

Safety Data Sheet

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SECTION 1: Identification

1.1. Product identifier

 $3M^{\rm TM}\,ESPE^{\rm TM}\,PROTEMP^{\rm TM}\,CROWN$

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, 70-2010-5194-6, 70-2010-5247-2, 70-2010-5248-0, 70-2010-5249-8, 70-2010-5328-0, 70-2010-5478-3, 70-2010-5595-4

1.2. Recommended use and restrictions on use

Recommended use Dental product, Temporization material. **Restrictions on use** For use only by dental professionals.

1.3. Supplier's details	
MANUFACTURER:	3M
DIVISION:	3M ESPE Dental Products
ADDRESS:	3M Center, St. Paul, MN 55144-1000, USA
Telephone:	1-888-3M HELPS (1-888-364-3577)

1.4. Emergency telephone number

1-800-364-3577 or (651) 737-6501 (24 hours)

SECTION 2: Hazard identification

This document has been prepared in accordance with the U.S. OSHA Hazard Communication Standard, which requires the inclusion of all known hazards of the product or ingredients regardless of the potential risk. The risks of the hazards communicated in this document may vary depending on the potential for exposure.

2.1. Hazard classification

Acute Toxicity (oral): Category 4. Skin Sensitizer: Category 1B.

2.2. Label elements Signal word Warning Symbols Exclamation mark |

Pictograms



Hazard Statements Harmful if swallowed. May cause an allergic skin reaction.

Precautionary Statements

Prevention:

Wear protective gloves. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace.

Response:

IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. Rinse mouth. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

Disposal:

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

2.3. Hazards not otherwise classified

None.

SECTION 3: Composition/information on ingredients

Ingredient	C.A.S. No.	% by Wt
SILANE TREATED CERAMIC	444758-98-9	70 - 80 Trade Secret *
BISPHENOL A DIGLYCIDYL ETHER	1565-94-2	5 - 15 Trade Secret *
DIMETHACRYLATE (BISGMA)		
FUNCTIONALIZED DIMETHACRYLATE	None	1 - 10 Trade Secret *
POLYMER		
SYNTHETIC AMORPHOUS SILICA, FUMED,	112945-52-5	1 - 10 Trade Secret *
CRYSTALLINE FREE		
WATER	7732-18-5	< 5 Trade Secret *
TRIETHYLENE GLYCOL DIMETHACRYLATE	109-16-0	< 1 Trade Secret *
(TEGDMA)		
BENZOTRIAZOL	96478-09-0	< 0.5 Trade Secret *
ETHYL 4-DIMETHYL AMINOBENZOATE	10287-53-3	< 0.5 Trade Secret *
(EDMAB)		
DIPHENYLIODONIUM	58109-40-3	< 0.5 Trade Secret *
HEXAFLUOROPHOSPHATE		

*The specific chemical identity and/or exact percentage (concentration) of this composition has been withheld as a trade

secret.

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

Substance	-
Carbon monoxide	
Carbon dioxide	

<u>Condition</u> 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

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

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.

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 SDS.

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

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

General Physical Form:	Solid
Specific Physical Form:	Paste
Odor, Color, Grade:	Characteristic odor, Opaque, off-white paste
Odor threshold	No Data Available
pH	Not Applicable
Melting point	No Data Available
Boiling Point	Not Applicable
Flash Point	Not Applicable
Evaporation rate	No Data Available
Flammability (solid, gas)	Not Classified
Flammable Limits(LEL)	Not Applicable
Flammable Limits(UEL)	Not Applicable

Vapor Pressure
Vapor Density
Density
Specific Gravity
Solubility in Water
Solubility- non-water
Partition coefficient: n-octanol/ water
Autoignition temperature
Decomposition temperature
Viscosity
Percent volatile

Not Applicable Not Applicable 1.5 g/cm3 1.5 [Ref Std: WATER=1] Negligible No Data Available 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 polymerization will not occur.

10.4. Conditions to avoid Light

10.5. Incompatible materials Not determined

10.6. Hazardous decomposition products

<u>Substance</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 labeling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

This document has been prepared in accordance with the U.S. OSHA Hazard Communication Standard, which requires the inclusion of all known hazards of the product or ingredients regardless of the potential risk. The risks of the hazards communicated in this document may vary depending on the potential for exposure.

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:

Condition

Inhalation:

This product may have a characteristic odor; 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 diarrhea.

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 300 - 2,000 mg/kg
SILANE TREATED CERAMIC	Dermal		LD50 estimated to be $> 5,000 \text{ mg/kg}$
SILANE TREATED CERAMIC	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
(BISGMA)	_		
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE	Dermal	Professio	LD50 estimated to be 2,000 - 5,000 mg/kg
(BISGMA)		nal	
		judgeme	
		nt	
SYNTHETIC AMORPHOUS SILICA, FUMED,	Dermal	Rabbit	LD50 > 5,000 mg/kg
CRYSTALLINE FREE			
SYNTHETIC AMORPHOUS SILICA, FUMED,	Inhalation-	Rat	LC50 > 0.691 mg/l
CRYSTALLINE FREE	Dust/Mist		
	(4 hours)		
SYNTHETIC AMORPHOUS SILICA, FUMED,	Ingestion	Rat	LD50 > 5,110 mg/kg
CRYSTALLINE FREE			
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	Dermal	Rat	LD50 > 2,000 mg/kg
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	Ingestion	Rat	LD50 > 2,000 mg/kg
DIPHENYLIODONIUM HEXAFLUOROPHOSPHATE	Ingestion	Rat	LD50 32 mg/kg
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Dermal	Professio	LD50 estimated to be $> 5,000 \text{ mg/kg}$
		nal	
		judgeme	
		nt	
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	No significant irritation
	compoun	
	ds	
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Not	Minimal irritation
	available	
SYNTHETIC AMORPHOUS SILICA, FUMED, CRYSTALLINE FREE	Rabbit	No significant irritation
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	Rabbit	No significant irritation
DIPHENYLIODONIUM HEXAFLUOROPHOSPHATE	Rabbit	No significant irritation
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Guinea	Mild irritant
	pig	

Serious Eye Damage/Irritation

Name	Species	Value
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SILANE TREATED CERAMIC	similar	Mild irritant
	compoun	
	ds	
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Not	Moderate irritant
	available	
SYNTHETIC AMORPHOUS SILICA, FUMED, CRYSTALLINE FREE	Rabbit	No significant irritation
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	Rabbit	Mild irritant
DIPHENYLIODONIUM HEXAFLUOROPHOSPHATE	Rabbit	Mild irritant
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Professio	Moderate irritant
	nal	
	judgeme	
	nt	

Skin Sensitization

Name	Species	Value
SILANE TREATED CERAMIC	similar	Some positive data exist, but the data are not
	compoun	sufficient for classification
	ds	
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Guinea	Sensitizing
	pig	
SYNTHETIC AMORPHOUS SILICA, FUMED, CRYSTALLINE FREE	Human	Not sensitizing
	and	
	animal	
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Human	Sensitizing
	and	
	animal	

Respiratory Sensitization

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Germ Cell Mutagenicity

Name	Route	Value
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	In Vitro	Some positive data exist, but the data are not
		sufficient for classification
SYNTHETIC AMORPHOUS SILICA, FUMED, CRYSTALLINE FREE	In Vitro	Not mutagenic
DIPHENYLIODONIUM HEXAFLUOROPHOSPHATE	In Vitro	Some positive data exist, but the data are not
		sufficient for classification
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	Some positive data exist, but the data are not
		compou	sufficient for classification
		nds	
SYNTHETIC AMORPHOUS SILICA, FUMED, CRYSTALLINE	Not	Mouse	Some positive data exist, but the data are not
FREE	Specified		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
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Ingestion	Not toxic to female reproduction	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Ingestion	Not toxic to male reproduction	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Ingestion	Not toxic to development	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
SYNTHETIC AMORPHOUS SILICA, FUMED, CRYSTALLINE FREE	Ingestion	Not toxic to female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation

SYNTHETIC AMORPHOUS SILICA, FUMED, CRYSTALLINE FREE	Ingestion	Not toxic to male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
SYNTHETIC AMORPHOUS SILICA, FUMED, CRYSTALLINE FREE	Ingestion	Not toxic to development	Rat	NOAEL 1,350 mg/kg/day	during organogenesi s
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Ingestion	Not toxic to female reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Ingestion	Not toxic to male reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Ingestion	Not toxic to development	Mouse	NOAEL 1 mg/kg/day	1 generation

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test Result	Exposure Duration
DIPHENYLIODONIUM HEXAFLUOROPHOSPH ATE	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification	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	Some positive data exist, but the data are not sufficient for classification	similar compoun ds	NOAEL Not available	
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Ingestion	endocrine system liver nervous system kidney and/or bladder	All data are negative	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
SYNTHETIC AMORPHOUS SILICA, FUMED, CRYSTALLINE FREE	Inhalation	respiratory system silicosis	All data are negative	Human	NOAEL Not available	occupational exposure
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	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
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Dermal	blood	All data are negative	Mouse	NOAEL 833 mg/kg/day	78 weeks

Aspiration Hazard

Name

Value

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

Ecotoxicological information

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

Chemical fate information

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

SECTION 13: Disposal considerations

13.1. Disposal methods

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

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.

EPA Hazardous Waste Number (RCRA): Not regulated

SECTION 14: Transport Information

For Transport Information, please visit http://3M.com/Transportinfo or call 1-800-364-3577 or 651-737-6501.

SECTION 15: Regulatory information

15.1. US Federal Regulations

Contact 3M for more information.

311/312 Hazard Categories:

Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No Immediate Hazard - Yes Delayed Hazard - No

15.2. State Regulations

Contact 3M for more information.

15.3. Chemical Inventories

This material contains one or more substances not listed on the TSCA Inventory. Commercial use of this material is regulated by the FDA.

Contact 3M for more information.

15.4. International Regulations

Contact 3M for more information.

This SDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.

SECTION 16: Other information

NFPA Hazard Classification

Health: 2 Flammability: 1 Instability: 0 Special Hazards: None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

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