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Safety Data Sheet according to WHS Regulations

Printing date 07.08.2023

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Revision: 07.08.2023

Trade name: Opal ^{IM} Bond ^{IM} Flo	w & Opal TM Bond TM Flow Blue	
Professional Orthodontic Adhesiv	bstance or mixture and uses advised against	
Details of the supplier of the safe Manufacturer/Supplier: Ultradent Products, Inc. 505 W. Ultradent Drive (10200 S) South Jordan, UT 84095-3942 USA onlineordersupport@ultradent.co	ty data sheet	
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 f Emergency telephone number: CHEMTREC (NORTH AMERICA (INTERNATIONAL)) :(800) 424-9300	
Hazard(s) Identification		
Classification of the substance of Skin Irrit. 2 Serious eye damage/irritation – C	mixture H315 Causes skin irritation. ategory 2A H319 Causes serious eye irritation. H317 May cause an allergic skin reaction.	
Hazard(s) Identification Classification of the substance of Version Section	H315 Causes skin irritation. ategory 2A H319 Causes serious eye irritation.	

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· Precautionary s	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.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves / eye protection / face protection.
P305+P351+P.	338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if
	present and easy to do. Continue rinsing.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
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:				
109-16-0	Triethylene Glycol Dimethacrylate	🚸 Skin Sens. 1, H317	>1-<20%	
	Trade Secret	🚸 Skin Corr. 1A, H314; Eye Dam. 1, H318	>0.1-<10%	
13463-67-7	Titanium Dioxide	🚸 Carc. 2, H351	>0.1-<10%	
162881-26-7	Organophosphine Oxide	🚸 Skin Sens. 1, H317	>0.1-<10%	
Additional informations Found and of the listed harmed abarrent of the section 16				

• *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: 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.

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

5 Fire Fighting Measures

· Suitable extinguishing agents:

Foam, dry chemical, carbon dioxide

Use fire extinguishing methods suitable to surrounding conditions.

• Special hazards arising from the substance or mixture No further relevant information available.

· Protective equipment: Wear fully protective suit.

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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 fire and explosion protection: No special measures required.
- · 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 Adhesive

8 Exposure controls and personal protection

• Additional information about design of technical facilities: No further data; see item 7.

· Ingredients with limit values that require monitoring at the workplace:

13463-67-7 Titanium Dioxide

- WES Long-term value: 10 mg/m³ inhalable dust
- 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.

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· 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.



Tightly sealed goggles

· Body protection: Protective work clothing

General Information		
Appearance:		
Form:	Paste	
Colour:	According to product specification	
Odour:	Acrylic	
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:	Not applicable.	
Flammability (solid, gas):	Not applicable.	
Decomposition temperature:	Not determined.	
Auto-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.	

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 Viscosity: Dynamic: Kinematic: 	Not determined. Not determined.	
• Other information	Not determined. No further relevant information available.	

10 Stability and Reactivity

- · Reactivity Stable
- 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

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

11 Toxicological Information

· Information on toxicological effects

· Acute toxicity Based on available data, the classification criteria are not met.

	*			
\cdot LD/LC5	0 values rel	levant for classification:		
109-16-	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)		
13463-6	13463-67-7 Titanium Dioxide			
Oral	LD50	>5,000 mg/kg (rat)		
Dermal	LD50	>5,000 mg/kg (rabbit)		
162881-	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)		
· Skin coi	rrosion/irrit	ation Causes skin irritation.		
· Serious	eye damage	p/irritation Causes serious eye irritation.		
		sensitisation May cause an allergic skin reaction.		
		icity Based on available data, the classification criteria are not met.		
	0 v	sed on available data, the classification criteria are not met.		
• Reprodi	ictive toxici	ty Based on available data, the classification criteria are not met.		
	0 1	ure Based on available data, the classification criteria are not met.		
·STOT-r	epeated exp	osure Based on available data, the classification criteria are not met.		

• Aspiration hazard Based on available data, the classification criteria are not met.

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Biodegradability28Aqua toxicity3213463-67-7 Titanium Dioxide26EC502162881-26-7 Organophosphine Uxit26EC50 (static)2	100 mg/kg (Algae) 8 days (Aerobic) (Biodegradability testing) 2 mg/l (daphnia) (No Observed Effect Concentration) 100 mg/kg (Algae) 1,000 mg/kg (Fish)
EC50>Biodegradability28Aqua toxicity3213463-67-7 Titanium Dioxide>EC50>I62881-26-7 Organophosphine OxiaEC50 (static)>	100 mg/kg (Algae) 8 days (Aerobic) (Biodegradability testing) 2 mg/l (daphnia) (No Observed Effect Concentration) 100 mg/kg (Algae) 1,000 mg/kg (Fish)
Biodegradability28Aqua toxicity3213463-67-7 Titanium Dioxide26EC50>162881-26-7 Organophosphine Oxid26EC50 (static)>	8 days (Aerobic) (Biodegradability testing) 2 mg/l (daphnia) (No Observed Effect Concentration) 100 mg/kg (Algae) 1,000 mg/kg (Fish)
Aqua toxicity 32 13463-67-7 Titanium Dioxide 2 EC50 > 162881-26-7 Organophosphine Oxia 2 EC50 (static) >	2 mg/l (daphnia) (No Observed Effect Concentration) 100 mg/kg (Algae) 1,000 mg/kg (Fish)
13463-67-7 Titanium Dioxide EC50 > 162881-26-7 Organophosphine Oxid EC50 (static) >	100 mg/kg (Algae) 1,000 mg/kg (Fish)
EC50 >	1,000 mg/kg (Fish)
>	1,000 mg/kg (Fish)
162881-26-7 Organophosphine OxidEC50 (static)	
<i>EC50 (static)</i> >.	de
· · · · ·	
	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)
	s: er relevant information available. information available. lation) (Self-assessment): slightly hazardous for water urge quantities of it to reach ground water, water course or sewage system. nt

· Recommendation

Dispose of contents/container in accordance with international, federal, state, and local regulations.

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

UN-Number ADG, ADN, IMDG, IATA	not regulated	
UN proper shipping name	0	
ADG, ADN, IMDG, IATA	not regulated	
Transport hazard class(es)		
ADG, ADN, IMDG, IATA		
Class	not regulated	

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· Packing group · ADG, IMDG, IATA	not regulated	
· Environmental hazards:	Not applicable.	
· Special precautions for user	Not Applicable	
• Transport in bulk according to Annex I and the IBC Code	I of Marpol Not applicable.	
· UN "Model Regulation":	not regulated	

15 Regulatory information

• Safety, health and environmental regulations/legislation specific for the substance or mixture

· Australian In	wentory of Industrial Chemicals		
65997-17-3	Inorganic Glass		
109-16-0	Triethylene Glycol Dimethacrylate		
41637-38-1	EOBPADMA		
	Trade Secret		
	Co-Cr-AL Spinel Blue Green		
13463-67-7	Titanium Dioxide		
10287-53-3	Ethyl-4-Dimethylamino Benzoate		
162881-26-7	Organophosphine Oxide		
10373-78-1	Camphorquinone		
14808-60-7	Silica Glass		
1332-37-2	Red Iron Oxide		
51274-00-1	Yellow Iron Oxide		
12737-27-8	Chromium Iron Oxide		
· Standard for	the Uniform Scheduling of Medicines and Poisons		
None of the ir	ngredients is listed.		
· Australia: Pr	iority Existing Chemicals		
None of the in	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

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H351 Suspected of causing cancer.

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Department issuing SDS: Environmental, Health, and Safety	
Contact: Customer Service	
bbreviations and acronyms:	
DR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning ti	he International
arriage of Dangerous Goods by Road)	
MDG: International Maritime Code for Dangerous Goods	
ATA: International Air Transport Association	
INECS: European Inventory of Existing Commercial Chemical Substances	
LINCS: European List of Notified Chemical Substances	
AS: Chemical Abstracts Service (division of the American Chemical Society)	
C50: Lethal concentration, 50 percent	
D50: Lethal dose, 50 percent	
BT: Persistent, Bioaccumulative and Toxic	
PvB: very Persistent and very Bioaccumulative	
kin Corr. 1A: Skin corrosion/irritation – Category 1A	
kin Irrit. 2: Skin corrosion/irritation – Category 2	
ye Dam. 1: Serious eye damage/eye irritation – Category 1	
erious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A	
kin Sens. 1: Skin sensitisation – Category 1	
arc. 2: Carcinogenicity – Category 2	
Data compared to the previous version altered.	
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