

Safety data sheet according to UK REACH

Printing date 19.08.2025

Version number 1

Revision: 19.08.2025

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

· **Product identifier**

· **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, 42812-P2, 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

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

2 Hazards identification

· **Classification of the substance or mixture**

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



Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

(Contd. on page 2)

Safety data sheet according to UK REACH

Printing date 19.08.2025

Version number 1

Revision: 19.08.2025

Trade name: FORMA

(Contd. of page 1)

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
Diurethane Dimethacrylate
Triethylene Glycol Dimethacrylate
- **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 carefully and follow all instructions.
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/information on ingredients

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

· **Dangerous components:**

CAS: 7631-86-9	Silicon Dioxide, Chemically Prepared	≥5-<25%
EINECS: 231-545-4	⚠ Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 72869-86-4	Diurethane Dimethacrylate	≥2.5-≤10%
EINECS: 276-957-5	⚠ Skin Sens. 1, H317; Aquatic Chronic 3, H412	
CAS: 109-16-0	Triethylene Glycol Dimethacrylate	≥1-≤10%
EINECS: 203-652-6	⚠ Skin Sens. 1, H317	
CAS: 1314-23-4	Zirconium Dioxide	≥1-≤10%
EINECS: 215-227-2	substance with a Community workplace exposure limit	
CAS: 68909-20-6	Hydrophobic Pyrogenic Silica	≥1-≤10%
EINECS: 272-697-1	⚠ STOT RE 2, H373, EUH066	
CAS: 10287-53-3	Ethyl-4-Dimethylamino Benzoate	≥0.1-<1%
EINECS: 233-634-3	⚠ Repr. 1B, H360; ⚠ Aquatic Chronic 2, H411	

- **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:**
This product is a thick paste, therefore inhalation is extremely unlikely.
Seek medical treatment in case of complaints.

(Contd. on page 3)

Safety data sheet according to UK REACH

Printing date 19.08.2025

Version number 1

Revision: 19.08.2025

Trade name: FORMA

(Contd. of page 2)

*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.***· 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: Use fire extinguishing methods suitable to surrounding conditions.**· 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 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

· 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:***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*

GB

(Contd. on page 4)

Safety data sheet according to UK REACH

Printing date 19.08.2025

Version number 1

Revision: 19.08.2025

Trade name: **FORMA**

(Contd. of page 3)

8 Exposure controls/personal protection

· Control parameters

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

1314-23-4 Zirconium Dioxide

WEL	Short-term value: 10 mg/m ³ Long-term value: 5 mg/m ³ as Zr
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· 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.

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

(Contd. on page 5)

Safety data sheet

according to UK REACH

Printing date 19.08.2025

Version number 1

Revision: 19.08.2025

Trade name: FORMA

(Contd. of page 4)

· Colour:	According to product specification
· Odour:	Characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling point and boiling range	>250 °C
· Flammability	Not applicable.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	>150 °C
· Auto-ignition temperature:	255 °C
· Decomposition temperature:	Not determined.
· pH	Not applicable (non-aqueous)
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Not miscible or difficult to mix.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density at 20 °C:	0.69538-1.83525 g/cm ³
· Relative density	Not determined.
· Bulk density:	695-1,835 kg/m ³
· Vapour density	Not determined.
· Other information	
· Appearance:	
· Form:	Fluid
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Evaporation rate	Not determined.
· Information with regard to physical hazard classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void

(Contd. on page 6)

GB

Safety data sheet according to UK REACH

Printing date 19.08.2025

Version number 1

Revision: 19.08.2025

Trade name: **FORMA**

(Contd. of page 5)

· **Desensitised explosives**

Void

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

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:**

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)

- **Primary irritant effect:**
- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **Information on other hazards**

· **Endocrine disrupting properties**

128-37-0	Butylated Hydroxytoluene
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List II

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.
- **Bioaccumulative potential** No further relevant information available.

(Contd. on page 7)

Safety data sheet according to UK REACH

Printing date 19.08.2025

Version number 1

Revision: 19.08.2025

Trade name: FORMA

(Contd. of page 6)

- **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**
- **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.

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.

14 Transport information

- | | |
|--|-----------------|
| · UN number or ID number | |
| · ADR, IMDG, IATA | not regulated |
| · UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | not regulated |
| · Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | not regulated |
| · Packing group | |
| · ADR, IMDG, IATA | not regulated |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not Applicable |
| · Maritime transport in bulk according to IMO instruments | 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.

(Contd. on page 8)

GB

Safety data sheet according to UK REACH

Printing date 19.08.2025

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Trade name: FORMA

(Contd. of page 7)

- **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**

- 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.

- H411 Toxic to aquatic life with long lasting effects.

- H412 Harmful to aquatic life with long lasting effects.

- EUH066 Repeated exposure may cause skin dryness or cracking.

- **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

- 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

- Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

- Skin Sens. 1: Skin sensitisation – Category 1

- Repr. 1B: Reproductive toxicity – Category 1B

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

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

- Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

- Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

- *** Data compared to the previous version altered.**