Avoid contact with the skin.

Avoid contact with the eyes and skin.

· 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:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

(Contd. on page 5)

Printing date 07/14/2025 Reviewed on 07/14/2025

Trade name: Opal<sup>TM</sup> Band<sup>TM</sup> Cement - Catalyst

(Contd. of page 4)

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 observed.

· Eye protection:



Tightly sealed goggles

· Body protection: Protective work clothing

## 9 Physical and chemical properties

· Information on basic physical and cl · General Information · Appearance:	hemical properties
Form:	Paste
Color:	Yellow
· 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 applicable.
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 determined.
Density:	Not determined
Relative density	Not determined
Vapor density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with	
Water:	Not miscible or difficult to mix.

(Contd. on page 6)

Printing date 07/14/2025 Reviewed on 07/14/2025

Trade name: Opal<sup>TM</sup> Band<sup>TM</sup> Cement - Catalyst

· Partition coefficient (n-octanol/water): Not determined.
· Viscosity:
Dynamic:
Kinematic:
Not determined
Not determined

No further relevant information available.

### 10 Stability and reactivity

- · Reactivity Polymerization occurs when exposed to visible light, ultraviolet light or extreme heat.
- · Chemical stability

· Other information

- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid Visible light, ultraviolet light, and extreme heat
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: Carbon dioxide

## 11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:

· LD/LC50 values that are relevant for classification:					
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-	72869-86-4 Diurethane Dimethacrylate				
Oral	LD50	>5,000 mg/kg (rat)			
Trade Seci	Trade Secret				
Oral	LD50	>15,000 mg/kg (mouse)			
		>3,300 mg/kg (rat)			
	LC50 Fish	>10,000 mg/l (Fish) (Toxicity to fish)			
Dermal	LD50	>5,000 mg/kg (rabbit)			
Inhalative	LC50/4 h	0.139 mg/l (rat)			
Organoph	osphine Oxi	ide			
Oral	LD50	>2,000 mg/kg (rat)			
	LC50 Fish	>0.09 mg/l (Fish) (Toxicity to fish)			
Dermal	LD50	>2,000 mg/kg (rat)			

- · Primary irritant effect:
- · on the skin: Irritant to skin and mucous membranes.
- · on the eye: Strong irritant with the danger of severe eye injury.
- · Sensitization: Sensitization possible through skin contact.
- · Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations: Harmful

Irritant

(Contd. on page 7)

Printing date 07/14/2025 Reviewed on 07/14/2025

Trade name: Opal<sup>TM</sup> Band<sup>TM</sup> Cement - Catalyst

(Contd. of page 6)

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

## 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 Dimethad	72869-86-4 Diurethane Dimethacrylate			
EC50	>0.6 mg/kg (Algae)			
Biodegradability	28 days (Aerobic) (Biodegradability testing)			
Trade Secret				
EC50	>1,000 mg/kg (daphnia)			
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.
- · Behavior 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 (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 bodies of water or drainage ditch undiluted or unneutralized.

- · 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.

(Contd. on page 8)

Printing date 07/14/2025 Reviewed on 07/14/2025

Trade name: Opal<sup>TM</sup> Band<sup>TM</sup> Cement - Catalyst

(Contd. of page 7)

- · Uncleaned packagings:
- 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	
Packing group		
DOT, IMDG, IATA	Not Regulated	
Environmental hazards:	Not Applicable.	
Special precautions for user	Not Applicable	
Transport in bulk according to Annex	II of	
MARPOL73/78 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 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):

26570-48-9	Poly(ethylene glycol) Diacrylate	ACTIVE
109-16-0	Triethylene Glycol Dimethacrylate	ACTIVE
72869-86-4	Diurethane Dimethacrylate	ACTIVE
10287-53-3	Ethyl-4-Dimethylamino Benzoate	ACTIVE
	Organophosphine Oxide	ACTIVE

#### · Hazardous Air Pollutants

None of the ingredients is listed.

· Proposition 65

### · Chemicals known to cause cancer:

None of the ingredients is listed.

## · Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

(Contd. on page 9)

Printing date 07/14/2025 Reviewed on 07/14/2025

Trade name: Opal<sup>TM</sup> Band<sup>TM</sup> Cement - Catalyst

(Contd. of page 8)

· 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)

Trade Secret A4

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

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.

- · Department issuing SDS: Environmental, Health, and Safety
- · Contact: Customer Service
- · Date of preparation / last revision 07/14/2025 / -
- · 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

Acute Toxicity - Inhalation 4: Acute toxicity - Category 4

Skin Irritation 2: Skin corrosion/irritation – Category 2

Eye Damage 1: Serious eye damage/eye irritation – Category 1

Sensitization - Skin 1: Skin sensitisation - Category 1

Toxic to Reproduction 1B: Reproductive toxicity – Category 1B

\* Data compared to the previous version altered.

US