



Safety Data Sheet

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This Safety Data Sheet has been prepared in accordance with the Preparation of Safety Data Sheets for Hazardous Chemicals Code of Practice (Safe Work Australia, December 2011)

SECTION 1: Identification

1.1. Product identifier

Paradigm™ Nano Hybrid Universal Restorative

Product Identification Numbers

70-2010-7953-3	70-2010-7954-1	70-2010-7955-8	70-2010-7956-6	70-2010-7957-4
70-2010-7958-2	70-2010-7959-0	70-2010-7960-8	70-2010-7961-6	70-2010-7963-2
70-2010-7964-0	70-2010-7965-7	70-2010-7966-5	70-2010-7967-3	70-2010-7968-1
70-2010-7969-9	70-2010-7970-7	70-2010-7971-5	70-2010-7972-3	70-2010-7973-1
70-2010-8548-0				

1.2. Recommended use and restrictions on use

Recommended use

Dental Product, Restorative

Restrictions on use

For use by dental professionals only.

1.3. Supplier's details

Address:	3M Australia - Building A, 1 Rivett Road, North Ryde NSW 2113
Telephone:	136 136
E Mail:	productinfo.au@mmm.com
Website:	www.3m.com.au

1.4. Emergency telephone number

EMERGENCY: 1800 097 146 (Australia only)

SECTION 2: Hazard identification

This product is classified as a hazardous chemical according to the Model Work Health and Safety Regulations, 2011, in accordance with applicable State and Territory legislation.

Refer to Section 14 of this Safety Data Sheets for product Dangerous Goods Classification.

2.1. Classification of the substance or mixture

Skin Sensitizer: Category 1.

2.2. Label elements

The label elements below were prepared in accordance with the Code of Practice on Preparation of Safety Data Sheets for Hazardous Chemicals (Safe Work Australia, December 2011). This information may be different from the actual product label.

Signal word

Warning

Symbols

Exclamation mark |

Pictograms**Hazard statements**

H317 May cause an allergic skin reaction.

Precautionary statements**Prevention:**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P272 Contaminated work clothing should not be allowed out of the workplace.
 P280E Wear protective gloves.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
 P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
 P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

P501 Dispose of contents/container in accordance with applicable local/regional/national/international regulations.

2.3. Other assigned/identified product hazards

None known.

2.4. Other hazards which do not result in classification

May be harmful if swallowed.

SECTION 3: Composition/information on ingredients

This material is a mixture.

Ingredient	CAS Nbr	% by Weight
Silane Treated Ceramic	444758-98-9	70 - 85
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	1565-94-2	1 - 10
Diurethane Dimethacrylate (UDMA)	72869-86-4	1 - 10
Silane Treated Silica	248596-91-0	1 - 10

Triethylene Glycol Dimethacrylate
(TEGDMA)

109-16-0

< 1

SECTION 4: First aid measures**4.1. Description of first aid measures****Inhalation**

Remove person to fresh air. If you feel unwell, get medical attention.

Skin contact

Immediately wash with soap and water. Remove contaminated clothing and wash before reuse. If signs/symptoms develop, get medical attention.

Eye contact

Flush with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. If signs/symptoms persist, get medical attention.

If swallowed

Rinse mouth. If you feel unwell, get medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Allergic skin reaction (redness, swelling, blistering, and itching).

4.3. Indication of any immediate medical attention and special treatment required

Not applicable

SECTION 5: Fire-fighting measures**5.1. Suitable extinguishing media**

In case of fire: Use a fire fighting agent suitable for ordinary combustible material such as water or foam to extinguish.

5.2. Special hazards arising from the substance or mixture

None inherent in this product.

Hazardous Decomposition or By-Products**Substance**

Carbon monoxide.
Carbon dioxide.

Condition

During combustion.
During combustion.

5.3. Special protective actions for fire-fighters

Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Evacuate area. Ventilate the area with fresh air. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapors, in accordance with good industrial hygiene practice. Refer to other sections of this SDS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate

authorities. Clean up residue. Seal the container. Dispose of collected material as soon as possible in accordance with applicable local/regional/national/international regulations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

A no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate commonly-used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. Avoid breathing dust/fume/gas/mist/vapours/spray. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not get in eyes.

7.2. Conditions for safe storage including any incompatibilities

No special storage requirements.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

No occupational exposure limit values exist for any of the components listed in Section 3 of this Safety Data Sheet.

8.2. Exposure controls

8.2.1. Engineering controls

Use in a well-ventilated area.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

Select and use eye/face protection to prevent contact based on the results of an exposure assessment. The following eye/face protection(s) are recommended:

Safety glasses with side shields.

Select and use eye protection in accordance with AS/NZS 1336. Eye protection should comply with the performance specifications of AS/NZS 1337.

Skin/hand protection

See Section 7.1 for additional information on skin protection.

Respiratory protection

None required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid.
Specific Physical Form:	Paste
Colour	Tooth
Odour	Slight Acrylate
Odour threshold	<i>No data available.</i>
pH	<i>Not applicable.</i>

Melting point/Freezing point	<i>No data available.</i>
Boiling point/Initial boiling point/Boiling range	<i>Not applicable.</i>
Flash point	No flash point
Evaporation rate	<i>Not applicable.</i>
Flammability (solid, gas)	Not classified
Flammable Limits(LEL)	<i>Not applicable.</i>
Flammable Limits(UEL)	<i>Not applicable.</i>
Vapour pressure	<i>Not applicable.</i>
Vapor Density and/or Relative Vapor Density	<i>Not applicable.</i>
Density	2.1 g/cm ³
Relative density	2.1 [Ref Std: WATER=1]
Water solubility	Negligible
Solubility- non-water	<i>No data available.</i>
Partition coefficient: n-octanol/water	<i>Not applicable.</i>
Autoignition temperature	<i>No data available.</i>
Decomposition temperature	<i>No data available.</i>
Viscosity/Kinematic Viscosity	<i>No data available.</i>
Volatile organic compounds (VOC)	<i>No data available.</i>
Percent volatile	<i>No data available.</i>
VOC less H₂O & exempt solvents	<i>No data available.</i>
Molecular weight	<i>No data available.</i>

SECTION 10: Stability and reactivity

10.1 Reactivity

This material is considered to be non reactive under normal use conditions

10.2 Chemical stability

Stable.

10.3. Conditions to avoid

Light.

10.4. Possibility of hazardous reactions

Hazardous polymerisation will not occur.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Substance

None known.

Condition

SECTION 11: Toxicological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labelling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

11.1 Information on Toxicological effects

Signs and Symptoms of Exposure

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation

This product may have a characteristic odour; however, no adverse health effects are anticipated.

Skin contact

Contact with the skin during product use is not expected to result in significant irritation. Allergic skin reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, and itching.

Eye contact

Contact with the eyes during product use is not expected to result in significant irritation.

Ingestion

May be harmful if swallowed.

Gastrointestinal irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhoea.

Toxicological Data

If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

Acute Toxicity

Name	Route	Species	Value
Overall product	Ingestion		No data available; calculated ATE >2,000 - =5,000 mg/kg
Silane Treated Ceramic	Dermal		LD50 estimated to be > 5,000 mg/kg
Silane Treated Ceramic	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
Silane Treated Silica	Dermal		LD50 estimated to be > 5,000 mg/kg
Silane Treated Silica	Ingestion		LD50 estimated to be > 5,000 mg/kg
Diurethane Dimethacrylate (UDMA)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Diurethane Dimethacrylate (UDMA)	Ingestion	Rat	LD50 > 5,000 mg/kg
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Ingestion	Rat	LD50 > 11,700 mg/kg
Triethylene Glycol Dimethacrylate (TEGDMA)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Triethylene Glycol Dimethacrylate (TEGDMA)	Ingestion	Rat	LD50 10,837 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silane Treated Ceramic	similar compounds	No significant irritation
Silane Treated Silica	Professional judgement	No significant irritation
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Rabbit	No significant irritation
Triethylene Glycol Dimethacrylate (TEGDMA)	Guinea pig	Mild irritant

Serious Eye Damage/Irritation

Name	Species	Value

Silane Treated Ceramic	similar compounds	Mild irritant
Silane Treated Silica	Professional judgement	No significant irritation
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	In vitro data	No significant irritation
Triethylene Glycol Dimethacrylate (TEGDMA)	Professional judgement	Moderate irritant

Skin Sensitisation

Name	Species	Value
Silane Treated Ceramic	similar compounds	Not classified
Diurethane Dimethacrylate (UDMA)	Guinea pig	Sensitising
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Mouse	Not classified
Triethylene Glycol Dimethacrylate (TEGDMA)	Human and animal	Sensitising

Respiratory Sensitisation

For the component/components, either no data are currently available or the data are not sufficient for classification.

Germ Cell Mutagenicity

Name	Route	Value
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	In Vitro	Not mutagenic
Triethylene Glycol Dimethacrylate (TEGDMA)	In Vitro	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
Silane Treated Ceramic	Inhalation	similar compounds	Some positive data exist, but the data are not sufficient for classification
Triethylene Glycol Dimethacrylate (TEGDMA)	Dermal	Mouse	Not carcinogenic

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Ingestion	Not classified for development	Rat	NOAEL 1,000 mg/kg/day	during gestation
Triethylene Glycol Dimethacrylate (TEGDMA)	Ingestion	Not classified for female reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
Triethylene Glycol Dimethacrylate (TEGDMA)	Ingestion	Not classified for male reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
Triethylene Glycol Dimethacrylate (TEGDMA)	Ingestion	Not classified for development	Mouse	NOAEL 1 mg/kg/day	1 generation

Target Organ(s)

Specific Target Organ Toxicity - single exposure

For the component/components, either no data are currently available or the data are not sufficient for classification.

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Silane Treated Ceramic	Inhalation	pulmonary fibrosis	Not classified	similar compounds	NOAEL Not available	
(1-methylethylidene)bis[4,1-phenyleneoxy (2-hydroxy-3,1-propanediyl)] bismethacrylate	Ingestion	endocrine system hematopoietic system liver heart skin gastrointestinal tract bone, teeth, nails, and/or hair immune system muscles nervous system eyes kidney and/or bladder respiratory system vascular system	Not classified	Rat	NOAEL 1,000 mg/kg/day	90 days
Triethylene Glycol Dimethacrylate (TEGDMA)	Dermal	kidney and/or bladder blood	Not classified	Mouse	NOAEL 833 mg/kg/day	78 weeks

Aspiration Hazard

For the component/components, either no data are currently available or the data are not sufficient for classification.

Exposure Levels

Refer Section 8.1 Control Parameters of this Safety Data Sheet.

Interactive Effects

Not determined.

SECTION 12: Ecological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. Additional information leading to material classification in Section 2 is available upon request. In addition, environmental fate and effects data on ingredients may not be reflected in this section because an ingredient is present below the threshold for labelling, an ingredient is not expected to be available for exposure, or the data is considered not relevant to the material as a whole.

12.1. Toxicity**Acute aquatic hazard:**

Not acutely toxic to aquatic life by GHS criteria.

Chronic aquatic hazard:

Not chronically toxic to aquatic life by GHS criteria.

No product test data available.

Material	CAS Number	Organism	Type	Exposure	Test endpoint	Test result
Silane Treated Ceramic	444758-98-9	N/A	Data not available or	N/A	N/A	N/A

			insufficient for classification			
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	1565-94-2	Common Carp	Analogous Compound	96 hours	No tox obs at lmt of water sol	>100 mg/l
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	1565-94-2	Green algae	Endpoint not reached	96 hours	EC50	>100 mg/l
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	1565-94-2	Green algae	Experimental	96 hours	EC10	1.1 mg/l
Diurethane Dimethacrylate (UDMA)	72869-86-4	Green algae	Endpoint not reached	72 hours	ErC50	>100 mg/l
Diurethane Dimethacrylate (UDMA)	72869-86-4	Water flea	Experimental	48 hours	EC50	>100 mg/l
Diurethane Dimethacrylate (UDMA)	72869-86-4	Zebra Fish	Experimental	96 hours	LC50	10.1 mg/l
Diurethane Dimethacrylate (UDMA)	72869-86-4	Green algae	Endpoint not reached	72 hours	ErC10	>100 mg/l
Silane Treated Silica	248596-91-0	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Triethylene Glycol Dimethacrylate (TEGDMA)	109-16-0	Green algae	Experimental	72 hours	ErC50	>100 mg/l
Triethylene Glycol Dimethacrylate (TEGDMA)	109-16-0	Zebra Fish	Experimental	96 hours	LC50	16.4 mg/l
Triethylene Glycol Dimethacrylate (TEGDMA)	109-16-0	Green algae	Experimental	72 hours	NOEC	18.6 mg/l
Triethylene Glycol Dimethacrylate (TEGDMA)	109-16-0	Water flea	Experimental	21 days	NOEC	32 mg/l

12.2. Persistence and degradability

Material	CAS Number	Test type	Duration	Study Type	Test result	Protocol
Silane Treated Ceramic	444758-98-9	Data not available-insufficient	N/A	N/A	N/A	N/A
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	1565-94-2	Experimental Biodegradation	28 days	BOD	21 %BOD/ThOD	similar to OECD 301F
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	1565-94-2	Experimental Hydrolysis		Hydrolytic half-life (pH 7)	29 days (t 1/2)	
Diurethane Dimethacrylate (UDMA)	72869-86-4	Experimental Biodegradation	28 days	CO2 evolution	22 %CO2 evolution/THCO2 evolution (does not pass 10-day window)	OECD 301B - Modified sturm or CO2
Silane Treated Silica	248596-91-0	Data not available-insufficient	N/A	N/A	N/A	N/A
Triethylene Glycol Dimethacrylate (TEGDMA)	109-16-0	Experimental Biodegradation	28 days	CO2 evolution	85 %CO2 evolution/THCO2 evolution	OECD 301B - Modified sturm or CO2

12.3 : Bioaccumulative potential

Material	CAS Number	Test type	Duration	Study Type	Test result	Protocol
Silane Treated Ceramic	444758-98-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	1565-94-2	Experimental Bioconcentration		Log Kow	4.63	
Diurethane Dimethacrylate (UDMA)	72869-86-4	Experimental Bioconcentration		Log Kow	3.39	
Silane Treated Silica	248596-91-0	Data not available or insufficient for	N/A	N/A	N/A	N/A

		classification				
Triethylene Glycol Dimethacrylate (TEGDMA)	109-16-0	Experimental Bioconcentration		Log Kow	2.3	EC A.8 Partition Coefficient

12.4. Mobility in soil

Please contact manufacturer for more details

12.5 Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Disposal methods

Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Dispose of waste product in a permitted industrial waste facility. As a disposal alternative, incinerate in a permitted waste incineration facility.

SECTION 14: Transport Information

Australian Dangerous Goods Code (ADG) - Road/Rail Transport

UN No.: Not applicable.

Proper shipping name: Not applicable.

Class/Division: Not applicable.

Sub Risk: Not applicable.

Packing Group: Not applicable.

Hazchem Code: Not applicable

IERG: Not applicable.

International Air Transport Association (IATA) - Air Transport

UN No.: Not applicable.

Proper shipping name: Not applicable.

Class/Division: Not applicable.

Sub Risk: Not applicable.

Packing Group: Not applicable.

International Maritime Dangerous Goods Code (IMDG)- Marine Transport

UN No.: Not applicable.

Proper shipping name: Not applicable.

Class/Division: Not applicable.

Sub Risk: Not applicable.

Packing Group: Not applicable.

Marine Pollutant: Not applicable.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**Australian Inventory Status:**

This product is regulated by the Therapeutics Goods Administration and is exempt from compliance with the Industrial Chemicals (Notification and Assessment) Act 1989 as amended.

SECTION 16: Other information

Revision information:

Complete document review.

DISCLAIMER: The information on this Safety Data Sheet is based on our experience and is correct to the best of our knowledge at the date of publication, but we do not accept any liability for any loss, damage or injury resulting from its use (except as required by law). The information may not be valid for any use not referred to in this Safety Data Sheet or use of the product in combination with other materials. For these reasons, it is important that customers carry out their own test to satisfy themselves as to the suitability of the product for their own intended applications.

Greenguard® is a United States based program. The 'Low VOC' reference related to United States Federal and State regulations exemptions for some solvents.

3M Australia SDSs are available at www.3m.com.au