

Printing date 09/16/2021 Reviewed on 12/04/2020

1 Identification

- · Product identifier
- · Trade name: OpalTM BandTM Cement Base
- · Article number: SDS 219-001.07, 71100
- · 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

- · Information department: 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



GHS08 Health hazard

Carc. 2 H351 Suspected of causing cancer.



GHS05 Corrosion

Skin Corr. 1A H314 Causes severe skin burns and eye damage.



Skin Sens. 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:

Trade Secret

Triethylene Glycol Dimethacrylate

Methacrylic Acid

Diurethane Dimethacrylate

· Hazard statements

Causes severe skin burns and eye damage.

May cause an allergic skin reaction.

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Suspected of causing cancer.

· Precautionary statements

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P260 Do not breathe dusts or mists. P264 Wash thoroughly after handling.

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

P301+P330+P331 If swallowed: Rinse mouth. Do NOT induce vomiting.

P303+P361+P353 If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/

shower.

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).

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)



Health = 3 Fire = 1 Reactivity = 0

· HMIS-ratings (scale 0 - 4)



Health = *3 *Fire* = 1

Reactivity = 0

3 Composition/information on ingredients

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

· Dangerous	components:	
20882-04-6	Mono-2-(Methacryloyloxy) Ethyl Succinate	≥1-<10%
	♦ Skin Irrit. 2, H315; Eye Irrit. 2A, H319	
	Trade Secret	≥5-≤10%
	♦ Skin Corr. 1A, H314; Eye Dam. 1, H318	
109-16-0	Triethylene Glycol Dimethacrylate	1-10%
	💠 Skin Sens. 1, H317	
72869-86-4	Diurethane Dimethacrylate	1-10%
	♦ Skin Sens. 1, H317	
79-41-4	Methacrylic Acid	≥1-<3%
	Acute Tox. 3, H331; Skin Corr. 1A, H314; Eye Dam. 1, H318; Nacute Tox. 4, H302; Acute Tox. 4, H312; Flam. Liq. 4, H227	

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_		(1)	Contd. of page 2)
		Ethyl Alcohol	<i>≥0-≤10%</i>
		♠ Flam. Liq. 2, H225	
	68187-11-1	Co-Cr-AL Spinel Blue Green	≥0.1-<25%
		♦ Carc. 2, H351	

4 First-aid measures

- · Description of 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 copious amounts of water and provide fresh air. Immediately call a doctor.
- · 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:

Carbon dioxide

Foam

Water spray

Use fire fighting measures that suit the environment.

· Special hazards arising from the substance or mixture

During heating or in case of fire poisonous gases are produced.

- Advice for firefighters
- · 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 neutralizing agent.

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

· Reference to other sections

See Section 7 for information on safe handling.

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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.

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:

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 item 7.
- · 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.

79-41·	79-41-4 Methacrylic Acid			
REL	Long-term value: 70 mg/m³, 20 ppm Skin			
TLV	Long-term value: 70 mg/m³, 20 ppm			
64-17-	-5 Ethyl Alcohol			
PEL	Long-term value: 1900 mg/m³, 1000 ppm			
REL	Long-term value: 1900 mg/m³, 1000 ppm			
STEL	Short-term value: 1000 mg/m³			
TLV	Short-term value: 1880 mg/m³, 1000 ppm			
TWA	Short-term value: 1900 mg/m³			
4.1.124	Additional information. The lists that were valid during the execution were used as basis			

- · 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 eyes and skin.

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· 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.

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	l and chemica	l properties
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· General Information

· Appearance:

Lower:

Paste Form: Color: Blue Sweetish Odor: Odor threshold: Not determined.

· pH-value: Not applicable (non-aqueous)

· Change in condition Undetermined. Melting point/Melting range: Boiling point/Boiling range: Undetermined >100 °C · Flash point: · Flammability (solid, gaseous): Not applicable. · Decomposition temperature: Not determined. Product is not selfigniting. · Auto igniting: · Danger of explosion: Product does not present an explosion hazard. · Explosion limits:

Not determined.

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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.	
Partition coefficient (n-octanol/w	ater): Not determined.	
Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined	
Solvent content:		
VOC content:	2.5-3 %	
	30.0 g/l / 0.25 lb/gal	
VOC (EC)	2.5-3 %	
Other information	No further relevant information available.	

10 Stability and reactivity

- · Reactivity Polymerization occurs when exposed to amine catalysts, metal, or pressure.
- · Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.

>2,000 mg/kg (mouse)

- · Conditions to avoid Pressure
- · Incompatible materials:

Amine Catalysts

Metals

· Hazardous decomposition products: Carbon dioxide

11 Toxicological information

LD50

- · Information on toxicological effects
- · Acute toxicity:

Dermal

	· LD/LC50	· LD/LC50 values that are relevant for classification:				
Ī	ATE (Acu	ATE (Acute Toxicity Estimate)				
Ī	Oral	LD50	53,000 mg/kg			
	Dermal	LD50	25,000 mg/kg			
	Inhalative	LC50/4 h	355 mg/l			
	109-16-0	109-16-0 Triethylene Glycol Dimethacrylate				
Ī	Oral	LD50	>5,000 mg/kg (rat)			
		LC50 Fish	16.4 mg/l (Fish) (Toxicity to fish)			

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72869-86-	4 Diurethan	ne Dimethacrylate
Oral	LD50	>5,000 mg/kg (rat)
79-41-4 M	ethacrylic A	1cid
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 E	thyl 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)

- Primary irritant effect:
- · on the skin: Strong caustic effect on skin and mucous membranes.
- · on the eye: Strong caustic effect.
- · Sensitization: Sensitization possible through skin contact.
- · Additional toxicological information:

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

Corrosive

Irritant

Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

· Carcinogenic categories

None of the ingredients is listed.

· IARC (International Agency for Research on Cancer)					
64-17-5	Ethyl Alcohol	1			
68187-11-1	Co-Cr-AL Spinel Blue Green	2B			
14808-60-7	Silica Glass	1			
128-37-0	Butylated Hydroxytoluene	3			
· NTP (Nation	· NTP (National Toxicology Program)				
14808-60-7 Silica Glass K					
· OSHA-Ca (Occupational Safety & Health Administration)					

- · Carcinogenicity Ethyl Alcohol, Silica Glass, Co-Cr-AL Spinel Blue Green are on the IARC list of carcinogens.
- · Reproductive toxicity Does not meet the classification criteria for this hazard class.
- Specific target organ toxicity single exposure Does not meet the classification criteria for this hazard class.
- · Specific target organ toxicity repeated exposure Does not meet the classification criteria for this hazard class.
- · Aspiration hazard Does not meet the classification criteria for this hazard class.

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12 Ecological information

· Toxicity

Toxicity	Toxicity			
· Aquatic toxicity:	· Aquatic toxicity:			
109-16-0 Triethy	lene 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 Diur	ethane Dimethacrylate			
EC50	>0.6 mg/kg (Algae)			
Biodegradability	28 days (Aerobic) (Biodegradability testing)			
79-41-4 Methacr	ylic Acid			
EC50	17,000 mg/kg (Algae)			
	<180 mg/kg (daphnia) (Toxicity to aquatic invertebrates)			
64-17-5 Ethyl Ald	64-17-5 Ethyl Alcohol			
Algae Toxicity	1,000 mg/l (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:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packagings:
- **Recommendation:** Disposal must be made according to official regulations.

14	Transport	inf	ormat	ion	

· UN-Number · DOT, ADN, IMDG, IATA

ATA Not Regulated

· UN proper shipping name

· DOT, ADN, IMDG, IATA Not Regulated

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· 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 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.

No further r • Sara	elevant information available.		
· Section 355	(extremely hazardous substances):		
None of the	ingredients is listed.		
· Section 313	(Specific toxic chemical listings):		
1344-28-1	Aluminium Oxide		
68187-11-1	Co-Cr-AL Spinel Blue Green		
· TSCA (Toxi	ic Substances Control Act):		
20882-04-6	Mono-2-(Methacryloyloxy) Ethyl Succinate	ACTIVE	
109-16-0	Triethylene Glycol Dimethacrylate	ACTIVE	
72869-86-4	Diurethane Dimethacrylate	ACTIVE	
79-41-4	Methacrylic Acid	ACTIVE	
64-17-5	Ethyl Alcohol	ACTIVE	
68187-11-1 Co-Cr-AL Spinel Blue Green ACTIVE			
· Hazardous Air Pollutants			
68187-11-1 Co-Cr-AL Spinel Blue Green			
. Proposition	45		

- · 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:

64-17-5 Ethyl Alcohol

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· Carcinogenic categories

· EPA (Envir	onmental Protection Agency)	
None of the	ingredients is listed.	
· ACGIH Car	cinogenicity (American Conference of Governmental Industrial Hygienists)	
1344-28-1	Aluminium Oxide	A4
64-17-5	Ethyl Alcohol	A3
14808-60-7	Silica Glass	A2
128-37-0	Butylated Hydroxytoluene	A4
· NIOSH-Ca (National Institute for Occupational Safety and Health)		
14808-60-7	Silica Glass	
· Chemical sa	fety 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 09/16/2021 / -
- · 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)

VOC: Volatile Organic Compounds (USA, EU)

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

Flam. Liq. 2: Flammable liquids – Category 2

Flam. Liq. 4: Flammable liquids - Category 4

Acute Tox. 4: Acute toxicity - Category 4

Acute Tox. 3: Acute toxicity - Category 3

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

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

 ${\it Eye Dam. 1: Serious \ eye \ damage/eye \ irritation-Category \ 1}$

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

Skin Sens. 1: Skin sensitisation – Category 1

Carc. 2: Carcinogenicity - Category 2