



Safety Data Sheet

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This Safety Data Sheet has been prepared in accordance with the REACH Regulation (EC) 1907/2006 and its modifications.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

5904-5907, 3021-3024, AND 8004 3M™ ESPE™ Z100™ RESTORATIVE PASTE

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses

Dental product

Restrictions on Use

For use only by dental professionals

1.3. Details of the supplier of the safety data sheet

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:

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

For full text of H phrases, see Section 16.

5904-5907, 3021-3024, AND 8004 3M™ ESPET™ Z100™ RESTORATIVE PASTE**2.2. Label elements****CLP REGULATION (EC) No 1272/2008****SIGNAL WORD**

WARNING.

Symbols:

GHS07 (Exclamation mark) |

Pictograms**Ingredients:**

Ingredient	CAS Nbr	EC No.	% by Wt
2,2'-ethylenedioxydiethyl dimethacrylate	109-16-0	203-652-6	1 - 10
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	1565-94-2	216-367-7	1 - 10
2-(2H-Benzotriazol-2-yl)-p-cresol	2440-22-4	219-470-5	< 0.2

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.	REACH Registration No.	% by Wt	Classification
Ceramic materials and wares, chemicals, hydrolysis products with 3-(trimethoxysilyl)propyl methacrylate	444758-98-9			80 - 90	Substance not classified as hazardous
2,2'-ethylenedioxydiethyl dimethacrylate	109-16-0	203-652-6	01-2119969287-21	1 - 10	Skin Sens. 1, H317
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	1565-94-2	216-367-7		1 - 10	Skin Sens. 1B, H317
2-(2H-Benzotriazol-2-yl)-p-cresol	2440-22-4	219-470-5		< 0.2	Aquatic Chronic 1, H410,M=1

					Acute Tox. 4, H332; Skin Sens. 1B, H317
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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 SDS

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. 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. 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 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.

6.4. Reference to other sections

Refer to Section 8 and Section 13 for more information

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.

7.3. Specific end use(s)

See information in Section 7.1 and 7.2 for handling and storage recommendations. See Section 8 for exposure controls and personal protection recommendations.

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 Safety Data Sheet.

Biological limit values

No biological limit values exist for any of the components listed in Section 3 of this safety data 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

Physical state	Solid.
Specific Physical Form:	Paste
Appearance/Odour	Slight acrylate odour, Tooth coloured
Odour threshold	<i>No data available.</i>
pH	<i>Not applicable.</i>
Boiling point/boiling range	<i>Not applicable.</i>
Melting point	<i>No data available.</i>
Flammability (solid, gas)	Not classified
Explosive properties	Not classified
Oxidising properties	Not classified
Flash point	No flash point
Autoignition temperature	<i>No data available.</i>
Flammable Limits(LEL)	<i>Not applicable.</i>
Flammable Limits(UEL)	<i>Not applicable.</i>
Vapour pressure	<i>Not applicable.</i>
Relative density	2.1 [Ref Std: WATER=1]
Water solubility	Negligible
Solubility- non-water	<i>No data available.</i>
Partition coefficient: n-octanol/water	<i>Not applicable.</i>
Evaporation rate	<i>Not applicable.</i>
Vapour density	<i>Not applicable.</i>
Decomposition temperature	<i>No data available.</i>
Viscosity	<i>Not applicable.</i>
Density	2.1 g/cm ³

9.2. Other information

EU Volatile Organic Compounds	<i>No data available.</i>
Molecular weight	<i>No data available.</i>
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**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. Allergic skin reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, and itching.

Eye contact

Moderate eye irritation: Signs/symptoms may include redness, swelling, pain, tearing, and blurred or hazy vision.

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	Dermal		No data available; calculated ATE >5,000 mg/kg
Overall product	Ingestion		No data available; calculated ATE 2,000 - 5,000 mg/kg
Ceramic materials and wares, chemicals, hydrolysis products with 3-(trimethoxysilyl)propyl methacrylate	Dermal		LD50 estimated to be > 5,000 mg/kg
Ceramic materials and wares, chemicals, hydrolysis products with 3-(trimethoxysilyl)propyl methacrylate	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
2,2'-ethylenedioxydiethyl dimethacrylate	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
2,2'-ethylenedioxydiethyl dimethacrylate	Ingestion	Rat	LD50 10,837 mg/kg
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-	Dermal	Professional judgement	LD50 estimated to be 2,000 - 5,000 mg/kg

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propanediyl)] bismethacrylate		nal judgeme nt	
2-(2H-Benzotriazol-2-yl)-p-cresol	Dermal	Rat	LD50 > 2,000 mg/kg
2-(2H-Benzotriazol-2-yl)-p-cresol	Inhalation- Dust/Mist (4 hours)	Rat	LC50 > 0.59 mg/l
2-(2H-Benzotriazol-2-yl)-p-cresol	Ingestion	Rat	LD50 10,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Ceramic materials and wares, chemicals, hydrolysis products with 3-(trimethoxysilyl)propyl methacrylate	similar compounds	No significant irritation
2,2'-ethylenedioxydiethyl dimethacrylate	Guinea pig	Mild irritant
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Not available	Minimal irritation
2-(2H-Benzotriazol-2-yl)-p-cresol	Rat	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Ceramic materials and wares, chemicals, hydrolysis products with 3-(trimethoxysilyl)propyl methacrylate	similar compounds	Mild irritant
2,2'-ethylenedioxydiethyl dimethacrylate	Professional judgement	Moderate irritant
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Not available	Moderate irritant
2-(2H-Benzotriazol-2-yl)-p-cresol	Rabbit	No significant irritation

Skin Sensitisation

Name	Species	Value
Ceramic materials and wares, chemicals, hydrolysis products with 3-(trimethoxysilyl)propyl methacrylate	similar compounds	Not classified
2,2'-ethylenedioxydiethyl dimethacrylate	Human and animal	Sensitising
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Guinea pig	Sensitising
2-(2H-Benzotriazol-2-yl)-p-cresol	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
2,2'-ethylenedioxydiethyl dimethacrylate	In Vitro	Some positive data exist, but the data are not sufficient for classification
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	In Vitro	Some positive data exist, but the data are not sufficient for classification
2-(2H-Benzotriazol-2-yl)-p-cresol	In Vitro	Not mutagenic
2-(2H-Benzotriazol-2-yl)-p-cresol	In vivo	Not mutagenic

5904-5907, 3021-3024, AND 8004 3M™ ESPET™ Z100™ RESTORATIVE PASTE**Carcinogenicity**

Name	Route	Species	Value
Ceramic materials and wares, chemicals, hydrolysis products with 3-(trimethoxysilyl)propyl methacrylate	Inhalation	similar compounds	Some positive data exist, but the data are not sufficient for classification
2,2'-ethylenedioxydiethyl dimethacrylate	Dermal	Mouse	Not carcinogenic
2-(2H-Benzotriazol-2-yl)-p-cresol	Ingestion	Rat	Not carcinogenic

Reproductive Toxicity**Reproductive and/or Developmental Effects**

Name	Route	Value	Species	Test result	Exposure Duration
2,2'-ethylenedioxydiethyl dimethacrylate	Ingestion	Not classified for female reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
2,2'-ethylenedioxydiethyl dimethacrylate	Ingestion	Not classified for male reproduction	Mouse	NOAEL 1 mg/kg/day	1 generation
2,2'-ethylenedioxydiethyl dimethacrylate	Ingestion	Not classified for development	Mouse	NOAEL 1 mg/kg/day	1 generation
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Ingestion	Not classified for female reproduction	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Ingestion	Not classified for male reproduction	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Ingestion	Not classified for development	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
2-(2H-Benzotriazol-2-yl)-p-cresol	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
2-(2H-Benzotriazol-2-yl)-p-cresol	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
Ceramic materials and wares, chemicals, hydrolysis products with 3-(trimethoxysilyl)propyl methacrylate	Inhalation	pulmonary fibrosis	Not classified	similar compounds	NOAEL Not available	
2,2'-ethylenedioxydiethyl dimethacrylate	Dermal	kidney and/or bladder blood	Not classified	Mouse	NOAEL 833 mg/kg/day	78 weeks
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	Ingestion	endocrine system liver nervous system kidney and/or bladder	Not classified	Mouse	NOAEL 0.8 mg/kg/day	premating & during gestation
2-(2H-Benzotriazol-2-yl)-p-cresol	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	Not classified	Rat	NOAEL 142 mg/kg/day	2 years

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		system				
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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 SDS for additional toxicological information on this material and/or its components.

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
Ceramic materials and wares, chemicals, hydrolysis products with 3-(trimethoxysilyl)propyl methacrylate	444758-98-9		Data not available or insufficient for classification			
2,2'-ethylenedioxydiethyl dimethacrylate	109-16-0	Zebra Fish	Experimental	96 hours	LC50	16.4 mg/l
2,2'-ethylenedioxydiethyl dimethacrylate	109-16-0	Green Algae	Experimental	72 hours	EC50	>100 mg/l
2,2'-ethylenedioxydiethyl dimethacrylate	109-16-0	Green algae	Experimental	72 hours	NOEC	18.6 mg/l
2,2'-ethylenedioxydiethyl dimethacrylate	109-16-0	Water flea	Experimental	21 days	NOEC	32 mg/l
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	1565-94-2		Data not available or insufficient for classification			
2-(2H-Benzotriazol-2-yl)-p-cresol	2440-22-4	Water flea	Experimental	24 hours	EC50	>1,000 mg/l
2-(2H-Benzotriazol-2-yl)-p-cresol	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
Ceramic materials and wares, chemicals, hydrolysis products with 3-(trimethoxysilyl)propyl methacrylate	444758-98-9	Data not available or insufficient			N/A	
2,2'-ethylenedioxydiethyl dimethacrylate	109-16-0	Experimental Biodegradation	28 days	CO2 evolution	85 % weight	OECD 301B - Modified Sturm or CO2
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-	1565-94-2	Estimated Biodegradation	28 days	BOD	32 % weight	OECD 301C - MITI test (I)

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3,1-propanediyl]] bismethacrylate						
2-(2H-Benzotriazol-2-yl)-p-cresol	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
Ceramic materials and wares, chemicals, hydrolysis products with 3-(trimethoxysilyl)propyl methacrylate	444758-98-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
2,2'-ethylenedioxydiethyl dimethacrylate	109-16-0	Experimental Bioconcentration		Log Kow	2.3	Other methods
(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate	1565-94-2	Estimated Bioconcentration		Bioaccumulation factor	5.8	Estimated: Bioconcentration factor
2-(2H-Benzotriazol-2-yl)-p-cresol	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**

See Section 11.1 Information on toxicological effects

Dispose of waste product in a permitted industrial waste facility. As a disposal alternative, incinerate in a permitted waste incineration facility. Proper destruction may require the use of additional fuel during incineration processes.

The coding of a waste stream is based on the application of the product by the consumer. Since this is out of the control of 3M, no waste code(s) for products after use will be provided. Please refer to the European Waste Code (EWC - 2000/532/EC and amendments) to assign the correct waste code to your waste stream. Ensure national and/or regional regulations are complied with and always use a licensed waste contractor.

EU waste code (product as sold)

180106* Chemicals consisting of or containing dangerous substances.

SECTION 14: Transportation information

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 3M for more information.

15.2. Chemical Safety Assessment

A chemical safety assessment has not been carried out for this mixture. Chemical safety assessments for the contained substances may have been carried out by the registrants of the substances in accordance with Regulation (EC) No 1907/2006, as amended.

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:

Section 1: Product identification numbers information was deleted.

Section 01: SAP Material Numbers information was deleted.

CLP: Ingredient table information was modified.

Section 3: Composition/ Information of ingredients table information was modified.

Section 5: Fire - Advice for fire fighters information information was modified.

Section 6: Accidental release personal information information was modified.

Section 7: Precautions safe handling information information was modified.

Section 9: Property description for optional properties information was modified.

Section 11: Acute Toxicity table information was modified.

Section 12: Component ecotoxicity information information was modified.

Section 12: No PBT/vPvB information available warning information was modified.

Section 12: Persistence and Degradability information information was modified.

Section 12: Bioaccumulative potential information information was modified.

Section 13: EU waste code (product as sold) information information was modified.

Section 13: Standard Phrase Category Waste GHS information was modified.

Section 14: Transportation classification information was modified.

Section 15: Chemical Safety Assessment information was modified.

DISCLAIMER: The information on this Safety Data Sheet is based on our experience and is correct to the best of our knowledge at the date of publication, but we do not accept any liability for any loss, damage or injury resulting from its use (except as required by law). The information may not be valid for any use not referred to in this Data Sheet or use of the product in combination with other materials. For these reasons, it is important that customers carry out their own test to satisfy themselves as to the suitability of the product for their own intended applications.

3M United Kingdom MSDSs are available at www.3M.com/uk