



Safety Data Sheet according to WHS Regulations

Date of issue: 19.08.2025

Revision: 19.08.2025

1 Identification

· **Other means of identification**

· **Trade name: FORMA**

· **Article number:**

SDS 442-001.02R01, FO00002, FO00003, 4201-P2, 4201P2-P3, FO00004, FO00005, 4202-P2, 4202P2-P3, FO00006, FO00007, 4263-P2, 4264-P2, 4265-P2, FO00008, FO00009, 4265P2-P3, 4266-P2, FO00010, FO00011, 4266P2-P3, 4267-P2, FO00012, FO00013, 4267P2-P3, 4268-P2, FO00014, FO00015, 4268P2-P3, 4269-P2, FO00016, FO00017, 4269P2-P3, 4270-P2, FO00018, FO00019, 4270P2-P3, 4271-P2, FO00020, FO00021, 4271P2-P3, 4272-P2, FO00022, FO00023, 4272P2-P3, 4273-P2, FO00031, FO00032, 4273P2-P3, 4274-P2, FO00033, FO00034, 4274P2-P3, 4275-P2, FO00044, FO00037, 4275P2-P3, 4276-P2, FO00001, FO00038, 4276P2-P3, 4277-P2, FO00030, FO00040, 4277P2-P3, 4280-P2, FO00042, FO00026, 4281-P2, 4281P2-P3, FO00043, FO0000G, 42813-P2, 4281P2-P3, FO00046, FO00047, 4286-P2, 4286P2-P3, FO0000S, 4287-P2, 4287P2-P3, 4288-P2, 4288P2-P3, 4289-P2, 4289P2-P3, 4290-P2, 4290P2-P3, 4291-P2, 4291P2-P3, 4292-P2, 4292P2-P3, 4293-P2, 4293P2-P3, 4294-P2, 4294P2-P3, 4295-P2, 4295P2-P3, 4296-P2, 4296P2-P3, 4297-P2, 4297P2-P3, 4298-P2, 4299-P2, 4300-P2, 4301-P2, 4302-P2, 4303-P2, 4304-P2, 4304P2-P3, 4305-P2, 4305P2-P3, 4306-P2, 4306P2-P3, 4307-P2, 4307P2-P3

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

· **Application of the substance / the mixture** Professional Dental Composite

· **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
(800) 552-5512

Ultradent Australia Pty Ltd.
Level 22/2 Market Street
Sydney NSW 2000
Australia

Email: info.au@ultradent.com
Toll Free: 1-800-290929

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

· **Emergency telephone number:**

CHEMTREC (NORTH AMERICA) : +1 (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) Identification

· **Classification of the substance or mixture**



Eye damage/irritation – Category 2A H319 Causes serious eye irritation.

Skin sensitisation – Category 1 H317 May cause an allergic skin reaction.

· **Label elements**

· **GHS label elements** Void

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- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
Diurethane Dimethacrylate (≥1-<10 %)
Triethylene Glycol Dimethacrylate (≥1-<10 %)
- **Hazard statements**
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
- **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.
P305+P351+P338 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:**

7631-86-9	Silicon Dioxide, Chemically Prepared	≥5-<25%
	⚠ Eye damage/irritation – Category 2A, H319; Specific target organ toxicity (single exposure) – Category 3, H335	
72869-86-4	Diurethane Dimethacrylate	≥1-<10%
	⚠ Skin sensitisation – Category 1, H317	
109-16-0	Triethylene Glycol Dimethacrylate	≥1-<10%
	⚠ Skin sensitisation – Category 1, H317	
1314-23-4	Zirconium Dioxide	≥1-≤10%
68909-20-6	Hydrophobic Pyrogenic Silica	≥1-≤10%
	⚠ Specific target organ toxicity (repeated exposure) – Category 2, H373	
10287-53-3	Ethyl-4-Dimethylamino Benzoate	≥0.1-<1%
	⚠ Reproductive toxicity – Category 1B, H360	

- **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.
Seek medical treatment in case of complaints.
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.

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*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 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: *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.*

6 Accidental Release Measures

· Personal precautions, protective equipment and emergency procedures *Wear protective equipment.***· 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 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:***Store in a cool place.**Protect from exposure to the light.**See product labelling.**Keep container tightly sealed.***· Specific end use(s)** *Professional Dental Composite*

8 Exposure controls and personal protection

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

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

7631-86-9 Silicon Dioxide, Chemically Prepared

WES Long-term value: 2 mg/m³

1314-23-4 Zirconium Dioxide

WES Short-term value: 10 mg/m³
Long-term value: 5 mg/m³
as Zr

· **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.

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:**

Fluid

· **Colour:**

According to product specification

· **Odour:**

Characteristic

· **Odour threshold:**

Not determined.

· **pH-value:**

Not applicable (non-aqueous)

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- **Change in condition**
- **Melting point/freezing point:** Undetermined.
- **Initial boiling point and boiling range:** >250 °C
- **Flash point:** >150 °C
- **Flammability** Not applicable.
- **Auto-ignition temperature:** 255 °C
- **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:** 0.69538-1.83525 g/cm³
- **Bulk density:** 695-1,835 kg/m³
- **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.
- **Viscosity:**
- **Dynamic:** Not determined.
- **Kinematic:** Not determined.
- **Other information**
- **Particle characteristics** Not applicable.
- **Physical state** Fluid

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
Heat
- **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.

· LD/LC50 values relevant for classification:

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)

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Dermal LD50	>2,000 mg/kg (mouse)
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- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **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** Based on available data, the classification criteria are not met.
- **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)

- **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.

13 Disposal considerations

· Waste treatment methods

· Recommendation

Do not allow product to reach sewage system.
 Must not be disposed together with household garbage. Do not allow product to reach sewage system.
 Dispose of contents/container in accordance with international, federal, state, and local regulations.

· Uncleaned packaging:

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

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14 Transport information

· UN-Number	
· ADG, IMDG, IATA	not regulated
· UN proper shipping name	
· ADG, 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
65997-17-3 Inorganic Glass
41637-38-1 EOBPADMA
7631-86-9 Silicon Dioxide, Chemically Prepared
72869-86-4 Diurethane Dimethacrylate
109-16-0 Triethylene Glycol Dimethacrylate
1314-23-4 Zirconium Dioxide
68909-20-6 Hydrophobic Pyrogenic Silica
67762-90-7 Amorphous Silica
10287-53-3 Ethyl-4-Dimethylamino Benzoate
2440-22-4 2-(2H-benzotriazol-2-yl)-p-cresol
10373-78-1 Camphorquinone
51274-00-1 Yellow Iron Oxide
128-37-0 Butylated Hydroxytoluene
Chromium Iron Oxide
1309-37-1 Ferric Oxide
14807-96-6 Talc (Mg3H2(SiO3)4)
· Standard for the Uniform Scheduling of Medicines and Poisons
None of the ingredients is listed.

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· **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**

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H360 May damage fertility or the unborn child.

H373 May cause damage to organs through prolonged or repeated exposure.

· **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

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

Skin sensitisation – Category 1: Skin sensitisation – Category 1

Reproductive toxicity – Category 1B: Reproductive toxicity – Category 1B

Specific target organ toxicity (single exposure) – Category 3: Specific target organ toxicity (single exposure) – Category 3

Specific target organ toxicity (repeated exposure) – Category 2: Specific target organ toxicity (repeated exposure) – Category 2