



Safety Information Sheet for Medical Devices

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A safety data sheet is not required for this Product. This Safety Information Sheet has been created on a voluntary basis.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

3M™ Protemp™ Crown

Product Identification Numbers

70-2010-5121-9	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	70-2010-5130-0
70-2010-5167-2	70-2010-5247-2	70-2010-5248-0	70-2010-5249-8	70-2010-5328-0
70-2010-5478-3	70-2010-5595-4			
7000030524	7000030523	7000030522	7000030521	7000030520
7000030519	7000030518	7000030517	7000030516	7000030515
7000128815	7000030531	7000030532	7100053839	7100111843

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses

Medical device; refer to Instructions for Use

Restrictions on Use

For use only by dental professionals.

1.3 Details of the supplier of the safety information sheet for medical devices

Address:	3M United Kingdom PLC, 3M Centre, Cain Road, Bracknell, Berkshire, RG12 8HT.
Telephone:	+44 (0)1344 858 000
E Mail:	tox.uk@mmm.com
Website:	www.3M.com/uk

1.4. Emergency telephone number

+44 (0)1344 858 000

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

CLP REGULATION (EC) No 1272/2008

The health and environmental classifications of this material have been derived using the calculation method, except in cases where test data are available or the physical form impacts classification. Classification(s) based on test data or physical form are noted below, if applicable.

This product is a medical device as defined in Directive 93/42/EEC (MDD) respectively Regulation (EU) 2017/745 (MDR), which is invasive or used in direct physical contact with the human body, and therefore is exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). Although not required, the classification and label information, as applicable, is provided below.

CLASSIFICATION:

This material is not classified as hazardous according to Regulation (EC) No. 1272/2008, as amended, on classification, labelling, and packaging of substances and mixtures.

2.2. Label elements

CLP REGULATION (EC) No 1272/2008

Not applicable

2.3. Other hazards

For information on hazards and safe use, please consider the corresponding sections of this document.
This material does not contain any substances that are assessed to be a PBT or vPvB

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Ingredient	Identifier(s)	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Silane treated ceramic	(CAS-No.) 444758-98-9	70 - 80	Substance not classified as hazardous
Carbosilane surfactant	(EC-No.) 701-308-4	5 - 15	Substance not classified as hazardous
Silica	(CAS-No.) 112945-52-5	1 - 10	Substance with a national occupational exposure limit
Prepolymer	None	1 - 10	Substance not classified as hazardous
Iodonium salt	(CAS-No.) 58109-40-3 (EC-No.) 261-134-5	< 0.5	Acute Tox. 2, H300

Any entry in the Identifier(s) column that begins with the numbers 6, 7, 8, or 9 are a Provisional List Number provided by ECHA pending publication of the official EC Inventory Number for the substance.
Please see section 16 for the full text of any H statements referred to in this section

For information on ingredient occupational exposure limits or PBT or vPvB status, see sections 8 and 12 of this SIS

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation

No need for first aid is anticipated.

Skin contact

No need for first aid is anticipated.

Eye contact

No need for first aid is anticipated.

If swallowed

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

SECTION 5: Fire-fighting measures**5.1. 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. Advice 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. Refer to other sections of this SIS 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

Refer to Instructions for Use (IFU) for more information.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational exposure limits**

If a component is disclosed in section 3 but does not appear in the table below, an occupational exposure limit is not available for the component.

Ingredient	CAS Nbr	Agency	Limit type	Additional comments
Silicon dioxide	112945-52-5	UK HSC	TWA(as respirable dust):2.4 mg/m ³ ;TWA(as inhalable dust):6 mg/m ³	

UK HSC : UK Health and Safety Commission
 TWA: Time-Weighted-Average
 STEL: Short Term Exposure Limit
 CEIL: Ceiling

Biological limit values

No biological limit values exist for any of the components listed in Section 3 of this safety information 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.

Applicable Norms/Standards

Use eye protection conforming to EN 166

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	Off-White
Odor	Characteristic Odour
Melting point/freezing point	<i>No data available.</i>
Boiling point/boiling range	<i>Not applicable.</i>
Flammability (solid, gas)	Not classified
Flammable Limits(LEL)	<i>Not applicable.</i>
Flammable Limits(UEL)	<i>Not applicable.</i>
Flash point	<i>Not applicable.</i>
Autoignition temperature	<i>No data available.</i>
Relative density	1.5 [Ref Std:WATER=1]
pH	<i>substance/mixture is non-soluble (in water)</i>
Kinematic Viscosity	<i>No data available.</i>
Water solubility	Negligible
Density	1.5 g/cm ³

9.2. Other information

9.2.2 Other safety characteristics

EU Volatile Organic Compounds	<i>No data available.</i>
Evaporation rate	<i>No data available.</i>

Percent volatile

No data available.

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 agree with the EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 11 are based on UN GHS calculation rules and classifications derived from internal hazard assessments.

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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.

Eye contact

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

Ingestion

May be harmful if swallowed.

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 >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
Carbosilane surfactant	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Carbosilane surfactant	Ingestion	Rat	LD50 > 11,700 mg/kg
Prepolymer	Dermal	Professional judgement	LD50 estimated to be 2,000 - 5,000 mg/kg
Prepolymer	Ingestion	similar compounds	LD50 estimated to be 2,000 - 5,000 mg/kg
Silica	Dermal	Rabbit	LD50 > 5,000 mg/kg
Silica	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Silica	Ingestion	Rat	LD50 > 5,110 mg/kg
Iodonium salt	Ingestion	Rat	LD50 32 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silane treated ceramic	similar compounds	No significant irritation
Carbosilane surfactant	Rabbit	No significant irritation
Silica	Rabbit	No significant irritation
Iodonium salt	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Silane treated ceramic	similar compounds	Mild irritant
Carbosilane surfactant	In vitro data	No significant irritation
Silica	Rabbit	No significant irritation
Iodonium salt	Rabbit	Mild irritant

Skin Sensitisation

Name	Species	Value
Silane treated ceramic	similar compounds	Not classified
Carbosilane surfactant	Mouse	Not classified
Silica	Human and animal	Not classified

Respiratory Sensitisation

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

Germ Cell Mutagenicity

Name	Route	Value
Carbosilane surfactant	In Vitro	Not mutagenic
Silica	In Vitro	Not mutagenic
Iodonium salt	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
Silica	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
Carbosilane surfactant	Ingestion	Not classified for development	Rat	NOAEL 1,000 mg/kg/day	during gestation
Silica	Ingestion	Not classified for female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
Silica	Ingestion	Not classified for male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Silica	Ingestion	Not classified for development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis

Target Organ(s)**Specific Target Organ Toxicity - single exposure**

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Iodonium salt	Inhalation	respiratory irritation	Not classified	Not available	Irritation Equivocal	

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	
Carbosilane surfactant	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
Silica	Inhalation	respiratory system silicosis	Not classified	Human	NOAEL Not available	occupational exposure

Aspiration Hazard

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

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

The product was evaluated by a toxicologist to be safe for its intended use.

11.2. Information on other hazards

This material does not contain any substances that are assessed to be an endocrine disruptor for human health.

SECTION 12: Ecological information

The information below may not agree with the EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 12 are based on UN GHS calculation rules and classifications derived from 3M assessments.

12.1. Toxicity

No product test data available.

Material	CAS #	Organism	Type	Exposure	Test endpoint	Test result
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Silane treated ceramic	444758-98-9		Data not available or insufficient for classification			N/A
Carbosilane surfactant	701-308-4	Green Algae	Endpoint not reached	96 hours	EC50	>100 mg/l
Carbosilane surfactant	701-308-4	Green Algae	Experimental	96 hours	EC10	1.1 mg/l
Carbosilane surfactant	701-308-4	Activated sludge	Experimental	3 hours	EC50	>100 mg/l
Prepolymer	None		Data not available or insufficient for classification			N/A
Silica	112945-52-5	Green Algae	Experimental	72 hours	EC50	>100 mg/l
Silica	112945-52-5	Water flea	Experimental	24 hours	EC50	>100 mg/l
Silica	112945-52-5	Zebra Fish	Experimental	96 hours	LC50	>100 mg/l
Silica	112945-52-5	Green Algae	Experimental	72 hours	NOEC	60 mg/l
Iodonium salt	58109-40-3	Water flea	Experimental	48 hours	EC50	9.5 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Silane treated ceramic	444758-98-9	Data not availbl-insufficient			N/A	
Carbosilane surfactant	701-308-4	Experimental Hydrolysis		Hydrolytic half-life (pH 7)	29 days (t 1/2)	
Carbosilane surfactant	701-308-4	Experimental Biodegradation	28 days	BOD	21 % BOD/ThBOD	similar to OECD 301F
Prepolymer	None	Data not availbl-insufficient			N/A	
Silica	112945-52-5	Data not availbl-insufficient			N/A	
Iodonium salt	58109-40-3	Data not availbl-insufficient			N/A	

12.3 : Bioaccumulative potential

Material	Cas No.	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
Carbosilane surfactant	701-308-4	Modeled Bioconcentration		Bioaccumulation factor	292.4	Episuite™
Carbosilane surfactant	701-308-4	Experimental Bioconcentration		Log Kow	4.63	OECD 117 log Kow HPLC method
Prepolymer	None	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silica	112945-52-5	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Iodonium salt	58109-40-3	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

12.4. Mobility in soil

Material	Cas No.	Test type	Study Type	Test result	Protocol
Carbosilane surfactant	701-308-4	Experimental Mobility in Soil	Koc	24,000 l/kg	OECD 121 Estim. of Koc by HPLC

12.5. Results of the PBT and vPvB assessment

This material does not contain any substances that are assessed to be a PBT or vPvB

12.6. Endocrine disrupting properties

This material does not contain any substances that are assessed to be an endocrine disruptor for environmental effects

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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

Refer to Instructions for Use (IFU) for more information.

EU waste code (product as sold)

180106* Chemicals consisting of or containing dangerous substances.

SECTION 14: Transportation information

Not hazardous for transportation.

ADR/IATA/IMDG: Not restricted for transport.

	Ground Transport (ADR)	Air Transport (IATA)	Marine Transport (IMDG)
14.1 UN number	No data available.	No data available.	No data available.
14.2 UN proper shipping name	No data available.	No data available.	No data available.
14.3 Transport hazard class(es)	No data available.	No data available.	No data available.
14.4 Packing group	No data available.	No data available.	No data available.
14.5 Environmental hazards	No data available.	No data available.	No data available.
14.6 Special precautions for user	Please refer to the other sections of the SDS for further information.	Please refer to the other sections of the SDS for further information.	Please refer to the other sections of the SDS for further information.
14.7 Transport in bulk according to Annex II of Marpol 73/78 and IBC Code	No data available.	No data available.	No data available.

Control Temperature	No data available.	No data available.	No data available.
Emergency Temperature	No data available.	No data available.	No data available.
ADR Classification Code	No data available.	No data available.	No data available.
IMDG Segregation Code	No data available.	No data available.	No data available.

Please contact the address or phone number listed on the first page of the SDS for additional information on the transport/shipment of the material by rail (RID) or inland waterways (ADN).

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Global inventory status

Contact the manufacturer for more information

SECTION 16: Other information

List of relevant H statements

H300 Fatal if swallowed.

Revision information:

Revision information not available

The product to which this Safety Information Sheet applies is classified as a medical device according to the EU Medical Device Regulation EU 2017/745. _x000D_

Medical devices which are invasive or used in direct physical contact with the human body are exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). _x000D_

The EU Medical Device Regulation does not foresee the use of Safety Data sheets for medical devices which are invasive or used in direct physical contact with the human body, as the safe use of the product is described through the Instructions for Use and /or the labelling for the product. Nevertheless, the 3M Safety Information Sheet is provided as a further service to customers to provide additional toxicology and chemical information on the product. In case of further questions, please contact your 3M representative listed on the Safety Information Sheet.

3M United Kingdom Safety Information Sheets are available at www.3M.com/uk