



Safety data sheet according to UK REACH

Printing date 03.10.2025

Version number 1

Revision: 03.10.2025

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

· **Product identifier**

· **Trade name:** FORMA™ S

· **Article number:**

SDS 518-001.01R01, 1012371, 1012372, 1012373, 1012374, 1012375, 1012376, 1012377, 1012378, 1012382, 1012383, 1012384, 1012385, 1012387, 1012393, 1012394, 1012395, 1012396, 1012397, 1012398, 1012399, 1012400, 1012405, 1012406, 1012407, 1012408, 1012409, 1012411, 1012493, 5585, 5586, 5587, 5588, 5589, 5592, 5594, 5596, 5598, 5599, 5639, 5642, 5651, 5653, 5654, 5656, 5657, 5658, 5659, 5660, 5661, 5666, 5667, 5668, 5669, 5670, 5672, 5673, 5674, 5677, 5686, 5688, 5689, 5691, 5692, 5693, 5694, 5828, 6027, 6028, 6029, 6038, S5696, S5697

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

No further relevant information available.

· **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
(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**



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

· **Label elements**

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

The product is classified and labelled according to the GB CLP regulation.

· **Hazard pictograms** GHS07

· **Signal word** Warning

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

Diurethane Dimethacrylate

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Triethylene Glycol Dimethacrylate

- **Hazard statements**

- 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.

- P362+P364 Take off contaminated clothing and wash it before reuse.

- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

- P321 Specific treatment (see on this label).

- 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 EINECS: 231-545-4 | Silicon Dioxide, Chemically Prepared ⚠ Eye Irrit. 2, H319; STOT SE 3, H335 | ≥1-<10% |
| CAS: 72869-86-4 EINECS: 276-957-5 | Diurethane Dimethacrylate ⚠ Skin Sens. 1, H317; Aquatic Chronic 3, H412 | ≥1-<10% |
| CAS: 109-16-0 EINECS: 203-652-6 | Triethylene Glycol Dimethacrylate ⚠ Skin Sens. 1, H317 | ≥1-<10% |
| CAS: 1314-23-4 EINECS: 215-227-2 | Zirconium Dioxide substance with a Community workplace exposure limit | ≥0-<5% |
| CAS: 13760-80-0 EINECS: 237-354-2 | Ytterbium Trifluoride substance with a Community workplace exposure limit | ≥0-≤5% |
| CAS: 10287-53-3 EINECS: 233-634-3 | Ethyl-4-Dimethylamino Benzoate ⚠ Repr. 1B, H360; ⚠ Aquatic Chronic 2, H411 | ≥0.1-<1% |

- **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:** Immediately wash with water and soap and rinse thoroughly.

- **After eye contact:** Rinse opened eye for several minutes under running water.

- **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.

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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:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
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:**
See product labeling.
Ensure good ventilation/exhaustion at the workplace.
- **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:** None.
- **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:**

1314-23-4 Zirconium Dioxide

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

13760-80-0 Ytterbium Trifluoride

| | |
|-----|--|
| WEL | Long-term value: 2.5 mg/m ³ as F |
|-----|--|

- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.

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- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
- **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** Not required.
- **Body protection:** Protective work clothing

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Solid
- **Colour:** Various
- **Odour:** Acrylic
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** Undetermined.
- **Boiling point or initial boiling point and boiling range** Undetermined.
- **Flammability** Not determined.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** Not applicable.
- **Auto-ignition temperature:** 255 °C (109-16-0 Triethylene Glycol Dimethacrylate)
- **Decomposition temperature:** Not determined.
- **pH** Not applicable.
- **Viscosity:**
- **Kinematic viscosity** Not applicable.
- **Dynamic:** Not applicable.
- **Solubility**
- **water:** Insoluble.
- **Partition coefficient n-octanol/water (log value)** Not determined.
- **Vapour pressure:** Not applicable.

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| | |
|--|---|
| · Density and/or relative density | |
| · Density at 20 °C: | 2.07 g/cm ³ |
| · Relative density | Not determined. |
| · Vapour density | Not applicable. |
| · Other information | |
| · Appearance: | |
| · Form: | Paste |
| · 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 applicable. |
| · 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 |
| · Desensitised explosives | Void |

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **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:** No further relevant information available.
- **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.

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· **LD/LC50 values relevant for classification:**

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) |
| Dermal | LD50 | >2,000 mg/kg (mouse) |

· **Respiratory or skin sensitisation** May cause an allergic skin reaction.

· **Information on other hazards**

· **Endocrine disrupting properties**

| | | |
|----------|--------------------------|---------|
| 128-37-0 | Butylated Hydroxytoluene | 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.

· **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**

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

15 Regulatory information

| |
|--|
| · Safety, health and environmental regulations/legislation specific for the substance or mixture |
| · NIOSH-Ca (National Institute for Occupational Safety and Health) <i>None of the ingredients is listed.</i> |
| · Poisons Act |
| · Regulated explosives precursors <i>None of the ingredients is listed.</i> |
| · Regulated poisons <i>None of the ingredients is listed.</i> |
| · Reportable explosives precursors <i>None of the ingredients is listed.</i> |
| · Reportable poisons <i>None of the ingredients is listed.</i> |
| · Directive 2012/18/EU |
| · Named dangerous substances - ANNEX I <i>None of the ingredients is listed.</i> |
| · Chemical safety assessment: <i>A chemical safety assessment has not been carried out.</i> |

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.

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H411 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

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

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.**

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