Safety Data Sheet

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This Safety Data Sheet has been prepared in accordance with the GHS guidelines & India Hazardous substances (Classification, Labeling & Packaging) Draft Rules 2011.

SECTION 1: Identification

1.1. Product identifier
3M™ Filtek™ P60 Posterior Restorative Paste

Product Identification Numbers
IE-4501-3609-8 IE-4501-3610-6

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 India Limited, plot-48-51, Electronic city, Hosur road, Bangalore-560100
Telephone: 080-45543000, contact Product EHS team
E Mail: productehs.in@mmm.com
Website: http://solutions.3mindia.co.in

1.4. Emergency telephone number
080-45543000 (Contact hours: 8:00 AM to 5:00 PM)

SECTION 2: Hazard identification

Under MSIHC Rules, information is noted below on flammability, acute toxicity and explosivity relevant to this product. In line with international standards, information on other hazard classes and associated precautionary statements relevant to this product are included as well.

2.1. Classification of the substance or mixture
Acute Toxicity (oral): Category 5.
Skin Sensitizer: Category 1.

2.2. Label elements
Signal Word
WARNING!

Symbols
Exclamation mark |

Pictograms

HAZARD STATEMENTS:

H303	May be harmful if swallowed.
H317	May cause an allergic skin reaction.

PRECAUTIONARY STATEMENTS

Prevention:

P280E	Wear protective gloves.

Response:

P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.

2.3. Other hazards
None known.

SECTION 3: Composition/information on ingredients

This material is a mixture.

Ingredient	CAS Nbr	% by Wt
Silane Treated Ceramic	444758-98-9	75 - 85
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	1565-94-2	1 - 10
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	41637-38-1	1 - 10
Diurethane Dimethacrylate (UDMA)	72869-86-4	1 - 10
Aluminium oxide	1344-28-1	< 5
Triethylene Glycol Dimethacrylate (TEGDMA)	109-16-0	< 5

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	Condition
Carbon monoxide.	During combustion.
Carbon dioxide.	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
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
Aluminum, insoluble compounds	1344-28-1	ACGIH	TWA(respirable fraction):1 mg/m3	A4: Not class. as human carcin
CAS NO SEQ117921	1344-28-1	ACGIH	TWA(inhalable particulates):10 mg/m3	
CAS NO SEQ117922	1344-28-1	ACGIH	TWA(respirable particles):3 mg/m3	

ACGIH : American Conference of Governmental Industrial Hygienists
AIHA : American Industrial Hygiene Association
CMRG : Chemical Manufacturer's Recommended Guidelines
TWA: Time-Weighted-Average
STEL: Short Term Exposure Limit
CEIL: Ceiling

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

Physical state	Solid.
Specific Physical Form:	Paste
Color	White
Odor	Slight Acrylate
Odour threshold	*No data available.*
pH	*Not applicable.*
Melting point/Freezing point: NA	*No data available.*
Boiling point/Initial boiling point/Boiling range	*Not applicable.*
Flash point	No flash point
Evaporation rate	*Not applicable.*
Flammability (solid, gas)	Not classified

Flammable Limits(LEL)	*No data available.*
Flammable Limits(UEL)	*No data available.*
Vapour pressure	*Not applicable.*
Vapor Density and/or Relative Vapor Density	*Not applicable.*
Density	2.1 g/cm3
Relative density	2.1 [*Ref Std:*WATER=1]
Water solubility	Negligible
Solubility- non-water	*No data available.*
Partition coefficient: n-octanol/water	*Not applicable.*
Autoignition temperature	*No data available.*
Decomposition temperature	*No data available.*
Viscosity/Kinematic Viscosity	± 300,000 mPa-s
Volatile organic compounds (VOC)	*No data available.*
Percent volatile	*No data available.*
VOC less H2O & exempt solvents	*No data available.*
Molecular weight	*No data available.*

Nanoparticles
This material contains nanoparticles.

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 Possibility of hazardous reactions
Hazardous polymerisation will not occur.

10.4 Conditions to avoid
None known.

10.5 Incompatible materials
None known.

10.6 Hazardous decomposition products

Substance	**Condition**
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:

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 (BISEMA-6)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Diurethane Dimethacrylate (UDMA)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	Ingestion	Rat	LD50 > 2,000 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
Aluminium oxide	Dermal		LD50 estimated to be > 5,000 mg/kg
Aluminium oxide	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 2.3 mg/l
Aluminium oxide	Ingestion	Rat	LD50 > 5,000 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	Rabbit	No significant irritation
Triethylene Glycol Dimethacrylate (TEGDMA)	Guinea pig	Mild irritant
Aluminium oxide	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	In vitro data	No significant irritation
Triethylene Glycol Dimethacrylate (TEGDMA)	Professional judgement	Moderate irritant
Aluminium oxide	Rabbit	No significant irritation

Sensitization:

Skin Sensitisation

Name	Species	Value
Silane Treated Ceramic	similar compounds	Not classified
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	Guinea pig	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
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	In Vitro	Not mutagenic
(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
Aluminium oxide	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
Triethylene Glycol Dimethacrylate (TEGDMA)	Dermal	Mouse	Not carcinogenic
Aluminium oxide	Inhalation	Rat	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
Aluminium oxide	Inhalation	pneumoconiosis	Some positive data exist, but the data are not sufficient for classification	Human	NOAEL Not available	occupational exposure
Aluminium oxide	Inhalation	pulmonary fibrosis	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

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 Nbr	Organism	Type	Exposure	Test endpoint	Test result
Silane Treated Ceramic	444758-98-9		Data not available or insufficient for classification			N/A
(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
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	41637-38-1	Activated sludge	Estimated	3 hours	EC50	>1,000 mg/l
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	41637-38-1	Green algae	Estimated	72 hours	No tox obs at lmt of water sol	>100 mg/l
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	41637-38-1	Rainbow trout	Estimated	96 hours	No tox obs at lmt of water sol	>100 mg/l
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	41637-38-1	Green algae	Estimated	72 hours	No tox obs at lmt of water sol	>100 mg/l
Diurethane	72869-86-4	Green algae	Endpoint not	72 hours	ErC50	>100 mg/l

Dimethacrylate (UDMA)			reached			
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
Aluminium oxide	1344-28-1	Fish	Experimental	96 hours	LC50	>100 mg/l
Aluminium oxide	1344-28-1	Green Algae	Experimental	72 hours	EC50	>100 mg/l
Aluminium oxide	1344-28-1	Water flea	Experimental	48 hours	LC50	>100 mg/l
Aluminium oxide	1344-28-1	Green Algae	Experimental	72 hours	NOEC	>100 mg/l
Triethylene Glycol Dimethacrylate (TEGDMA)	109-16-0	Green Algae	Experimental	72 hours	EC50	>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 Nbr	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	Experimental Hydrolysis		Hydrolytic half-life (pH 7)	29 days (t 1/2)	
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]	1565-94-2	Experimental Biodegradation	28 days	BOD	21 % BOD/ThBOD	similar to OECD 301F

bismethacrylate						
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	41637-38-1	Experimental Biodegradation	28 days	BOD	24 % BOD/ThBOD	OECD 301D - Closed bottle test
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
Aluminium oxide	1344-28-1	Data not available-insufficient			N/A	
Triethylene Glycol Dimethacrylate (TEGDMA)	109-16-0	Experimental Biodegradation	28 days	CO2 evolution	85 % weight	OECD 301B - Modified sturm or CO2

12.3 : Bioaccumulative potential

Material	CAS Nbr	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	
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	41637-38-1	Estimated Bioconcentration		Bioaccumulation factor	6.6	Estimated: Bioconcentration factor
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	41637-38-1	Experimental Bioconcentration		Log Kow	≥4.66	OECD 117 log Kow HPLC method
Diurethane Dimethacrylate (UDMA)	72869-86-4	Experimental Bioconcentration		Log Kow	3.39	Non-standard method
Aluminium oxide	1344-28-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Triethylene Glycol Dimethacrylate (TEGDMA)	109-16-0	Experimental Bioconcentration		Log Kow	2.3	Non-standard method

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

Not hazardous for transportation.

Air Transport (IATA)Regulations

UN No Not applicable
Proper Shipping Name Not applicable
Hazard Classs/Division Not applicable
Subsidiary Risk Not applicable
Packing Group: Not applicable

Marine Transport (IMDG)
UN No Not applicable
Proper Shipping Name Not applicable
Hazard Classs/Division Not applicable
Subsidiary Risk Not applicable
Packing Group: Not applicable
Environmental Hazards: Not applicable

SECTION 15: Regulatory information

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

Global inventory status
Contact 3M for more information.

Applicable Environmental, Health and Safety Regulations
The Manufacture, Storage and Import of Hazardous Chemical Rules, 1989
The Bio Medical Waste (Management & Handling) Rules, 1998
Hazardous Chemicals (Classification, Packaging and Labelling Draft Rules), 2011

The following ingredients are listed as hazardous on Part II of Schedule I of the India Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) rules
None.

The following ingredients are classified as hazardous based on the criteria listed under Part I of Schedule I of the India Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) rules:
The product is classified as Non-Hazardous as per MSIHC Rules, 1989.

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.

Revision information:
No revision information

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3M India SDSs are available at http://solutions.3mindia.co.in