Safety Information Sheet for Medical Devices

Document group:	16-1922-0	**Version number:**	1.00
Revision date:	11/11/2019	**Supersedes date:**	Initial issue.

Transportation version number: 1.00 (11/11/2019)

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™ ESPE™ RELYX™ VENEER TRY-IN PASTE

Product Identification Numbers

LE-F100-0702-1	70-2010-3189-8	70-2010-3190-6	70-2010-3191-4	70-2010-3192-2
70-2010-3193-0	70-2010-3194-8			
7000003154	7000003155	7000003156	7000003157	7000054258
7000128794				

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

This product is a medical device as defined in Directive 93/42/EEC (MDD), 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.

SECTION 3: Composition/information on ingredients

Ingredient	CAS Nbr	EC No.	% by Wt	Classification
Polyglycol	25322-68-3		80 - 95	Substance not classified as hazardous
Ceramic	66402-68-4	266-340-9	5 - 15	Substance not classified as hazardous
Titanium dioxide (REACH Reg. No.:01-2119489379-17)	13463-67-7	236-675-5	< 1	Substance with a Community level exposure limit in the workplace

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
Remove person to fresh air. If you feel unwell, get medical attention.

Skin contact
Wash with soap and water. 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.

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	Condition
Carbon monoxide.	During combustion.
Carbon dioxide.	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
Ventilate the area with fresh air. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapours, in accordance with good industrial hygiene practice. Observe precautions from other sections.

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. 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
Titanium dioxide	13463-67-7	UK HSC	TWA(Inhalable):10 mg/m3;TWA(respirable):4 mg/m³	

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

Appearance	
Physical state	Solid.
Colour	Multicolor
Specific Physical Form:	Paste
Odor	Characteristic Odour
pH	*Not applicable.*
Boiling point/boiling range	*Not applicable.*
Melting point	*No data available.*
Flammability (solid, gas)	Not classified
Explosive properties	Not classified
Oxidising properties	Not classified
Flash point	*Not applicable.*
Autoignition temperature	*No data available.*
Flammable Limits(LEL)	*Not applicable.*
Flammable Limits(UEL)	*Not applicable.*
Relative density	1.3 [*Ref Std:*WATER=1]
Water solubility	Appreciable
Viscosity	*No data available.*
Density	1.3 g/cm3

9.2. Other information

EU Volatile Organic Compounds	*No data available.*
Molecular weight	*No data available.*
Percent volatile	*Not applicable.*

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 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 3M assessments.

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.

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

Ingestion
Gastrointestinal irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhoea.

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.

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 >5,000 mg/kg
Polyglycol	Dermal	Rabbit	LD50 > 20,000 mg/kg
Polyglycol	Ingestion	Rat	LD50 32,770 mg/kg
Ceramic	Dermal		LD50 estimated to be > 5,000 mg/kg
Ceramic	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
Titanium dioxide	Dermal	Rabbit	LD50 > 10,000 mg/kg
Titanium dioxide	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 6.82 mg/l
Titanium dioxide	Ingestion	Rat	LD50 > 10,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Polyglycol	Rabbit	Minimal irritation
Ceramic	Rabbit	No significant irritation
Titanium dioxide	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Polyglycol	Rabbit	Mild irritant
Ceramic	Rabbit	Mild irritant
Titanium dioxide	Rabbit	No significant irritation

Skin Sensitisation

Name	Species	Value
Polyglycol	Guinea pig	Not classified
Titanium dioxide	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
Polyglycol	In Vitro	Not mutagenic
Polyglycol	In vivo	Not mutagenic
Ceramic	In Vitro	Some positive data exist, but the data are not sufficient for classification
Titanium dioxide	In Vitro	Not mutagenic
Titanium dioxide	In vivo	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
Polyglycol	Ingestion	Rat	Not carcinogenic
Ceramic	Inhalation	Multiple animal species	Some positive data exist, but the data are not sufficient for classification
Titanium dioxide	Ingestion	Multiple animal species	Not carcinogenic
Titanium dioxide	Inhalation	Rat	Carcinogenic.

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
Polyglycol	Ingestion	Not classified for female reproduction	Rat	NOAEL 1,125 mg/kg/day	during gestation
Polyglycol	Ingestion	Not classified for male reproduction	Rat	NOAEL 5699 +/- 1341	5 days

				mg/kg/day	
Polyglycol	Not specified.	Not classified for reproduction and/or development		NOEL N/A	
Polyglycol	Ingestion	Not classified for development	Mouse	NOAEL 562 mg/animal/day	during gestation

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Polyglycol	Inhalation	respiratory irritation	Not classified	Rat	NOAEL 1.008 mg/l	2 weeks

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Polyglycol	Inhalation	respiratory system	Not classified	Rat	NOAEL 1.008 mg/l	2 weeks
Polyglycol	Ingestion	kidney and/or bladder | heart | endocrine system | hematopoietic system | liver | nervous system	Not classified	Rat	NOAEL 5,640 mg/kg/day	13 weeks
Ceramic	Inhalation	pulmonary fibrosis	Not classified	Multiple animal species	NOAEL not available	
Ceramic	Inhalation	respiratory system	Not classified	Human	NOAEL not available	occupational exposure
Titanium dioxide	Inhalation	respiratory system	Some positive data exist, but the data are not sufficient for classification	Rat	LOAEL 0.01 mg/l	2 years
Titanium dioxide	Inhalation	pulmonary fibrosis	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.

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
Polyglycol	25322-68-3	Atlantic Salmon	Experimental	96 hours	LC50	>1,000 mg/l
Ceramic	66402-68-4		Data not available or insufficient for classification			
Titanium dioxide	13463-67-7	Diatom	Experimental	72 hours	EC50	>10,000 mg/l
Titanium dioxide	13463-67-7	Fathead minnow	Experimental	96 hours	LC50	>100 mg/l

Titanium dioxide	13463-67-7	Water flea	Experimental	48 hours	EC50	>100 mg/l
Titanium dioxide	13463-67-7	Diatom	Experimental	72 hours	NOEC	5,600 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Polyglycol	25322-68-3	Experimental Biodegradation	28 days	BOD	53 % BOD/ThBOD	OECD 301C - MITI test (I)
Ceramic	66402-68-4	Data not availbl-insufficient			N/A	
Titanium dioxide	13463-67-7	Data not availbl-insufficient			N/A	

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Polyglycol	25322-68-3	Estimated Bioconcentration		Bioaccumulation factor	2.3	Estimated: Bioconcentration factor
Ceramic	66402-68-4	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Titanium dioxide	13463-67-7	Experimental BCF-Carp	42 days	Bioaccumulation factor	9.6	Other methods

12.4. Mobility in soil
Please contact manufacturer for more details

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. 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)
180107 Chemicals other than those mentioned in 18 01 06

SECTION 14: Transportation information

70-2010-3189-8, 70-2010-3190-6, 70-2010-3191-4, 70-2010-3192-2, 70-2010-3193-0, 70-2010-3194-8

Not hazardous for transportation

ADR/IMDG/IATA: Not restricted for transport.

SECTION 15: Regulatory information

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

Carcinogenicity
Contact the manufacturer for more information

Global inventory status
Contact the manufacturer for more information

SECTION 16: Other information

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