



Safety Data Sheet according to WHS Regulations

Date of issue: 13.03.2025

Revision: 13.03.2025

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1 Identification

· **Other means of identification**

· **Trade name:** Mosaic™ Universal Composite (All Shades)

· **Article number:**

SDS 370-001.05R01, 1003971, 4760, 4761, 4762, 1003661, 1003662, 4763, 4764, 4765, 1003663, 1003664, 1003665, 1003666, 4766, 4767, 4768, 1003667, 1003668, 1003669, 1003670, 1003671, 1003672, 4769, 4770, 4771, 1003673, 1003674, 1003675, 1003676, 1003677, 1003678, 1003679, 1003681, 4772, 4773, 4774, 1003682, 4775, 4776, 4777, 1003651, 1003652, 1003653, 1003654, 1003655, 1003656, 4778, 4779, 4780, 1003657, 1003658, 1003659, 1003660, 4781, 4782, 4783, 4784, 4785, 4786, 4787, 4788, 4789, 4790, 4791, 4792, 4793, 4794, 4795, 4796, 4797, 4798, 4799, 1002667, 1002666, 4803, S4801, S4802, S4803

· **Relevant identified uses of the substance or mixture and uses advised against**

Professional Dental Restorative Material

· **Application of the substance / the mixture** Professional Dental Restorative Material

· **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

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) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) Identification

· **Classification of the substance or mixture**



Skin corrosion/irritation – Category 2

Eye damage/irritation – Category 2A

Skin sensitisation – Category 1

Specific target organ toxicity (single exposure) –
Category 3

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

· **Label elements**

· **GHS label elements** Void

· **Hazard pictograms** GHS07

· **Signal word** Warning

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· **Hazard-determining components of labelling:**

Diurethane Dimethacrylate (≥ 0 -<40 %)Silane (≥ 0 -<25 %)Triethylene Glycol Dimethacrylate (≥ 0 -<12 %)

· **Hazard statements**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

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.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves / eye protection / face protection.

P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position 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.

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:**

72869-86-4	Diurethane Dimethacrylate	≥ 0 -<40%
	⚠ Skin sensitisation – Category 1, H317	
2530-85-0	Silane	≥ 0 -<25%
	⚠ Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319; Specific target organ toxicity (single exposure) – Category 3, H335	
109-16-0	Triethylene Glycol Dimethacrylate	≥ 0 -<12%
	⚠ Skin sensitisation – Category 1, H317	
128-37-0	Butylated Hydroxytoluene	≥ 0 -<3%
	⚠ Acute toxicity - oral – Category 4, H302	

· **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:**

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. If symptoms persist, consult a doctor.

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- **After swallowing:** If symptoms persist consult 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

- **Suitable extinguishing agents:**
Water spray, fog, or mist, foam, dry chemical, carbon dioxide
Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** Carbon Oxides
- **Advice for firefighters:**
General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.
- **Protective equipment:** Wear fully protective suit.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:**
Dilute with plenty of water.
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 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.

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:** 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:**
Protect from exposure to the light.
Protect from heat
See product labelling.
Keep container tightly sealed.
- **Specific end use(s)** No further relevant information available.

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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:**

128-37-0 Butylated Hydroxytoluene

WES Long-term value: 10 mg/m³

· **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.

· **Eye protection:**



Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and Chemical Properties

· **General Information**

· **Appearance:**

· **Form:**

Paste

· **Colour:**

Color Dependent

· **Odour:**

Acrylic

· **Odour threshold:**

Not determined.

· **pH-value:**

Not applicable (non-aqueous)

· **Change in condition**

· **Melting point/freezing point:**

Undetermined.

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- **Initial boiling point and boiling range:** Undetermined.
- **Flash point:** Not applicable.
- **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 at 20 °C:** 1.9-2.1 g/cm³
- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.
- **Solubility in / Miscibility with**
- **water:** Fully miscible.
- **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 under the influence of light.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:**
 - Flames
 - Light
 - Heat
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Carbon monoxide and 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	>87,972 mg/kg (rat)
72869-86-4 Diurethane Dimethacrylate		
Oral	LD50	>5,000 mg/kg (rat)
109-16-0 Triethylene Glycol Dimethacrylate		
Oral	LD50	>5,000 mg/kg (rat)
	LC50 Fish	16.4 mg/l (Fish) (Toxicity to fish)

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Dermal	LD50	>2,000 mg/kg (mouse)
128-37-0 Butylated Hydroxytoluene		
Oral	LD50	10,700 mg/kg (guinea pig)
		1,040 mg/kg (mouse)
		890 mg/kg (rat)
	LC50 Fish	5.3 mg/l (Fish)
Dermal	LD50	>2,000 mg/kg (rat)

- **Primary irritant effect:**
- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** May cause respiratory irritation.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

12 Ecological Information

· Toxicity

· Aquatic toxicity:

72869-86-4 Diurethane Dimethacrylate	
EC50	>0.6 mg/kg (Algae)
Biodegradability	28 days (Aerobic) (Biodegradability testing)
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)
128-37-0 Butylated Hydroxytoluene	
Aqua toxicity (static)	0.48 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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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13 Disposal considerations

- **Waste treatment methods**
- **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.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

· UN-Number	
· ADG, 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)	
None of the ingredients is listed.	
· Australian Inventory of Industrial Chemicals	
1565-94-2	Bis - GMA
41637-38-1	EOBPADMA
72869-86-4	Diurethane Dimethacrylate
2530-85-0	Silane
109-16-0	Triethylene Glycol Dimethacrylate
25852-47-5	PEGDMA
128-37-0	Butylated Hydroxytoluene
13463-67-7	Titanium Dioxide
51274-00-1	Yellow Iron Oxide
	Chromium Iron Oxide

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1332-37-2	Red Iron Oxide
51274-00-1	Yellow Iron Oxide
· Standard for the Uniform Scheduling of Medicines and Poisons	
None of the ingredients is listed.	
· 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**

H302 Harmful if swallowed.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
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
Acute toxicity - oral – Category 4: Acute toxicity – Category 4
Skin corrosion/irritation – Category 2: Skin corrosion/irritation – Category 2
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.**

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