



## Safety Information Sheet for Medical Devices

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**Document group:** 05-4615-0 **Version number:** 1.01  
**Revision date:** 23/04/2020 **Supersedes date:** 23/04/2020  
**Transportation version number:** 1.00 (23/04/2020)

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™ Z100™ Restorative Paste (5904-5907, 3021-3024, 8004)

##### Product Identification Numbers

70-2010-1318-5	70-2010-1319-3	70-2010-1320-1	70-2010-1321-9	70-2010-1322-7
70-2010-1323-5	70-2010-1324-3	70-2010-1325-0	70-2010-1329-2	70-2010-1331-8
70-2010-1420-9	70-2010-1485-2	70-2010-1486-0	70-2010-1487-8	70-2010-1488-6
70-2010-1489-4	70-2010-1490-2	70-2010-1491-0	70-2010-1492-8	70-2010-1496-9
70-2010-1498-5	70-2010-1499-3	70-2010-1531-3	70-2010-1533-9	70-2010-1535-4
70-2010-2371-3	70-2010-2372-1	70-2010-2373-9	70-2010-2374-7	70-2010-2375-4
70-2010-2376-2	70-2010-2377-0	70-2010-2378-8	70-2010-3791-1	70-2010-3792-9
70-2010-3793-7	70-2010-3794-5	70-2010-3795-2	70-2010-3796-0	70-2010-3797-8
70-2010-3798-6	70-2010-3802-6	70-2010-3804-2	70-2010-3805-9	70-2010-3806-7
70-2010-3807-5	70-2010-3808-3	70-2010-3809-1	70-2010-3810-9	70-2010-3811-7
70-2010-3812-5	70-2010-3813-3	70-2010-3817-4	70-2010-3819-0	70-2010-3820-8
70-2010-5171-4	70-2010-5172-2	70-2010-5173-0	70-2010-5174-8	70-2010-5175-5
70-2010-5176-3	70-2010-5177-1	70-2010-5178-9	70-2010-5182-1	70-2010-5184-7
70-2010-5185-4	70-2010-8785-8	70-2010-8786-6		
7000128777	7000128778	7000128779	7000128780	7000128781
7000128782	7000128783	7000128784	7000128785	7000128786
7000128787	7000054185	7000054186	7000054187	7000054188
7000054189	7000054190	7000054191	7000054192	7010342577
7000054193	7000054194	7000054195	7000054196	7000054197
7000054213	7000054214	7000054215	7000054216	7000054217
7000054218	7000054219	7000054220	7000054304	7000054302
7000054297	7000003165	7000054294	7000054295	7000054296
7000054298	7000054299	7000054300	7000054303	7000003162
7000003163	7000003164	7000003166	7000003167	7000003168

**3M™ Z100™ Restorative Paste (5904-5907, 3021-3024, 8004)**  
23/04/2020

7000003169	7000128798	7000003171	7000128799	7000054301
7000003181	7000003182	7000003183	7000003184	7000003185
7000003186	7000003187	7000030527	7000003188	7000003189
7100111815				

**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) respectively Regulation (EU) 2017/745 (MDR), 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:**

Skin Sensitization, Category 1 - Skin Sens. 1; H317

For full text of H phrases, see Section 16.

**2.2. Label elements**

**CLP REGULATION (EC) No 1272/2008**

**SIGNAL WORD**

WARNING.

**Symbols:**

GHS07 (Exclamation mark) |

**Pictograms**



**Ingredients:**

**3M™ Z100™ Restorative Paste (5904-5907, 3021-3024, 8004)**  
23/04/2020

Ingredient	CAS Nbr	EC No.	% by Wt
Triethyleneglycol dimethacrylate (TEGDMA)	109-16-0	203-652-6	1 - 10
Stabilizer	2440-22-4	219-470-5	< 1

**HAZARD STATEMENTS:**

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**

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
Carbosilane surfactant		701-308-4	1 - 10	Substance not classified as hazardous
Silane treated ceramic	444758-98-9		80 - 90	Substance not classified as hazardous
Triethyleneglycol dimethacrylate (TEGDMA) (REACH Reg. No.:01-2119969287-21)	109-16-0	203-652-6	1 - 10	Skin Sens. 1, H317
Stabilizer	2440-22-4	219-470-5	< 1	Aquatic Chronic 1, H410,M=1 Acute Tox. 4, H332; Skin Sens. 1B, H317

Note: Any entry in the EC# column that begins with the numbers 6, 7, 8, or 9 are a Provisional List Number provided by ECHA pending publication of the official EC Inventory Number for the substance. 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**

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.

## 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

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

Evacuate area. 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. Refer to other sections of this SIS 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

Refer to Instructions for Use (IFU) for more information.

## 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 SIS.

#### 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

Tooth

Specific Physical Form:

Paste

Odor

Slight Acrylate

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

No flash point

Autoignition temperature

*No data available.*

Flammable Limits(LEL)

*Not applicable.*

Flammable Limits(UEL)

*Not applicable.*

Relative density

2.1 [Ref Std:WATER=1]

Water solubility

Negligible

Viscosity

*Not applicable.*

Density

2.1 g/cm<sup>3</sup>

### 9.2. Other information

EU Volatile Organic Compounds

*No data available.*

Molecular weight

*No data available.*

Percent volatile

Negligible

## 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

<u>Substance</u>	<u>Condition</u>
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. 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
------	-------	---------	-------

**3M™ Z100™ Restorative Paste (5904-5907, 3021-3024, 8004)**  
23/04/2020

Overall product	Ingestion		No data available; calculated ATE <sub>2,000</sub> - 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
Triethyleneglycol dimethacrylate (TEGDMA)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Triethyleneglycol dimethacrylate (TEGDMA)	Ingestion	Rat	LD50 10,837 mg/kg
Carbosilane surfactant	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Carbosilane surfactant	Ingestion	Rat	LD50 > 11,700 mg/kg
Stabilizer	Dermal	Rat	LD50 > 2,000 mg/kg
Stabilizer	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.59 mg/l
Stabilizer	Ingestion	Rat	LD50 10,000 mg/kg

ATE = acute toxicity estimate

### Skin Corrosion/Irritation

Name	Species	Value
Silane treated ceramic	similar compounds	No significant irritation
Triethyleneglycol dimethacrylate (TEGDMA)	Guinea pig	Mild irritant
Carbosilane surfactant	Rabbit	No significant irritation
Stabilizer	Rat	No significant irritation

### Serious Eye Damage/Irritation

Name	Species	Value
Silane treated ceramic	similar compounds	Mild irritant
Triethyleneglycol dimethacrylate (TEGDMA)	Professional judgement	Moderate irritant
Carbosilane surfactant	In vitro data	No significant irritation
Stabilizer	Rabbit	No significant irritation

### Skin Sensitisation

Name	Species	Value
Silane treated ceramic	similar compounds	Not classified
Triethyleneglycol dimethacrylate (TEGDMA)	Human and animal	Sensitising
Carbosilane surfactant	Mouse	Not classified
Stabilizer	Guinea pig	Sensitising

### 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
Triethyleneglycol dimethacrylate (TEGDMA)	In Vitro	Some positive data exist, but the data are not sufficient for classification
Carbosilane surfactant	In Vitro	Not mutagenic
Stabilizer	In Vitro	Not mutagenic
Stabilizer	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
Triethyleneglycol dimethacrylate (TEGDMA)	Dermal	Mouse	Not carcinogenic
Stabilizer	Ingestion	Rat	Not carcinogenic

### Reproductive Toxicity

**Reproductive and/or Developmental Effects**

Name	Route	Value	Species	Test result	Exposure Duration
Triethyleneglycol dimethacrylate (TEGDMA)	Ingestion	Not classified for female reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
Triethyleneglycol dimethacrylate (TEGDMA)	Ingestion	Not classified for male reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
Triethyleneglycol dimethacrylate (TEGDMA)	Ingestion	Not classified for development	Mouse	NOAEL 1 mg/kg/day	1 generation
Carbositane surfactant	Ingestion	Not classified for development	Rat	NOAEL 1,000 mg/kg/day	during gestation
Stabilizer	Ingestion	Not classified for development	Rat	NOAEL 1,000 mg/kg/day	during organogenesis

**Target Organ(s)**

**Specific Target Organ Toxicity - single exposure**

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Stabilizer	Ingestion	nervous system   respiratory system	Not classified	Rat	LOAEL 4,640 mg/kg	

**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	
Triethyleneglycol dimethacrylate (TEGDMA)	Dermal	kidney and/or bladder   blood	Not classified	Mouse	NOAEL 833 mg/kg/day	78 weeks
Carbositane surfactant	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
Stabilizer	Ingestion	endocrine system   kidney and/or bladder   heart   bone, teeth, nails, and/or hair   blood   liver   immune system   muscles   nervous system   eyes   respiratory system   vascular system	Not classified	Rat	NOAEL 142 mg/kg/day	2 years

**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
Carbosilane surfactant	701-308-4	Water flea	Endpoint not reached	48 hours		>100 mg/l
Carbosilane surfactant	701-308-4	Green Algae	Endpoint not reached	96 hours		>100 mg/l
Carbosilane surfactant	701-308-4	Green Algae	Experimental	96 hours	Effect Concentration 10%	1.1 mg/l
Silane treated ceramic	444758-98-9		Data not available or insufficient for classification			
Triethyleneglycol dimethacrylate (TEGDMA)	109-16-0	Zebra Fish	Experimental	96 hours	LC50	16.4 mg/l
Triethyleneglycol dimethacrylate (TEGDMA)	109-16-0	Green Algae	Experimental	72 hours	EC50	>100 mg/l
Triethyleneglycol dimethacrylate (TEGDMA)	109-16-0	Green algae	Experimental	72 hours	NOEC	18.6 mg/l
Triethyleneglycol dimethacrylate (TEGDMA)	109-16-0	Water flea	Experimental	21 days	NOEC	32 mg/l
Stabilizer	2440-22-4	Water flea	Experimental	24 hours	EC50	>1,000 mg/l
Stabilizer	2440-22-4	Water flea	Experimental	21 days	NOEC	0.013 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 availbl-insufficient			N/A	
Triethyleneglycol dimethacrylate (TEGDMA)	109-16-0	Experimental Biodegradation	28 days	CO2 evolution	85 % weight	OECD 301B - Modified sturm or CO2
Stabilizer	2440-22-4	Experimental Biodegradation	28 days	BOD	2 % weight	OECD 301B - Modified sturm or CO2

## 12.3 : Bioaccumulative potential

Material	Cas No.	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
Triethyleneglycol dimethacrylate (TEGDMA)	109-16-0	Experimental Bioconcentration		Log Kow	2.3	Other methods
Stabilizer	2440-22-4	Experimental BCF-Carp	56 days	Bioaccumulation factor	494	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)

180106\* Chemicals consisting of or containing dangerous substances.

## SECTION 14: Transportation information

70-2010-1318-5,	70-2010-1319-3,	70-2010-1320-1,	70-2010-1321-9,
70-2010-1322-7,	70-2010-1323-5,	70-2010-1324-3,	70-2010-1325-0,
70-2010-1329-2,	70-2010-1331-8,	70-2010-1420-9,	70-2010-1485-2,
70-2010-1486-0,	70-2010-1487-8,	70-2010-1488-6,	70-2010-1489-4,
70-2010-1490-2,	70-2010-1491-0,	70-2010-1492-8,	70-2010-1496-9,
70-2010-1498-5,	70-2010-1499-3,	70-2010-1531-3,	70-2010-1533-9,
70-2010-1535-4,	70-2010-2371-3,	70-2010-2372-1,	70-2010-2373-9,
70-2010-2374-7,	70-2010-2375-4,	70-2010-2376-2,	70-2010-2377-0,
70-2010-2378-8,	70-2010-3791-1,	70-2010-3792-9,	70-2010-3793-7,
70-2010-3794-5,	70-2010-3795-2,	70-2010-3796-0,	70-2010-3797-8,
70-2010-3798-6,	70-2010-3802-6,	70-2010-3804-2,	70-2010-3805-9,
70-2010-3806-7,	70-2010-3807-5,	70-2010-3808-3,	70-2010-3809-1,
70-2010-3810-9,	70-2010-3811-7,	70-2010-3812-5,	70-2010-3813-3,
70-2010-3817-4,	70-2010-3819-0,	70-2010-3820-8,	70-2010-5171-4,
70-2010-5172-2,	70-2010-5173-0,	70-2010-5174-8,	70-2010-5175-5,
70-2010-5176-3,	70-2010-5177-1,	70-2010-5178-9,	70-2010-5182-1,
70-2010-5184-7,	70-2010-5185-4		

Not hazardous for transportation

70-2010-8785-8

70-2010-8786-6

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

#### Global inventory status

Contact the manufacturer for more information

## SECTION 16: Other information

### List of relevant H statements

H317	May cause an allergic skin reaction.
H332	Harmful if inhaled.
H410	Very toxic to aquatic life with long lasting effects.

### Revision information:

A revision has been performed due to the need to update the safety information for the medical device.

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](http://www.3M.com/uk)**