



# Safety data sheet according to UK REACH

Printing date 13.03.2025

Version number 1

Revision: 13.03.2025

## 1 Identification of the substance/mixture and of the company/undertaking

· **Product identifier**

· **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

EC Responsible Person  
Ultradent Products GmbH  
Am Westhoyer Berg 30  
51149 Cologne Germany  
Email: infoDE@ultradent.com  
Office Phone: +49(0)2203-35-92-0

· **Further information obtainable from:** Customer Service

· **Emergency telephone number:**

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

## 2 Hazards identification

· **Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008**



Skin Irrit. 2            H315 Causes skin irritation.  
Eye Irrit. 2            H319 Causes serious eye irritation.  
Skin Sens. 1            H317 May cause an allergic skin reaction.  
STOT SE 3            H335 May cause respiratory irritation.  
.....  
Aquatic Chronic 3    H412 Harmful to aquatic life with long lasting effects.

· **Label elements**

· **Labelling according to Regulation (EC) No 1272/2008** Void

· **Hazard pictograms** GHS07

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· **Signal word** Warning

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

Diurethane Dimethacrylate

Silane

Triethylene Glycol Dimethacrylate

· **Hazard statements**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements**

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read carefully and follow all instructions.

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

P280 Wear protective gloves / eye protection / face protection.

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.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

### 3 Composition/information on ingredients

· **Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 72869-86-4	Diurethane Dimethacrylate	≥0-<40%
EINECS: 276-957-5	⚠ Skin Sens. 1, H317; Aquatic Chronic 3, H412	
CAS: 2530-85-0	Silane	≥0-<25%
EINECS: 219-785-8	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 109-16-0	Triethylene Glycol Dimethacrylate	≥0-<12%
EINECS: 203-652-6	⚠ Skin Sens. 1, H317	
CAS: 128-37-0	Butylated Hydroxytoluene	≥0-<3%
EINECS: 204-881-4	⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410; ⚠ Acute Tox. 4, H302	

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 4 First aid measures

· **Description of 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.

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- **After eye contact:**  
*Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.*
- **After swallowing:** *If symptoms persist consult 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 Firefighting measures

- **Extinguishing media**
- **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:**  
*Do not allow product to reach sewage system or any water course.*  
*Inform respective authorities in case of seepage into water course or sewage system.*  
*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

- **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.*
- **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.*  
*Protect from heat*  
*See product labelling.*  
*Keep container tightly sealed.*

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· **Specific end use(s)** No further relevant information available.

## 8 Exposure controls/personal protection

· **Control parameters**

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

**128-37-0 Butylated Hydroxytoluene**

WEL Long-term value: 10 mg/m<sup>3</sup>

· **Additional information:** The lists valid during the making were used as basis.

· **Exposure controls**

· **Appropriate engineering controls** No further data; see section 7.

· **Individual protection measures, such as 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.

· **Hand protection**



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/face protection**



Tightly sealed goggles

· **Body protection:** Protective work clothing

## 9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Physical state**

Fluid

· **Colour:**

Color Dependent

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· <b>Odour:</b>	Acrylic
· <b>Odour threshold:</b>	Not determined.
· <b>Melting point/freezing point:</b>	Undetermined.
· <b>Boiling point or initial boiling point and boiling range</b>	Undetermined.
· <b>Flammability</b>	Not applicable.
· <b>Lower and upper explosion limit</b>	
· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.
· <b>Flash point:</b>	Not applicable.
· <b>Decomposition temperature:</b>	Not determined.
· <b>pH</b>	Not applicable (non-aqueous)
· <b>Viscosity:</b>	
· <b>Kinematic viscosity</b>	Not determined.
· <b>Dynamic:</b>	Not determined.
· <b>Solubility</b>	
· <b>water:</b>	Fully miscible.
· <b>Partition coefficient n-octanol/water (log value)</b>	Not determined.
· <b>Vapour pressure:</b>	Not determined.
· <b>Density and/or relative density</b>	
· <b>Density at 20 °C:</b>	1.9-2.1 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Other information</b>	
· <b>Appearance:</b>	
· <b>Form:</b>	Paste
· <b>Important information on protection of health and environment, and on safety.</b>	
· <b>Ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Change in condition</b>	
· <b>Evaporation rate</b>	Not determined.
· <b>Information with regard to physical hazard classes</b>	
· <b>Explosives</b>	Void
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Void
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	Void

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### 10 Stability and reactivity

- **Reactivity** Polymerization under the influence of light.
- **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:**
  - Flames
  - Light
  - Heat
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Carbon monoxide and carbon dioxide

### 11 Toxicological information

- **Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **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)
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#### 72869-86-4 Diurethane Dimethacrylate

Oral	LD50	>5,000 mg/kg (rat)
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#### 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)

#### 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.
- **STOT-single exposure** May cause respiratory irritation.

- **Information on other hazards**

- **Endocrine disrupting properties**

128-37-0	Butylated Hydroxytoluene
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List II

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### 12 Ecological information

- **Toxicity**

- **Aquatic toxicity:**

**72869-86-4 Diurethane Dimethacrylate**

EC50	>0.6 mg/kg (Algae)
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Biodegradability	28 days (Aerobic) (Biodegradability testing)
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**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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**128-37-0 Butylated Hydroxytoluene**

Aqua toxicity (static)	0.48 mg/l (daphnia) (Toxicity to aquatic invertebrates)
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- **Persistence and degradability** No further relevant information available.
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **Other adverse effects**
- **Remark:** Harmful to fish
- **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.  
Harmful to aquatic organisms

### 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

- |                                     |               |
|-------------------------------------|---------------|
| · <b>UN number or ID number</b>     |               |
| · <b>ADR, IMDG, IATA</b>            | not regulated |
| · <b>UN proper shipping name</b>    |               |
| · <b>ADR, ADN, IMDG, IATA</b>       | not regulated |
| · <b>Transport hazard class(es)</b> |               |
| · <b>ADR, ADN, IMDG, IATA</b>       |               |
| · <b>Class</b>                      | not regulated |

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- |  |                 |
|--|-----------------|
| · <b>Packing group</b>   |                 |
| · <b>ADR, IMDG, IATA</b>   | not regulated   |
| · <b>Environmental hazards:</b>                                  | Not applicable. |
| · <b>Special precautions for user</b>                            | Not Applicable  |
| · <b>Maritime transport in bulk according to IMO instruments</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>                                  | 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.

- **Poisons Act**

- **Regulated explosives precursors**

None of the ingredients is listed.

- **Regulated poisons**

None of the ingredients is listed.

- **Reportable explosives precursors**

None of the ingredients is listed.

- **Reportable poisons**

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.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

- **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

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*IATA: International Air Transport Association**GHS: Globally Harmonised System of Classification and Labelling of Chemicals**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**ATE: Acute toxicity estimate values**Acute Tox. 4: Acute toxicity – Category 4**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Eye Irrit. 2: Serious eye damage/eye irritation – Category 2**Skin Sens. 1: Skin sensitisation – Category 1**STOT SE 3: Specific target organ toxicity (single exposure) – Category 3**Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1**Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1**Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3***\* Data compared to the previous version altered.**

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