



Safety Data Sheet

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Product identifier

8020TP/8021TP 3M™ ESPE™ FILTEK™ Z500 UNIVERSAL RESTORATIVE SINGLE SHADE INTRO KIT

ID Number(s):

70-2010-7861-8, 70-2010-7870-9

Recommended use

Dental Product, Dental Restorative

Restrictions on use

For use only by dental professionals

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)

Emergency telephone number

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

This product is a kit or a multipart product which consists of multiple, independently packaged components. A Safety Data Sheet (SDS), Article Information Sheet (AIS), or Article Information Letter (AIL) for each of these components is included. Please do not separate the component documents from this cover page. The document numbers for components of this product are:

28-0649-5

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Document Group:	28-0649-5	Version Number:	4.05
Issue Date:	12/22/22	Supersedes Date:	09/07/21

SECTION 1: Identification

1.1. Product identifier

3M™ Filtek™ Z500 Universal Restorative (8020, 8021)

Product Identification Numbers

70-2010-7852-7, 70-2010-7853-5, 70-2010-7854-3, 70-2010-7855-0, 70-2010-7856-8, 70-2010-7857-6, 70-2010-7858-4, 70-2010-7859-2, 70-2010-7862-6, 70-2010-7863-4, 70-2010-7864-2, 70-2010-7865-9, 70-2010-7866-7, 70-2010-7867-5, 70-2010-7868-3, 70-2010-7869-1, 70-2010-7871-7, 70-2010-7872-5, 70-2010-7873-3, 70-2014-1980-4, 70-2014-1981-2, 70-2014-1982-0, 70-2014-1983-8, 70-2014-1984-6, 70-2014-1985-3, 70-2014-1986-1, 70-2014-1987-9, 70-2014-1988-7, 70-2014-1989-5, 70-2014-1990-3, 70-2014-1991-1, 70-2014-1992-9, 70-2014-1993-7, 70-2014-1994-5, 70-2014-1995-2, 7000054510, 7000054491, 7000054492, 7000054493, 7000054494, 7000054495, 7000054496, 7000054497, 7000054498, 7000054501, 7000054502, 7000054503, 7000054512, 7000054504, 7000054505, 7000054506, 7000054507, 7000054508, 7000054511, 7100295219, 7100295214, 7100295251, 7100295273, 7100295215, 7100295233, 7100295234, 7100295235, 7100295254, 7100295315, 7100295255, 7100295256, 7100295257, 7100295258, 7100295259, 7100295260

1.2. Recommended use and restrictions on use

Recommended use

Dental Product, Composite restorative material

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 1.
 Reproductive Toxicity: Category 1B.

2.2. Label elements

Signal word

Danger

Symbols

Exclamation mark | Health Hazard |

Pictograms



Hazard Statements

May cause an allergic skin reaction.
 May damage fertility or the unborn child.

Precautionary Statements

Prevention:

Obtain special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 Avoid breathing dust.
 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	65 - 75 Trade Secret *
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	1565-94-2	1 - 10 Trade Secret *
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	41637-38-1	5 - 10 Trade Secret *
Diurethane Dimethacrylate (UDMA)	72869-86-4	5 - 10 Trade Secret *
Silane Treated Silica	248596-91-0	5 - 10 Trade Secret *
Triethylene Glycol Dimethacrylate (TEGDMA)	109-16-0	< 5 Trade Secret *
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	10287-53-3	< 0.3 Trade Secret *
Diphenyliodonium Hexafluorophosphate	58109-40-3	< 0.2 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

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

<u>Substance</u>	<u>Condition</u>
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

Avoid breathing of dust created by cutting, sanding, grinding or machining. 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. Do not breathe dust/fume/gas/mist/vapors/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. 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

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

Appearance

Physical state

Solid

Color

Tooth

Specific Physical Form:

Paste

Odor

Slight Acrylate

Odor threshold

No Data Available

pH

Not Applicable

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	1.9 g/cm ³
Specific Gravity	1.9 [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	<i>Not Applicable</i>
Volatile Organic Compounds	<i>Not Applicable</i>
Percent volatile	<i>Not Applicable</i>
VOC Less H ₂ O & Exempt Solvents	<i>Not Applicable</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 polymerization will not occur.

10.4. Conditions to avoid

Light

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.

The information below represents toxicological information associated with the individual components of the uncured product. Once properly mixed and/or cured, the product is safe for its intended use.

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.

May cause additional health effects (see below).

Additional Health Effects:

Reproductive/Developmental Toxicity:

Contains a chemical or chemicals which can cause birth defects or other reproductive harm.

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 >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
Silane Treated Silica	Dermal		LD50 estimated to be > 5,000 mg/kg
Silane Treated Silica	Ingestion		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 (BISEMA-6)	Dermal	Rat	LD50 > 2,000 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
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	Dermal	Professional judgment	LD50 estimated to be > 5,000 mg/kg
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	Ingestion	Rat	LD50 > 11,700 mg/kg
Triethylene Glycol Dimethacrylate (TEGDMA)	Dermal	Professional	LD50 estimated to be > 5,000 mg/kg

		judgeme nt	
Triethylene Glycol Dimethacrylate (TEGDMA)	Ingestion	Rat	LD50 10,837 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
Diphenyliodonium Hexafluorophosphate	Ingestion	Rat	LD50 32 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silane Treated Ceramic	similar compounds	No significant irritation
Silane Treated Silica	Professional judgment	No significant irritation
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	In vitro data	No significant irritation
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	Rabbit	No significant irritation
Triethylene Glycol Dimethacrylate (TEGDMA)	Guinea pig	Mild irritant
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	Rabbit	No significant irritation
Diphenyliodonium Hexafluorophosphate	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Silane Treated Ceramic	similar compounds	Mild irritant
Silane Treated Silica	Professional judgment	No significant irritation
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	In vitro data	No significant irritation
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	In vitro data	No significant irritation
Triethylene Glycol Dimethacrylate (TEGDMA)	Professional judgment	Moderate irritant
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	Rabbit	No significant irritation
Diphenyliodonium Hexafluorophosphate	Rabbit	Mild irritant

Skin Sensitization

Name	Species	Value
Silane Treated Ceramic	similar compounds	Not classified
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	Multiple animal species	Not classified
Diurethane Dimethacrylate (UDMA)	Guinea pig	Sensitizing
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	Mouse	Not classified
Triethylene Glycol Dimethacrylate (TEGDMA)	Human and animal	Sensitizing
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)		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 (BISEMA-6)	In Vitro	Not mutagenic
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	In Vitro	Not mutagenic
Triethylene Glycol Dimethacrylate (TEGDMA)	In Vitro	Some positive data exist, but the data are not sufficient for classification
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	In vivo	Not mutagenic
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	In Vitro	Some positive data exist, but the data are not sufficient for classification
Diphenyliodonium Hexafluorophosphate	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
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 Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	Ingestion	Not classified for female reproduction	Rat	NOAEL 1,000 mg/kg/day	prematuring into lactation
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	Ingestion	Not classified for male reproduction	Rat	NOAEL 1,000 mg/kg/day	28 days
Bisphenol A Polyethylene Glycol Diether Dimethacrylate (BISEMA-6)	Ingestion	Not classified for development	Rat	NOAEL 1,000 mg/kg/day	during gestation
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	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
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	Ingestion	Not classified for female reproduction	Rat	NOAEL 600 mg/kg/day	prematuring into lactation
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	Ingestion	Not classified for development	Rat	NOAEL 50 mg/kg/day	prematuring into lactation
ETHYL 4-DIMETHYL AMINO BENZOATE (EDMAB)	Ingestion	Toxic to male reproduction	Rat	NOAEL 50 mg/kg/day	53 days

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test Result	Exposure Duration
Diphenyliodonium Hexafluorophosphate	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	
Bisphenol A Polyethylene	Ingestion	hematopoietic	Not classified	Rat	NOAEL	13 weeks

Glycol Diether Dimethacrylate (BISEMA-6)		system liver immune system kidney and/or bladder endocrine system eyes			1,000 mg/kg/day	
Bisphenol A Diglycidyl Ether Dimethacrylate (BISGMA)	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
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	Ingestion	hematopoietic system	Some positive data exist, but the data are not sufficient for classification	Rat	NOAEL 74 mg/kg/day	28 days
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	Ingestion	liver heart endocrine system 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 900 mg/kg/day	28 days

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.

Dispose of waste product in a permitted industrial waste facility. As a disposal alternative, 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

Reproductive toxicity

Respiratory or Skin Sensitization

Additional TSCA Information

Components	CAS No	Additional Information
Silane Treated Silica	248596-91-0	Allowed use(s): Coating additive.

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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