

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: ESPE™ Protemp™ Crown

Manufacturer: 3M

SDS Expiry: 27 November 2023

Supplier Details: Henry Schein New Zealand
23 William Pickering Drive, Albany
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 Toxic 6.7 Group Standard 2017 HSR002560

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

Date Prepared: This coversheet was prepared on 30 November 2018

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

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This Safety Data Sheet has been prepared in accordance with the New Zealand, Hazardous Substances (Safety Data Sheets) Notice 2017.

SECTION 1: Identification

1.1. Product identifier

3M™ ESPE™ Protemp™ Crown

Product Identification Numbers

70-2010-5122-7 70-2010-5123-5 70-2010-5124-3 70-2010-5125-0 70-2010-5126-8
 70-2010-5127-6 70-2010-5128-4 70-2010-5129-2 70-2010-5167-2

1.2. Recommended use and restrictions on use

Recommended use

Dental product, Temporization material.

Restrictions on use

For use by dental professionals only.

1.3. Supplier's details

Address: 3M New Zealand Ltd, 94 Apollo Drive, Rosedale 0632, Auckland
Telephone: (09) 477 4040
E Mail: innovation@nz.mmm.com
Website: 3m.co.nz

1.4. Emergency telephone number

24 hr Medical Emergency, National Poisons Centre, 0800 764 766 (0800 POISON)

SECTION 2: Hazard identification

Classified as hazardous in accordance with the relevant criteria of the HSNO Act 1996, the Hazardous Substances (Classification) Notice 2017 and Hazardous Substances (Minimum Degrees of Hazard) Notice 2017.

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

2.1. Classification of the substance or mixture

GHS	HSNO
Acute Toxicity (oral): Category 4	6.1D Acute toxicity (oral)
Skin Sensitiser: Category 1	6.5B Skin sensitiser

2.2. Label elements

SIGNAL WORD

WARNING!

Symbols:

Exclamation mark |

Pictograms



HAZARD STATEMENTS:

H302 Harmful if swallowed.
H317 May cause an allergic skin reaction.

PRECAUTIONARY STATEMENTS

General:

P102 Keep out of reach of children.

Prevention:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280E Wear protective gloves.
P270 Do not eat, drink or smoke when using this product.
P264B Wash exposed skin thoroughly after handling.
P272A Contaminated work clothing must 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.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P330 Rinse mouth.
P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
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.

SECTION 3: Composition/information on ingredients

Ingredient	CAS Nbr	% by Weight
Silane treated ceramic	444758-98-9	70 - 80
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	1565-94-2	5 - 15
Synthetic amorphous silica, fumed, crystalline free	112945-52-5	1 - 10

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

No need for first aid is anticipated.

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

<u>Substance</u>	<u>Condition</u>
Carbon monoxide.	During combustion.
Carbon dioxide.	During combustion.

5.3. Special protective actions for fire-fighters

No special protective actions for fire-fighters are anticipated.

5.4. Hazchem code: Not applicable.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Evacuate area. 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 in accordance with applicable local/regional/national/international regulations.

SECTION 7: Handling and storage

Refer to Section 15 - Controls for more information

7.1. Precautions for safe handling

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. Wash contaminated clothing before reuse. A no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove.

7.2. Conditions for safe storage including any incompatibilities

No special storage requirements.

7.3. Certified handler

Not required

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.

Refer AS/NZS 1336 - Recommended practices for occupational eye protection and for performance specifications AS/NZS 1337, Parts 1 - 6 - Personal eye-protection.

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
Appearance/Odour	Characteristic odour, Opaque, off-white paste.
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	<i>Not applicable.</i>
Evaporation rate	<i>No data available.</i>
Flammability (solid, gas)	Not classified
Flammable Limits(LEL)	<i>Not applicable.</i>
Flammable Limits(UEL)	<i>Not applicable.</i>
Vapour density	<i>Not applicable.</i>
Density	1.5 g/cm ³
Relative density	1.5 [Ref Std: WATER=1]
Water solubility	Negligible
Solubility- non-water	<i>No data available.</i>
Partition coefficient: n-octanol/water	<i>No data available.</i>
Autoignition temperature	<i>No data available.</i>
Decomposition temperature	<i>No data available.</i>
Viscosity	<i>No data available.</i>
Percent volatile	<i>No data available.</i>

SECTION 10: Stability and reactivity

10.1 Reactivity

This material may be reactive with certain agents under certain conditions - see the remaining headings in this section

10.2 Chemical stability

Stable.

10.3 Possibility of hazardous reactions

Hazardous polymerisation will not occur.

10.4 Conditions to avoid

Light.

10.5 Incompatible materials

Not determined

10.6 Hazardous decomposition products

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

Refer to Section 5.2 for hazardous decomposition products during combustion.

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:

3M™ ESPE™ Protemp™ Crown**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

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	Dermal		No data available; calculated ATE >5,000 mg/kg
Overall product	Ingestion		No data available; calculated ATE 300 - 2,000 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
(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
Synthetic amorphous silica, fumed, crystalline free	Dermal	Rabbit	LD50 > 5,000 mg/kg
Synthetic amorphous silica, fumed, crystalline free	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Synthetic amorphous silica, fumed, crystalline free	Ingestion	Rat	LD50 > 5,110 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silane treated ceramic	similar compounds	No significant irritation
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Not available	Minimal irritation
Synthetic amorphous silica, fumed, crystalline free	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Silane treated ceramic	similar compounds	Mild irritant
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Not available	Moderate irritant
Synthetic amorphous silica, fumed, crystalline free	Rabbit	No significant irritation

Skin Sensitisation

Name	Species	Value
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Silane treated ceramic	similar compounds	Not classified
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Guinea pig	Sensitising
Synthetic amorphous silica, fumed, crystalline free	Human and animal	Not classified

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	Some positive data exist, but the data are not sufficient for classification
Synthetic amorphous silica, fumed, crystalline free	In Vitro	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
Silane treated ceramic	Inhalation	similar compounds	Some positive data exist, but the data are not sufficient for classification
Synthetic amorphous silica, fumed, crystalline free	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification

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 female reproduction	Mouse	NOAEL 0.8 mg/kg/day	prematuring & during gestation
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Ingestion	Not classified for male reproduction	Mouse	NOAEL 0.8 mg/kg/day	prematuring & during gestation
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Ingestion	Not classified for development	Mouse	NOAEL 0.8 mg/kg/day	prematuring & during gestation
Synthetic amorphous silica, fumed, crystalline free	Ingestion	Not classified for female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
Synthetic amorphous silica, fumed, crystalline free	Ingestion	Not classified for male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Synthetic amorphous silica, fumed, crystalline free	Ingestion	Not classified for development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis

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-	Ingestion	endocrine system liver nervous	Not classified	Mouse	NOAEL 0.8 mg/kg/day	prematuring & during

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phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate		system kidney and/or bladder				gestation
Synthetic amorphous silica, fumed, crystalline free	Inhalation	respiratory system silicosis	Not classified	Human	NOAEL Not available	occupational exposure

Aspiration Hazard

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

Please contact the address or phone number listed on the first page of the SDS for additional toxicological information on this material and/or its components.

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

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			
Synthetic amorphous silica, fumed, crystalline free	112945-52-5	Water flea	Experimental	24 hours	EC50	>100 mg/l
Synthetic amorphous silica, fumed, crystalline free	112945-52-5	Zebra Fish	Experimental	96 hours	LC50	>100 mg/l
Synthetic amorphous silica, fumed, crystalline free	112945-52-5	Green Algae	Experimental	72 hours	EC50	>100 mg/l
Synthetic amorphous silica, fumed, crystalline free	112945-52-5	Green Algae	Experimental	72 hours	NOEC	60 mg/l

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- insufficient			N/A	
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	1565-94-2	Estimated Biodegradation	28 days	BOD	32 % weight	OECD 301C - MITI test (I)
Synthetic amorphous silica, fumed, crystalline free	112945-52-5	Data not available- insufficient			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	Estimated Bioconcentration		Bioaccumulation factor	5.8	Estimated: Bioconcentration factor
Synthetic amorphous silica, fumed, crystalline free	112945-52-5	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**

In accordance with the Hazardous Substances (Disposal) Notice 2017 and the relevant criteria of the HSNO Act 1996.

Dispose of completely cured (or polymerized) material in a permitted industrial waste facility. As a disposal alternative, incinerate uncured product in a permitted waste incineration facility. If no other disposal options are available, waste product that has been completely cured or polymerized may be placed in a landfill properly designed for industrial waste.

Packaging (that may or may not contain any residual substance) may be lawfully disposed of by householders or other consumers through public or commercial waste collection services.

SECTION 14: Transport Information

New Zealand Land Transport Rule: Dangerous Goods - 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

HSNO Approval number	HSR002558
Group standard name	Dental Products (Subsidiary Hazard) Group Standard 2017
HSNO Hazard classification	Refer to Section 2: Hazard identification

NZ Inventory of Chemicals (NZIoC) Status

All applicable chemical ingredients in this material are in compliance with NZIoC listing requirements.

Controls in accordance with the Health and Safety at Work (Hazardous Substances) Regulations 2017

Certified handler	Not required
Location Compliance Certificate	Not required
Hazardous atmosphere zone	Not required
Fire extinguishers	Not required
Emergency response plan	100 L or 100 kg (for a HSNO 9.1A substance); or 1,000 L or 1,000 kg (for a HSNO 6.1D, 6.5A, 6.5B, 9.1B or 9.1C substance); or 10,000 L or 10,000 kg (for a HSNO 6.6A, 6.8A, 6.9A, 8.3A, 9.1D substance)
Secondary containment	100 L or 100 kg (for a HSNO 9.1A substance); or 1,000 L or 1,000 kg (for a HSNO 6.1D, 6.5A, 6.5B, 9.1B or 9.1C substance); or 10,000 L or 10,000 kg (for a HSNO 6.6A, 6.8A, 6.9A, 8.3A, 9.1D substance)
Tracking	Not required
Warning signage	100 L or 100 kg (for a HSNO 9.1A substance); or 1,000 L or 1,000 kg (for a HSNO 8.3A, 9.1B or 9.1C substance); or 10,000 L or 10,000 kg (for a HSNO 6.1D or 9.1D substance)

SECTION 16: Other information

Revision information:

Complete document review.

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Key to abbreviations and acronyms**GHS** means the Globally Harmonised System of Classification and Labelling of Chemicals, 5th revised edition 2013**HSNO** means Hazardous Substances and New Organisms Act 1996

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