

Material Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product and must be read in conjunction with the Safety Data Sheet (SDS) attached

Product Name: Forma

Manufacturer: Ultradent

SDS Expiry: Current SDS as provided by Supplier

Supplier Details: Henry Schein New Zealand
243-249 Bush Road, Rosedale, Auckland, 0632
PO Box 101 140, North Shore, Auckland 0745
Ph. 0800 808 855
www.henryschein.co.nz

Emergency Contacts: Poisons/Hazardous Chemical Info Centre –
0800POISON/0800764766 (24 Hours)
Phone 111 for Fire, Ambulance or Police

HSNO Class/Category: 6

HSNO Group Standard: Dental Products Subsidiary Hazard Group Standard 2020
HSR002558

Statements/Pictograms: As per attached Safety Data Sheet (SDS)

Date Prepared: This coversheet was prepared – May 2025

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.

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, FO000003, FO000004, FO000005, FO000006, FO000007, FO000008, FO000009, FO000010, FO000011, FO000012, FO000013, FO000014, FO000015, FO000016, FO000017, FO000018, FO000019, FO000020, FO000021, FO000022, FO000023, FO000031, FO000032, FO000033, FO000034, FO000044, FO000037, FO000001
- **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.

(Contd. on page 2)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/24/2021

Reviewed on 12/10/2019

Trade name: **Forma**

(Contd. of page 1)

- 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.

(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/24/2021

Reviewed on 12/10/2019

Trade name: **Forma**

(Contd. of page 2)

- **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.

(Contd. on page 4)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/24/2021

Reviewed on 12/10/2019

Trade name: Forma

(Contd. of page 3)

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.

(Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/24/2021

Reviewed on 12/10/2019

Trade name: *Forma*

(Contd. of page 4)

- **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 %

(Contd. on page 6)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/24/2021

Reviewed on 12/10/2019

Trade name: Forma

(Contd. of page 5)

Solids content: <95 %

· Other information No further relevant information available.

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 (Mg3H2(SiO3)4)	3
128-37-0	Butylated Hydroxytoluene	3

· NTP (National Toxicology Program)

None of the ingredients is listed.

(Contd. on page 7)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/24/2021

Reviewed on 12/10/2019

Trade name: *Forma*

(Contd. of page 6)

· **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

(Contd. on page 8)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/24/2021

Reviewed on 12/10/2019

Trade name: *Forma*

(Contd. of page 7)

- | | |
|---|-----------------|
| · 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 MARPOL 73/78 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:
--

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

· EPA (Environmental Protection Agency)
--

None of the ingredients is listed.

(Contd. on page 9)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/24/2021

Reviewed on 12/10/2019

Trade name: Forma

(Contd. of page 8)

· 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