



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	70-2010-7962-3
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	70-2010-7974-9	70-2010-7975-6	70-2010-7976-4	70-2010-7977-2
70-2010-8548-0				

1.2. Recommended use and restrictions on use

Recommended use

Dental Product, Restorative

For Industrial or Professional use only.

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.

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

2.1. Classification of the substance or mixture

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Skin Sensitizer: Category 1B.

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.
P280E Wear protective gloves.
P272 Contaminated work clothing should not be allowed out of the workplace.

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.
P363 Wash contaminated clothing before reuse.
P321 Specific treatment (see Notes to Physician on this label).

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.
Harmful to aquatic life.
Harmful to aquatic life with long lasting effects.

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-	1565-94-2	1 - 10

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phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate		
Bisphenol A polyethylene glycol diether dimethacrylate	41637-38-1	1 - 10
Diurethane dimethacrylate	72869-86-4	1 - 10
2-Propenoic acid, 2-methyl-, 3-(trimetoxysilyl)propyl ester, hydrolysis products with silica	248596-91-0	1 - 10
2,2'-ethylenedioxydiethyl dimethacrylate	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

See Section 11.1. Information on toxicological effects.

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

No special protective actions for fire-fighters are anticipated.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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Ventilate the area with fresh air. 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.

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. Do not get in eyes, on skin, or on clothing. 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. Avoid release to the environment. Wash contaminated clothing before reuse.

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

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Physical state	Solid.
Specific Physical Form:	Paste
Appearance/Odour	Slight acrylate odor, tooth-colored various shades
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>
Vapour 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	<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

<u>Substance</u>	<u>Condition</u>
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None known.

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 ATE2,000 - 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
Bisphenol A polyethylene glycol diether dimethacrylate	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Diurethane dimethacrylate	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Bisphenol A polyethylene glycol diether dimethacrylate	Ingestion	Rat	LD50 > 2,000 mg/kg
Diurethane dimethacrylate	Ingestion	Rat	LD50 > 5,000 mg/kg
2-Propenoic acid, 2-methyl-, 3-(trimetoxysilyl)propyl ester, hydrolysis products with silica	Dermal		LD50 estimated to be > 5,000 mg/kg
2-Propenoic acid, 2-methyl-, 3-(trimetoxysilyl)propyl ester, hydrolysis products with silica	Ingestion		LD50 estimated to be > 5,000 mg/kg
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Dermal	Professional judgement	LD50 estimated to be 2,000 - 5,000 mg/kg
2,2'-ethylenedioxydiethyl dimethacrylate	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
2,2'-ethylenedioxydiethyl dimethacrylate	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

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2-Propenoic acid, 2-methyl-, 3-(trimetoxysilyl)propyl ester, hydrolysis products with silica		No significant irritation
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Not available	Minimal irritation
2,2'-ethylenedioxydiethyl dimethacrylate	Guinea pig	Mild irritant

Serious Eye Damage/Irritation

Name	Species	Value
Silane treated ceramic	similar compounds	Mild irritant
2-Propenoic acid, 2-methyl-, 3-(trimetoxysilyl)propyl ester, hydrolysis products with silica		No significant irritation
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Not available	Moderate irritant
2,2'-ethylenedioxydiethyl dimethacrylate	Professional judgement	Moderate irritant

Skin Sensitisation

Name	Species	Value
Silane treated ceramic	similar compounds	Some positive data exist, but the data are not sufficient for classification
Bisphenol A polyethylene glycol diether dimethacrylate	Guinea pig	Not sensitizing
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Guinea pig	Sensitising
2,2'-ethylenedioxydiethyl dimethacrylate	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
Bisphenol A polyethylene glycol diether dimethacrylate	In Vitro	Not mutagenic
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	In Vitro	Some positive data exist, but the data are not sufficient for classification
2,2'-ethylenedioxydiethyl dimethacrylate	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
2,2'-ethylenedioxydiethyl dimethacrylate	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 toxic to female reproduction	Mouse	NOAEL 0.8 mg/kg/day	prematuring & during gestation

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(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Ingestion	Not toxic to male reproduction	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Ingestion	Not toxic to development	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
2,2'-ethylenedioxydiethyl dimethacrylate	Ingestion	Not toxic to female reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
2,2'-ethylenedioxydiethyl dimethacrylate	Ingestion	Not toxic to male reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
2,2'-ethylenedioxydiethyl dimethacrylate	Ingestion	Not toxic to 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	Some positive data exist, but the data are not sufficient for classification	similar compounds	NOAEL Not available	
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Ingestion	endocrine system liver nervous system kidney and/or bladder	All data are negative	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
2,2'-ethylenedioxy diethyl dimethacrylate	Dermal	kidney and/or bladder	Some positive data exist, but the data are not sufficient for classification	Mouse	NOAEL 833 mg/kg/day	78 weeks
2,2'-ethylenedioxy diethyl dimethacrylate	Dermal	blood	All data are negative	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:

GHS Acute 3: Harmful to aquatic life.

Chronic aquatic hazard:

GHS Chronic 3: Harmful to aquatic life with long lasting effects.

No product test data available.

Material	CAS Number	Organism	Type	Exposure	Test endpoint	Test result
Silane treated ceramic	444758-98-9		Data not available or insufficient for classification			
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	1565-94-2		Data not available or insufficient for classification			
2,2'-ethylenedioxydiethyl dimethacrylate	109-16-0		Data not available or insufficient for classification			
Bisphenol A polyethylene glycol diether dimethacrylate	41637-38-1		Data not available or insufficient for classification			
Diurethane dimethacrylate	72869-86-4	Fathead minnow	Estimated	96 hours	LC50	1.4 mg/l
2-Propenoic acid, 2-methyl-, 3-(trimetoxysilyl)propyl ester, hydrolysis products with silica	248596-91-0		Data not available or insufficient for classification			

12.2. Persistence and degradability

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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	Estimated Biodegradation	28 days	BOD	33 % weight	OECD 301C - MITI test (I)
2,2'-ethylenedioxydiethyl dimethacrylate	109-16-0	Estimated Biodegradation	28 days	BOD	60 % weight	Other methods
Bisphenol A polyethylene glycol diether dimethacrylate	41637-38-1	Calculated Biodegradation	28 days	BOD	38 % weight	OECD 301C - MITI test (I)
Diurethane dimethacrylate	72869-86-4	Estimated Biodegradation	28 days	BOD	52 % weight	OECD 301C - MITI test (I)
2-Propenoic acid, 2-methyl-, 3-(trimetoxysilyl)propyl ester, hydrolysis products with silica	248596-91-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

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	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
2,2'-ethylenedioxydiethyl dimethacrylate	109-16-0	Experimental Bioaccumulation		Log Kow	1.88	Other methods
Bisphenol A polyethylene glycol diether	41637-38-1	Calculated Bioconcentration		Bioaccumulation factor	6.7	Estimated: Bioconcentration factor

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dimethacrylate						
Diurethane dimethacrylate	72869-86-4	Estimated BCF - Other		Bioaccumulation factor	5	Estimated: Bioconcentration factor
2-Propenoic acid, 2-methyl-, 3-(trimetoxysilyl)propyl ester, hydrolysis products with silica	248596-91-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

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.

Incinerate in a permitted waste incineration facility. Proper destruction may require the use of additional fuel during incineration processes.

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.

Poison Schedule: This product has not been assessed for poisons scheduling as the product is intended for industrial and professional use only.

SECTION 16: Other information

Revision information:

Conversion to GHS format SDS.

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