

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: Filtek Z250 Universal Restorative (Shades B05 & B1)

Manufacturer: 3M

SDS Expiry: 28 December 2022

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 22 November 2018

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Safety Data Sheet

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SECTION 1: Identification

1.1. Product identifier

3M™ ESPE™ FILTEK™ Z250™ UNIVERSAL RESTORATIVE SHADES B0.5 and B1

Product Identification Numbers

70-2010-2231-9, 70-2010-2247-5, 70-2010-2570-0, 70-2010-2591-6, 70-2010-5206-8, 70-2010-9551-3, 70-2010-9562-0

1.2. Recommended use and restrictions on use

Recommended use

Dental Product, Dental restorative.

Restrictions on use

For use only by dental professionals.

1.3. Supplier's details

MANUFACTURER:	3M
DIVISION:	Oral Care Solutions Division
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

Skin Sensitizer: Category 1B.

Carcinogenicity: Category 2.

2.2. Label elements

Signal word

Warning

Symbols

Exclamation mark | Health Hazard |

Pictograms**Hazard Statements**

May cause an allergic skin reaction.

Suspected of causing cancer by inhalation.

Precautionary Statements**Prevention:**

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Avoid breathing dust/fume/gas/mist/vapors/spray.

Wear protective gloves.

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.

IF exposed or concerned: Get medical advice/attention.

Disposal:

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

SECTION 3: Composition/information on ingredients

Ingredient	C.A.S. No.	% by Wt
SILANE TREATED CERAMIC	444758-98-9	75 - 85 Trade Secret *
BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE (BISEMA6)	41637-38-1	1 - 10 Trade Secret *
DIURETHANE DIMETHACRYLATE (UDMA)	72869-86-4	1 - 10 Trade Secret *
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	1565-94-2	1 - 10 Trade Secret *
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	109-16-0	< 5 Trade Secret *
ALUMINUM OXIDE	1344-28-1	< 1 Trade Secret *
BENZOTRIAZOL	96478-09-0	< 0.5 Trade Secret *
TITANIUM OXIDE	13463-67-7	< 0.5 Trade Secret *
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	10287-53-3	< 0.5 Trade Secret *

*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:

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**

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

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 handle until all safety precautions have been read and understood. Avoid breathing dust/fume/gas/mist/vapors/spray. 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. Use personal protective equipment (gloves, respirators, etc.) as required.

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	C.A.S. No.	Agency	Limit type	Additional Comments
ALUMINUM OXIDE	1344-28-1	OSHA	TWA(as total dust):15 mg/m ³ ;TWA(respirable fraction):5 mg/m ³	
Aluminum, insoluble compounds	1344-28-1	ACGIH	TWA(respirable fraction):1 mg/m ³	A4: Not class. as human carcin
TITANIUM OXIDE	13463-67-7	ACGIH	TWA:10 mg/m ³	A4: Not class. as human carcin
TITANIUM OXIDE	13463-67-7	OSHA	TWA(as total dust):15 mg/m ³	

ACGIH : American Conference of Governmental Industrial Hygienists

AIHA : American Industrial Hygiene Association

CMRG : Chemical Manufacturer's Recommended Guidelines

OSHA : United States Department of Labor - Occupational Safety and Health Administration

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

General Physical Form:	Solid
Specific Physical Form:	Paste
Odor, Color, Grade:	Slight acrylate odor, various shades
Odor threshold	<i>No Data Available</i>
pH	<i>Not Applicable</i>
Melting point	<i>No Data Available</i>
Boiling Point	<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>
Vapor Pressure	<i>Not Applicable</i>
Vapor Density	<i>Not Applicable</i>
Density	2.1 g/cm ³
Specific Gravity	2.1 [Ref Std:WATER=1]
Solubility in Water	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	Approximately 300,000 centipoise
Volatile Organic Compounds	<i>No Data Available</i>
Percent volatile	<i>No Data Available</i>
VOC Less H ₂ O & Exempt Solvents	<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. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

None known.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Substance

None known.

Condition

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:

Inhalation:

Respiratory Tract Irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.

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 diarrhea.

Additional Health Effects:

Carcinogenicity:

Exposures needed to cause the following health effect(s) are not expected during normal, intended use:

Contains a chemical or chemicals which can cause cancer.

Ingredient	CAS No.	Class Description	Regulation
TITANIUM OXIDE	13463-67-7	Grp. 2B: Possible human carc.	International Agency for Research on Cancer

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 (BISEMA6)	Dermal	Professional judgment	LD50 estimated to be > 5,000 mg/kg

DIURETHANE DIMETHACRYLATE (UDMA)	Dermal	Professional judgment	LD50 estimated to be > 5,000 mg/kg
BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE (BISEMA6)	Ingestion	Rat	LD50 > 2,000 mg/kg
DIURETHANE DIMETHACRYLATE (UDMA)	Ingestion	Rat	LD50 > 5,000 mg/kg
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Dermal	Professional judgment	LD50 estimated to be 2,000 - 5,000 mg/kg
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Dermal	Professional judgment	LD50 estimated to be > 5,000 mg/kg
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Ingestion	Rat	LD50 10,837 mg/kg
ALUMINUM OXIDE	Dermal		LD50 estimated to be > 5,000 mg/kg
ALUMINUM OXIDE	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 2.3 mg/l
ALUMINUM OXIDE	Ingestion	Rat	LD50 > 5,000 mg/kg
TITANIUM OXIDE	Dermal	Rabbit	LD50 > 10,000 mg/kg
TITANIUM OXIDE	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 6.82 mg/l
TITANIUM OXIDE	Ingestion	Rat	LD50 > 10,000 mg/kg
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	Dermal	Rat	LD50 > 2,000 mg/kg
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	Ingestion	Rat	LD50 > 2,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
SILANE TREATED CERAMIC	similar compounds	No significant irritation
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Not available	Minimal irritation
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Guinea pig	Mild irritant
ALUMINUM OXIDE	Rabbit	No significant irritation
TITANIUM OXIDE	Rabbit	No significant irritation
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
SILANE TREATED CERAMIC	similar compounds	Mild irritant
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Not available	Moderate irritant
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Professional judgment	Moderate irritant
ALUMINUM OXIDE	Rabbit	No significant irritation
TITANIUM OXIDE	Rabbit	No significant irritation
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	Rabbit	Mild irritant

Skin Sensitization

Name	Species	Value
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SILANE TREATED CERAMIC	similar compounds	Not classified
BISPHENOL A POLYETHYLENE GLYCOL DIETHER DIMETHACRYLATE (BISEMA6)	Guinea pig	Not classified
DIURETHANE DIMETHACRYLATE (UDMA)	Guinea pig	Sensitizing
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Guinea pig	Sensitizing
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Human and animal	Sensitizing
TITANIUM OXIDE	Human and animal	Not classified

Respiratory Sensitization

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 (BISEMA6)	In Vitro	Not mutagenic
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	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
ALUMINUM OXIDE	In Vitro	Not mutagenic
TITANIUM OXIDE	In Vitro	Not mutagenic
TITANIUM OXIDE	In vivo	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
ALUMINUM OXIDE	Inhalation	Rat	Not carcinogenic
TITANIUM OXIDE	Ingestion	Multiple animal species	Not carcinogenic
TITANIUM OXIDE	Inhalation	Rat	Carcinogenic

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test Result	Exposure Duration
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Ingestion	Not classified for female reproduction	Mouse	NOAEL 0.8 mg/kg/day	prematuring & during gestation
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Ingestion	Not classified for male reproduction	Mouse	NOAEL 0.8 mg/kg/day	prematuring & during gestation
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Ingestion	Not classified for development	Mouse	NOAEL 0.8 mg/kg/day	prematuring & 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	
BISPHENOL A DIGLYCIDYL ETHER DIMETHACRYLATE (BISGMA)	Ingestion	endocrine system liver nervous system kidney and/or bladder	Not classified	Mouse	NOAEL 0.8 mg/kg/day	prematuring & during gestation
TRIETHYLENE GLYCOL DIMETHACRYLATE (TEGDMA)	Dermal	kidney and/or bladder blood	Not classified	Mouse	NOAEL 833 mg/kg/day	78 weeks
ALUMINUM OXIDE	Inhalation	pneumoconiosis	Some positive data exist, but the data are not sufficient for classification	Human	NOAEL Not available	occupational exposure
ALUMINUM OXIDE	Inhalation	pulmonary fibrosis	Not classified	Human	NOAEL Not available	occupational exposure
TITANIUM OXIDE	Inhalation	respiratory system	Some positive data exist, but the data are not sufficient for classification	Rat	LOAEL 0.01 mg/l	2 years
TITANIUM 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**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.

Incinerate in a permitted waste incineration facility.

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.

EPCRA 311/312 Hazard Classifications:

Physical Hazards

Not applicable

Health Hazards

Carcinogenicity

Respiratory or Skin Sensitization

Section 313 Toxic Chemicals subject to the reporting requirements of that section and 40 CFR part 372 (EPCRA):

<u>Ingredient</u>	<u>C.A.S. No</u>	<u>% by Wt</u>
ALUMINUM OXIDE	1344-28-1	Trade Secret < 1

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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