Safety Data Sheet
acc. to OSHA HCS

Printing date 11/08/2022 Reviewed on 11/02/2022

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1 Identification

· **Product identifier**

· **Trade name: Opal™ Bond™ Flow & Opal™ Bond™ Flow Blue**

· **Article number:** SDS 75-001.12, 71161, 71050
· **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) :(800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) identification

· **Classification of the substance or mixture**

GHS07

Skin Irritation 2	H315 Causes skin irritation.
Eye Irritation 2A	H319 Causes serious eye irritation.
Sensitization - Skin 1	H317 May cause an allergic skin reaction.

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** GHS07
· **Signal word** Warning

· **Health Hazard-determining components of labeling:**
Triethylene Glycol Dimethacrylate
Organophosphine Oxide
· **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
· **Precautionary statements**

P261	Avoid breathing dust/fume/gas/mist/vapors/spray
P264	Wash thoroughly after handling.
P272	Contaminated work clothing must not be allowed out of the workplace.
P280	Wear protective gloves / eye protection / face protection.
P302+P352	If on skin: Wash with plenty of water.
P305+P351+P338	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P362+P364	Take off contaminated clothing and wash it before reuse.

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P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P321	Specific treatment (see on this label).
P337+P313	If eye irritation persists: Get medical advice/attention.
P363	Wash contaminated clothing before reuse.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**
· **NFPA ratings (scale 0 - 4)**

Health = 1
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = 1
Fire = 0
Reactivity = 0

3 Composition/information on ingredients

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

· **Dangerous components:**		
109-16-0	Triethylene Glycol Dimethacrylate	>1-<20%
	Trade Secret	>0.1-<10%
13463-67-7	Titanium Dioxide	>0.1-<10%
162881-26-7	Organophosphine Oxide	>0.1-<10%

· **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.
· **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:** Immediately wash with water and soap and rinse thoroughly.
· **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, 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.

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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 fully protective suit.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
· **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).
Dispose contaminated material as waste according to item 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**
Avoid release to the environment
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
· **Information about protection against explosions and fires:** No special measures required.

· **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 Adhesive

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

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

13463-67-7 Titanium Dioxide	
ACGIH TLV	Short-term value: 10* 5 mg/m³
PEL	Long-term value: 15* mg/m³ *total dust
REL	See Pocket Guide App. A
TLV	Long-term value: 0.2* 2.5** mg/m³ resp. fraction, *nanoscale,**finescale, A3
TWA	Short-term value: 15* 5 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.
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.
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

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9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Paste
Color:	According to product specification
· **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 (solid, gaseous):**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	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.
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
Dynamic:	Not determined.
Kinematic:	Not determined
· **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
Sparks
Ignition sources
Heat
Flames

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· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known.

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)
13463-67-7 Titanium Dioxide		
Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)
162881-26-7 Organophosphine Oxide		
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:** Irritating effect.
· **Sensitization:** Sensitization possible through skin contact.
· **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**		
	Co-Cr-AL Spinel Blue Green	2B
14808-60-7	Silica Glass	1

· **NTP (National Toxicology Program)**		
14808-60-7	Silica Glass	K

· **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)

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13463-67-7 Titanium Dioxide	
EC50	>100 mg/kg (Algae) >1,000 mg/kg (Fish)
162881-26-7 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.
· **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:**
Dispose of contents/container in accordance with international, federal, state, and local regulations.

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

14 Transport information

· **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.

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· **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
Co-Cr-AL Spinel Blue Green

· **TSCA (Toxic Substances Control Act):**

109-16-0	Triethylene Glycol Dimethacrylate	ACTIVE
13463-67-7	Titanium Dioxide	ACTIVE
162881-26-7	Organophosphine Oxide	ACTIVE

· **Hazardous Air Pollutants**
Co-Cr-AL Spinel Blue Green

· **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)**

	Trade Secret	A4
14808-60-7	Silica Glass	A2

· **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

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· **Contact:** Customer Service
· **Date of preparation / last revision** 11/08/2022 / -
· **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
Skin Irritation 2: Skin corrosion/irritation – Category 2
Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A
Sensitization - Skin 1: Skin sensitisation – Category 1
· *** Data compared to the previous version altered.**