

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/24/2021

Reviewed on 12/10/2019

1 Identification

· **Product identifier**

· **Trade name:** Forma

· **Article number:**

SDS 442-001.01, FO000002, FO00003, FO00004, FO00005, FO00006, FO00007, FO00008, FO00009, FO00010, FO00011, FO00012, FO00013, FO00014, FO00015, FO00016, FO00017, FO00018, FO00019, FO00020, FO00021, FO00022, FO00023, FO00031, FO00032, FO00033, FO00034, FO00044, FO00037, FO00001

· **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

· **Information department:** 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**



GHS08 Health hazard

Carc. 2 H351 Suspected of causing cancer. Route of exposure: Inhalation.



GHS07

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

· **Label elements**

· **GHS label elements** Void

· **Hazard pictograms** GHS07, GHS08

· **Signal word** Warning

· **Health Hazard-determining components of labeling:**

Triethylene Glycol Dimethacrylate

Titanium Dioxide

Diurethane Dimethacrylate

· **Hazard statements**

May cause an allergic skin reaction.

Suspected of causing cancer. Route of exposure: Inhalation.

· **Precautionary statements**

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

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- P261 Avoid breathing dust/fume/gas/mist/vapors/spray
 P272 Contaminated work clothing must not be allowed out of the workplace.
 P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P302+P352 If on skin: Wash with plenty of water.
 P308+P313 IF exposed or concerned: Get medical advice/attention.
 P321 Specific treatment (see on this label).
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P363 Wash contaminated clothing before reuse.
 P405 Store locked up.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**· **NFPA ratings (scale 0 - 4)**· **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	1	Fire = 1
REACTIVITY	0	Reactivity = 0

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**· **Description:** Mixture of the substances listed below with nonhazardous additions.· **Dangerous components:**

7631-86-9	Silicon Dioxide, Chemically Prepared		≥0-≤25%
109-16-0	Triethylene Glycol Dimethacrylate	⚠ Skin Sens. 1, H317	≥1-≤10%
72869-86-4	Diurethane Dimethacrylate	⚠ Skin Sens. 1, H317	≥1-≤10%
1314-23-4	Zirconium Dioxide		≥0-≤10%
12737-27-8	Chromium Iron Oxide		≥0-≤10%
13463-67-7	Titanium Dioxide	⚠ Carc. 2, H351	≥0.1-≤10%

4 First-aid measures

· **Description of first aid measures**· **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.

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.· **Information for doctor:**· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

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- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **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 item 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.
Open and handle receptacle with care.
Prevent formation of aerosols.
- **Information about protection against explosions and fires:** Keep respiratory protective device available.
- **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 receptacle tightly sealed.
- **Specific end use(s)** Professional Dental Composite

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.

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At this time, the other constituents have no known exposure limits.

7631-86-9 Silicon Dioxide, Chemically Prepared	
ACGIH	Long-term value: 10* 5** mg/m ³
IDLH	Short-term value: 3000 mg/m ³
1314-23-4 Zirconium Dioxide	
PEL	Long-term value: 5 mg/m ³ as Zr
REL	Short-term value: 10 mg/m ³ Long-term value: 5 mg/m ³ as Zr
TLV	Short-term value: 10 mg/m ³ Long-term value: 5 mg/m ³ as Zr
12737-27-8 Chromium Iron Oxide	
TWA	Short-term value: 0.5 mg/m ³ ACGIH, OSHA Z-1, NIOSH REL
13463-67-7 Titanium Dioxide	
ACGIH TLV	Short-term value: 10* 5 mg/m ³
PEL	Long-term value: 15* mg/m ³ *total dust
REL	See Pocket Guide App. A
TLV	Long-term value: 10 mg/m ³
TWA	Short-term value: 15* 5 mg/m ³

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

· **Exposure controls**

· **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.

Store protective clothing separately.

· **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· **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 is based 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.

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- **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:** Goggles recommended during refilling.
- **Body protection:** Protective work clothing

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Fluid
Color:	According to product specification
Odor:	Characteristic
Odor threshold:	Not determined.

· **pH-value:** Not applicable (non-aqueous)

· Change in condition

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	>250 °C

· **Flash point:** >150 °C

· **Flammability (solid, gaseous):** Not applicable.

· **Ignition temperature:** 255 °C

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

· **Vapor pressure:** Not determined.

· **Density at 20 °C:** 0.69538-1.83525 g/cm³

· **Bulk density:** 695-1,835 kg/m³

· **Relative density** Not determined

· **Vapor 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

· Solvent content:

VOC content:	0.00 %
	0.0 g/l / 0.00 lb/gal
VOC (EC)	0.00 %

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Solids content:	<95 %
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Other information	No further relevant information available.
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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 toxicological effects**
- **Acute toxicity:**

· LD/LC50 values that are relevant for classification:

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)

72869-86-4 Diurethane Dimethacrylate

Oral	LD50	>5,000 mg/kg (rat)
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13463-67-7 Titanium Dioxide

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

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

- **Carcinogenic categories**

· IARC (International Agency for Research on Cancer)

13760-80-0	Ytterbium Trifluoride	3
1309-37-1	Ferric Oxide	3
14807-96-6	Talc (Mg ₃ H ₂ (SiO ₃) ₄)	3
128-37-0	Butylated Hydroxytoluene	3

· NTP (National Toxicology Program)
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None of the ingredients is listed.

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· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**

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)

72869-86-4 Diurethane Dimethacrylate

EC50	>0.6 mg/kg (Algae)
Biodegradability	28 days (Aerobic) (Biodegradability testing)

13463-67-7 Titanium Dioxide

EC50	>100 mg/kg (Algae)
	>1,000 mg/kg (Fish)

· **Persistence and degradability** No further relevant information available.

· **Behavior 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 (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 of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**

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

14 Transport information

· **UN-Number**

· **DOT, IMDG, IATA**

Not Regulated

· **UN proper shipping name**

· **DOT, IMDG, IATA**

Not Regulated

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- | | |
|--|-----------------|
| · Transport hazard class(es) | |
| · DOT, ADN, IMDG, IATA | |
| · Class | Not Regulated |
| · Packing group | |
| · DOT, IMDG, IATA | Not Regulated |
| · Environmental hazards: | Not Applicable. |
| · Special precautions for user | Not Applicable |
| · Transport in bulk according to Annex II of MARPOL73/78 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**
No further relevant information available.
- Sara**

· Section 355 (extremely hazardous substances):
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None of the ingredients is listed.

· Section 313 (Specific toxic chemical listings):
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None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):

7631-86-9	Silicon Dioxide, Chemically Prepared	ACTIVE
109-16-0	Triethylene Glycol Dimethacrylate	ACTIVE
72869-86-4	Diurethane Dimethacrylate	ACTIVE
1314-23-4	Zirconium Dioxide	ACTIVE
12737-27-8	Chromium Iron Oxide	ACTIVE
13463-67-7	Titanium Dioxide	ACTIVE

· Hazardous Air Pollutants

None of the ingredients is listed.

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:
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None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:
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None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

· EPA (Environmental Protection Agency)
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None of the ingredients is listed.

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· ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)		
13760-80-0	Ytterbium Trifluoride	A4
1314-23-4	Zirconium Dioxide	A4
1309-37-1	Ferric Oxide	A4
14807-96-6	Talc (Mg ₃ H ₂ (SiO ₃) ₄)	A4
128-37-0	Butylated Hydroxytoluene	A4

· NIOSH-Ca (National Institute for Occupational Safety and Health)		
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.

- **Department issuing SDS:** Environmental, Health, and Safety
- **Contact:** Customer Service
- **Date of preparation / last revision** 09/24/2021 / -
- **Abbreviations and acronyms:**
 - IMDG: International Maritime Code for Dangerous Goods
 - DOT: US Department of Transportation
 - 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)
 - NFPA: National Fire Protection Association (USA)
 - HMIS: Hazardous Materials Identification System (USA)
 - VOC: Volatile Organic Compounds (USA, EU)
 - 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
 - OSHA: Occupational Safety & Health
 - TLV: Threshold Limit Value
 - PEL: Permissible Exposure Limit
 - REL: Recommended Exposure Limit
 - Skin Sens. 1: Skin sensitisation – Category 1
 - Carc. 2: Carcinogenicity – Category 2