



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

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

Identified uses

Dental Product

1.3. Details of the supplier of the substance or mixture

Address: 3M United Kingdom PLC, 3M Centre, Cain Road, Bracknell, Berkshire, RG12 8HT.

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

CLASSIFICATION:

This material is exempt from hazard classification according to Regulation (EC) No. 1272/2008, as amended, on classification, labelling, and packaging of substances and mixtures.

Dangerous substances(67/548/EEC)/preparations(1999/45/EC) directive

2.2. Label elements

CLP REGULATION (EC) No 1272/2008

Not applicable

Dangerous substances(67/548/EEC)/preparations(1999/45/EC) directive

Not applicable

3M™ ESPE™IMPRINT™ 4 REGULAR BASE**Special provisions concerning the labelling of certain substances**

This product contains a substance classified as R48/20. Based on the physical form, exposure by inhalation is not expected.

Notes on labelling

This product is exempt from labelling per Directive 1999/45/EC as it is defined as a medical device according to Directive 93/42/EEC and is invasive or comes into contact with the human body.

2.3. Other hazards

None known.

SECTION 3: Composition/information on ingredients

Ingredient	CAS Nbr	EU Inventory	% by Wt	Classification
Siloxanes and silicones, Di-Me, vinyl group-terminated	68083-19-2		30 - 50	
Cristobalite	14464-46-1	EINECS 238-455-4	20 - 30	Xn:R48/20 (Vendor) STOT RE 2, H373 (Vendor)
Dimethyl methyl hydrogen silicone fluid	68037-59-2		10 - 20	Xn:R20 (Self Classified) Acute Tox. 4, H332 (Self Classified)
Dimethyl siloxane, reaction product with silica	67762-90-7		1 - 10	
Silica, vitreous	60676-86-0	EINECS 262-373-8	1 - 10	
Glycols,polyethylene,methyl 3-[1,3,3,3-tetramethyl-1-(trimethylsiloxy)disiloxanyl]propyl ether	27306-78-1		1 - 10	Xn:R20; Xi:R36 (Self Classified) Acute Tox. 4, H332; Eye Irrit. 2, H319 (Self Classified)
Silane, trimethyl-2-propenyl-	762-72-1	EINECS 212-104-5	< 5	
FLUORINATED POLYETHER	Trade Secret		1 - 5	
Tridymite	15468-32-3	EINECS 239-487-1	< 1	
Quartz	14808-60-7	EINECS 238-878-4	< 0.5	Xn:R48/20 (Vendor) STOT RE 1, H372 (Self Classified)
Oils, mint, Mentha arvensis piperascenssis, var. piperascens, Labiatae.	68917-18-0		< 0.5	Xn:R22; Xi:R36; R43 (Self Classified) Acute Tox. 4, H302; Eye Irrit. 2, H319; Skin Sens. 1B, H317 (Self Classified)

Please see section 16 for the full text of any R phrases and H statements referred to in this section

Please refer to section 15 for the any applicable Notas that have been applied to the above components

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.
Irritant vapours or gases.

Condition

During combustion.
During combustion.
During combustion.

5.3. Advice for fire-fighters

No unusual fire or explosion hazards 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.

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

Avoid prolonged or repeated skin contact. 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

Store away from heat.

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

Ingredient	CAS Nbr	Agency	Limit type	Additional comments
Quartz	14464-46-1	Health and Safety Comm. (UK)	TWA(respirable):0.1 mg/m ³	
Quartz	14808-60-7	Health and Safety Comm. (UK)	TWA(respirable):0.1 mg/m ³	
Quartz	15468-32-3	Health and Safety Comm. (UK)	TWA(respirable):0.1 mg/m ³	
Silica, vitreous	60676-86-0	Health and Safety Comm. (UK)	TWA(as respirable dust):0.08 mg/m ³	

Health and Safety Comm. (UK) : 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 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.

Skin/hand protection

No chemical protective gloves are required.

Respiratory protection

Under normal use conditions, airborne exposures are not expected to be significant enough to require respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid.
Specific Physical Form:	Paste
Appearance/Odour	Smell of mint; white colour paste
Odour threshold	<i>No data available.</i>
pH	<i>Not applicable.</i>
Boiling point/boiling range	<i>Not applicable.</i>
Melting point	<i>Not applicable.</i>
Flammability (solid, gas)	Not classified
Explosive properties	Not classified
Oxidising properties	Not classified
Flash point	No flash point
Autoignition temperature	<i>Not applicable.</i>
Flammable Limits(LEL)	<i>Not applicable.</i>
Flammable Limits(UEL)	<i>Not applicable.</i>
Vapour pressure	<i>No data available.</i>
Relative density	1.1 - 1.3 [Ref Std:WATER=1]
Water solubility	Negligible
Solubility- non-water	<i>No data available.</i>
Partition coefficient: n-octanol/water	<i>No data available.</i>
Evaporation rate	<i>Not applicable.</i>
Vapour density	<i>No data available.</i>
Decomposition temperature	<i>No data available.</i>
Viscosity	<i>No data available.</i>
Density	1.1 g/cm ³ - 1.3 g/cm ³

9.2. Other information

Volatile organic compounds (VOC)	<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 is considered to be non reactive under normal use conditions. 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

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Hazardous polymerisation will not occur.

10.4 Conditions to avoid

Heat.

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 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 labelling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

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

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

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	Dermal		No data available; calculated ATE >5,000 mg/kg
Overall product	Ingestion		No data available; calculated ATE >5,000 mg/kg
Siloxanes and silicones, Di-Me, vinyl group-terminated	Dermal	Rabbit	LD50 > 15,440 mg/kg
Siloxanes and silicones, Di-Me, vinyl group-terminated	Ingestion	Rat	LD50 > 15,440 mg/kg

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Cristobalite	Ingestion		LD50 estimated to be > 5,000 mg/kg
Dimethyl methyl hydrogen silicone fluid	Dermal	Rabbit	LD50 > 2,000 mg/kg
Dimethyl methyl hydrogen silicone fluid	Inhalation-Dust/Mist (4 hours)	Rat	LC50 4.2 mg/l
Dimethyl methyl hydrogen silicone fluid	Ingestion	Rat	LD50 > 2,000 mg/kg
Dimethyl siloxane, reaction product with silica	Dermal	Rabbit	LD50 > 5,000 mg/kg
Dimethyl siloxane, reaction product with silica	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Dimethyl siloxane, reaction product with silica	Ingestion	Rat	LD50 > 5,110 mg/kg
Silica, vitreous	Dermal	Rabbit	LD50 > 5,000 mg/kg
Silica, vitreous	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Silica, vitreous	Ingestion	Rat	LD50 > 5,110 mg/kg
Glycols,polyethylene,methyl 3-[1,3,3,3-tetramethyl-1-(trimethylsiloxy)disiloxanyl]propyl ether	Dermal	Rabbit	LD50 > 2,000 mg/kg
Glycols,polyethylene,methyl 3-[1,3,3,3-tetramethyl-1-(trimethylsiloxy)disiloxanyl]propyl ether	Inhalation-Dust/Mist (4 hours)	Rat	LC50 2 mg/l
Glycols,polyethylene,methyl 3-[1,3,3,3-tetramethyl-1-(trimethylsiloxy)disiloxanyl]propyl ether	Ingestion	Rat	LD50 > 2,000 mg/kg
Quartz	Dermal		LD50 estimated to be > 5,000 mg/kg
Quartz	Ingestion		LD50 estimated to be > 5,000 mg/kg
Oils, mint, Mentha arvensis piperascensis, var. piperascens, Labiatae.	Dermal	Rabbit	LD50 > 5,000 mg/kg
Oils, mint, Mentha arvensis piperascensis, var. piperascens, Labiatae.	Ingestion	Rat	LD50 1,240 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Dimethyl siloxane, reaction product with silica	Rabbit	No significant irritation
Silica, vitreous	Rabbit	No significant irritation
Glycols,polyethylene,methyl 3-[1,3,3,3-tetramethyl-1-(trimethylsiloxy)disiloxanyl]propyl ether	Rabbit	No significant irritation
Quartz		No significant irritation
Oils, mint, Mentha arvensis piperascensis, var. piperascens, Labiatae.	Rabbit	Mild irritant

Serious Eye Damage/Irritation

Name	Species	Value
Dimethyl siloxane, reaction product with silica	Rabbit	No significant irritation
Silica, vitreous	Rabbit	No significant irritation
Glycols,polyethylene,methyl 3-[1,3,3,3-tetramethyl-1-(trimethylsiloxy)disiloxanyl]propyl ether	Rabbit	Severe irritant
Oils, mint, Mentha arvensis piperascensis, var. piperascens, Labiatae.	In vitro data	Severe irritant

Skin Sensitisation

Name	Species	Value
Dimethyl siloxane, reaction product with silica	Human and animal	Not sensitizing
Silica, vitreous	Human and animal	Not sensitizing
Glycols,polyethylene,methyl 3-[1,3,3,3-tetramethyl-1-(trimethylsiloxy)disiloxanyl]propyl ether	Guinea pig	Not sensitizing
Oils, mint, Mentha arvensis piperascensis, var. piperascens, Labiatae.	Guinea pig	Sensitising

Respiratory Sensitisation

Name	Species	Value

3M™ ESPE™IMPRINT™ 4 REGULAR BASE**Germ Cell Mutagenicity**

Name	Route	Value
Dimethyl siloxane, reaction product with silica	In Vitro	Not mutagenic
Silica, vitreous	In Vitro	Not mutagenic
Glycols,polyethylene,methyl 3-[1,3,3,3-tetramethyl-1-(trimethylsiloxy)disiloxanyl]propyl ether	In Vitro	Not mutagenic
Glycols,polyethylene,methyl 3-[1,3,3,3-tetramethyl-1-(trimethylsiloxy)disiloxanyl]propyl ether	In vivo	Not mutagenic
Quartz	In Vitro	Some positive data exist, but the data are not sufficient for classification
Quartz	In vivo	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
Dimethyl siloxane, reaction product with silica	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification
Silica, vitreous	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification
Quartz	Inhalation	Human and animal	Carcinogenic.

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

Name	Route	Value	Species	Test result	Exposure Duration
Dimethyl siloxane, reaction product with silica	Ingestion	Not toxic to female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
Dimethyl siloxane, reaction product with silica	Ingestion	Not toxic to male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Dimethyl siloxane, reaction product with silica	Ingestion	Not toxic to development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis
Silica, vitreous	Ingestion	Not toxic to female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
Silica, vitreous	Inhalation	Not toxic to male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Silica, vitreous	Ingestion	Not toxic to development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis
Glycols,polyethylene,methyl 3-[1,3,3,3-tetramethyl-1-(trimethylsiloxy)disiloxanyl]propyl ether	Ingestion	Some positive reproductive/developmental data exist, but the data are not sufficient for classification	Rat	NOAEL 450 mg/kg/day	prematuring & during gestation

Target Organ(s)**Specific Target Organ Toxicity - single exposure**

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Dimethyl siloxane, reaction product with silica	Inhalation	respiratory system silicosis	All data are negative	Human	NOAEL Not available	occupational exposure
Silica, vitreous	Inhalation	respiratory system silicosis	All data are negative	Human	NOAEL Not available	occupational exposure
Quartz	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure

3M™ ESPE™IMPRINT™ 4 REGULAR BASE**Aspiration Hazard**

Name	Value

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 be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. Additional information leading to material classification in Section 2 is available upon request. In addition, environmental fate and effects data on ingredients may not be reflected in this section because an ingredient is present below the threshold for labelling, an ingredient is not expected to be available for exposure, or the data is considered not relevant to the material as a whole.

12.1. Toxicity

No product test data available.

Material	CAS Nbr	Organism	Type	Exposure	Test endpoint	Test result
Silica, vitreous	60676-86-0	Common Carp	Experimental	72 hours	LC50	>10,000 mg/l
Cristobalite	14464-46-1		Data not available or insufficient for classification			
Dimethyl methyl hydrogen silicone fluid	68037-59-2		Data not available or insufficient for classification			
Dimethyl siloxane, reaction product with silica	67762-90-7		Data not available or insufficient for classification			
Glycols,polyethylene,methyl 3-[1,3,3,3-tetramethyl-1-(trimethylsiloxy)disiloxanyl]propyl ether	27306-78-1		Data not available or insufficient for classification			
Oils, mint, Mentha arvensis piperascensis, var. piperascens, Labiatae.	68917-18-0		Data not available or insufficient for classification			
FLUORINATED POLYETHER	Trade Secret		Data not available or insufficient for classification			
Quartz	14808-60-7		Data not available or			

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			insufficient for classification			
Silane, trimethyl-2-propenyl-	762-72-1		Data not available or insufficient for classification			
Siloxanes and silicones, Di-Me, vinyl group-terminated	68083-19-2		Data not available or insufficient for classification			
Tridymite	15468-32-3		Data not available or insufficient for classification			

12.2. Persistence and degradability

No test data available.

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Dimethyl methyl hydrogen silicone fluid	68037-59-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Siloxanes and silicones, Di-Me, vinyl group-terminated	68083-19-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silane, trimethyl-2-propenyl-	762-72-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Dimethyl siloxane, reaction product with silica	67762-90-7	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
FLUORINATED POLYETHER	Trade Secret	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silica, vitreous	60676-86-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Glycols, polyethylene, methyl 3-[1,3,3,3-tetramethyl-1-(trimethylsiloxy)disiloxanyl]propyl ether	27306-78-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Tridymite	15468-32-3	Data not available or	N/A	N/A	N/A	N/A

3M™ ESPE™IMPRINT™ 4 REGULAR BASE

		insufficient for classification				
Cristobalite	14464-46-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Quartz	14808-60-7	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Oils, mint, Mentha arvensis piperascensis, var. piperascens, Labiatae.	68917-18-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

12.3 : Bioaccumulative potential

No test data available.

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Siloxanes and silicones, Di-Me, vinyl group-terminated	68083-19-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silane, trimethyl-2-propenyl-	762-72-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Dimethyl siloxane, reaction product with silica	67762-90-7	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silica, vitreous	60676-86-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Tridymite	15468-32-3	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Dimethyl methyl hydrogen silicone fluid	68037-59-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
FLUORINATED POLYETHER	Trade Secret	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Glycols, polyethylene, methyl 3-[1,3,3,3-	27306-78-1	Data not available or insufficient for	N/A	N/A	N/A	N/A

3M™ ESPE™IMPRINT™ 4 REGULAR BASE

tetramethyl-1-(trimethylsiloxy)disiloxanyl]propyl ether		classification				
Cristobalite	14464-46-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Quartz	14808-60-7	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Oils, mint, Mentha arvensis piperascensis, var. piperascens, Labiatae.	68917-18-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

12.4. Mobility in soil

Please contact manufacturer for more details

12.5. Results of the PBT and vPvB assessment

No information available at this time, contact manufacturer for more details

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 completely cured (or polymerised) material in a permitted industrial waste facility. If no other disposal options are available, waste product that has been completely cured or polymerised may be placed in a landfill properly designed for industrial waste.

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)

180107 Chemicals other than those mentioned in 18 01 06

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**

Carcinogenicity**Ingredient**

Cristobalite

Quartz

CAS Nbr

14464-46-1

14808-60-7

Classification

Grp. 1: Carcinogenic to humans

Grp. 1: Carcinogenic to humans

Regulation

International Agency for Research on Cancer

International Agency for Research on Cancer

Global inventory status

Contact 3M for more information. The components of this material are in compliance with the China "Measures on Environmental Management of New Chemical Substance". Certain restrictions may apply. Contact the selling division for additional information. The components of this product are in compliance with the new substance notification requirements of CEPA.

15.2. Chemical Safety Assessment

Not applicable

SECTION 16: Other information**List of relevant H statements**

H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.

List of relevant R-phrases

R20	Harmful by inhalation.
R22	Harmful if swallowed.
R36	Irritating to eyes.
R43	May cause sensitisation by skin contact.
R48/20	Harmful: danger of serious damage to health by prolonged exposure through inhalation.

Revision information:

Not applicable.

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



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

3M™ ESPE™IMPRINT™ 4 REGULAR CATALYST

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

Identified uses

Dental Product

1.3. Details of the supplier of the substance or mixture

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

CLASSIFICATION:

This material is exempt from hazard classification according to Regulation (EC) No. 1272/2008, as amended, on classification, labelling, and packaging of substances and mixtures.

Dangerous substances(67/548/EEC)/preparations(1999/45/EC) directive

2.2. Label elements

CLP REGULATION (EC) No 1272/2008

Not applicable

Dangerous substances(67/548/EEC)/preparations(1999/45/EC) directive

Not applicable

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This product is exempt from labelling per Directive 1999/45/EC as it is defined as a medical device according to Directive 93/42/EEC and is invasive or comes into contact with the human body.

2.3. Other hazards

None known.

SECTION 3: Composition/information on ingredients

Ingredient	CAS Nbr	EU Inventory	% by Wt	Classification
Siloxanes and silicones, Di-Me, vinyl group-terminated	68083-19-2		40 - 60	
Cristobalite	14464-46-1	EINECS 238-455-4	20 - 40	Xn:R48/20 (Self Classified) STOT RE 1, H372 (Self Classified)
Silica, vitreous	60676-86-0	EINECS 262-373-8	5 - 20	
Siloxanes and silicones, di-Me	63148-62-9		1 - 10	
Dimethyl siloxane, reaction product with silica	67762-90-7		1 - 10	
CI Pig Yellow 109	5045-40-9	EINECS 225-744-5	< 2	
Tridymite	15468-32-3	EINECS 239-487-1	< 2	Xn:R48/20 (Self Classified) STOT RE 1, H372 (Self Classified)
COBALT TITANATE GREEN SPINEL	68186-85-6	EINECS 269-047-4	< 0.9	
Quartz	14808-60-7	EINECS 238-878-4	< 0.3	Xn:R48/20 (Vendor) STOT RE 1, H372 (Self Classified)

Please see section 16 for the full text of any R phrases and H statements referred to in this section

Please refer to section 15 for the any applicable Notas that have been applied to the above components

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

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.

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

Formaldehyde
Carbon monoxide.
Carbon dioxide.
Hydrogen Chloride
Irritant vapours or gases.

Condition

During combustion.
During combustion.
During combustion.
During combustion.
During combustion.

5.3. Advice for fire-fighters

No unusual fire or explosion hazards are anticipated.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ventilate the area with fresh air. 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.

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

Avoid prolonged or repeated skin contact. Do not eat, drink or smoke when using this product. Wash thoroughly after handling.

7.2. Conditions for safe storage including any incompatibilities

Store away from heat.

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

Ingredient	CAS Nbr	Agency	Limit type	Additional comments
Quartz	14464-46-1	Health and Safety Comm. (UK)	TWA(respirable):0.1 mg/m3	
Quartz	14808-60-7	Health and Safety Comm. (UK)	TWA(respirable):0.1 mg/m3	
Quartz	15468-32-3	Health and Safety Comm. (UK)	TWA(respirable):0.1 mg/m3	
Silica, vitreous	60676-86-0	Health and Safety Comm. (UK)	TWA(as respirable dust):0.08 mg/m ³	
Silicon dioxide	60676-86-0	Health and Safety Comm. (UK)	TWA(as inhalable dust):6 mg/m3	
Silicon dioxide	67762-90-7	Health and Safety Comm. (UK)	TWA(as inhalable dust):6 mg/m3;TWA(as respirable dust):2.4 mg/m3	
Cobalt compounds	68186-85-6	Health and Safety Comm. (UK)	TWA(as Co):0.1 mg/m3	Respiratory Sensitizer
Nickel, water-insoluble inorganic compounds, N.O.S.	68186-85-6	Health and Safety Comm. (UK)	TWA(as Ni):0.5 mg/m3	Skin notation; Resp Sensitizer
Nickel, water-soluble inorganic compounds, except nickel carbonyl	68186-85-6	Health and Safety Comm. (UK)	TWA(as Ni):0.1 mg/m3	Skin notation; Resp Sensitizer

Health and Safety Comm. (UK) : 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 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.

Skin/hand protection

No chemical protective gloves are required. See Section 7.1 for additional information on skin protection.

Respiratory protection

Respiratory protection is not 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 characteristic odour; white coloured paste
Odour threshold	<i>No data available.</i>
pH	<i>Not applicable.</i>
Boiling point/boiling range	<i>Not applicable.</i>
Melting point	<i>Not applicable.</i>
Flammability (solid, gas)	Not classified
Explosive properties	Not classified
Oxidising properties	Not classified
Flash point	No flash point
Autoignition temperature	<i>Not applicable.</i>
Flammable Limits(LEL)	<i>Not applicable.</i>
Flammable Limits(UEL)	<i>Not applicable.</i>
Vapour pressure	<i>No data available.</i>
Relative density	1.2 - 1.4 [Ref Std:WATER=1]
Water solubility	Negligible
Solubility- non-water	<i>No data available.</i>
Partition coefficient: n-octanol/water	<i>No data available.</i>
Evaporation rate	<i>Not applicable.</i>
Vapour density	<i>No data available.</i>
Decomposition temperature	<i>No data available.</i>
Viscosity	<i>No data available.</i>
Density	1.2 g/cm ³ - 1.4 g/cm ³

9.2. Other information

Volatile organic compounds (VOC)	<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 polymerisation will not occur.

10.4 Conditions to avoid

Heat.

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.

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
Siloxanes and silicones, Di-Me, vinyl group-terminated	Dermal	Rabbit	LD50 > 15,440 mg/kg
Siloxanes and silicones, Di-Me, vinyl group-terminated	Ingestion	Rat	LD50 > 15,440 mg/kg
Cristobalite	Dermal		LD50 estimated to be > 5,000 mg/kg
Cristobalite	Ingestion		LD50 estimated to be > 5,000 mg/kg
Silica, vitreous	Dermal	Rabbit	LD50 > 5,000 mg/kg
Silica, vitreous	Inhalation-	Rat	LC50 > 0.691 mg/l

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	Dust/Mist (4 hours)		
Silica, vitreous	Ingestion	Rat	LD50 > 5,110 mg/kg
Dimethyl siloxane, reaction product with silica	Dermal	Rabbit	LD50 > 5,000 mg/kg
Dimethyl siloxane, reaction product with silica	Inhalation- Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Dimethyl siloxane, reaction product with silica	Ingestion	Rat	LD50 > 5,110 mg/kg
Tridymite	Dermal		LD50 estimated to be > 5,000 mg/kg
Tridymite	Ingestion		LD50 estimated to be > 5,000 mg/kg
Siloxanes and silicones, di-Me	Dermal	Rabbit	LD50 > 19,400 mg/kg
Siloxanes and silicones, di-Me	Ingestion	Rat	LD50 > 17,000 mg/kg
Quartz	Dermal		LD50 estimated to be > 5,000 mg/kg
Quartz	Ingestion		LD50 estimated to be > 5,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Siloxanes and silicones, Di-Me, vinyl group-terminated	Rabbit	No significant irritation
Cristobalite		No significant irritation
Silica, vitreous	Rabbit	No significant irritation
Dimethyl siloxane, reaction product with silica	Rabbit	No significant irritation
Tridymite		No significant irritation
Siloxanes and silicones, di-Me	Rabbit	No significant irritation
Quartz		No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Siloxanes and silicones, Di-Me, vinyl group-terminated	Rabbit	Mild irritant
Silica, vitreous	Rabbit	No significant irritation
Dimethyl siloxane, reaction product with silica	Rabbit	No significant irritation
Siloxanes and silicones, di-Me	Rabbit	No significant irritation

Skin Sensitisation

Name	Species	Value
Silica, vitreous	Human and animal	Not sensitizing
Dimethyl siloxane, reaction product with silica	Human and animal	Not sensitizing

Respiratory Sensitisation

Name	Species	Value

Germ Cell Mutagenicity

Name	Route	Value
Cristobalite	In Vitro	Some positive data exist, but the data are not sufficient for classification
Cristobalite	In vivo	Some positive data exist, but the data are not sufficient for classification
Silica, vitreous	In Vitro	Not mutagenic
Dimethyl siloxane, reaction product with silica	In Vitro	Not mutagenic
Tridymite	In Vitro	Some positive data exist, but the data are not sufficient for classification
Tridymite	In vivo	Some positive data exist, but the data are not sufficient for classification
Quartz	In Vitro	Some positive data exist, but the data are not sufficient for classification
Quartz	In vivo	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

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Name	Route	Species	Value
Cristobalite	Inhalation	Human and animal	Carcinogenic.
Silica, vitreous	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification
Dimethyl siloxane, reaction product with silica	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification
Tridymite	Inhalation	Human and animal	Carcinogenic.
Quartz	Inhalation	Human and animal	Carcinogenic.

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

Name	Route	Value	Species	Test result	Exposure Duration
Silica, vitreous	Ingestion	Not toxic to female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
Silica, vitreous	Inhalation	Not toxic to male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Silica, vitreous	Ingestion	Not toxic to development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis
Dimethyl siloxane, reaction product with silica	Ingestion	Not toxic to female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
Dimethyl siloxane, reaction product with silica	Ingestion	Not toxic to male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Dimethyl siloxane, reaction product with silica	Ingestion	Not toxic to development	Rat	NOAEL 1,350 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

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Cristobalite	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
Silica, vitreous	Inhalation	respiratory system silicosis	All data are negative	Human	NOAEL Not available	occupational exposure
Dimethyl siloxane, reaction product with silica	Inhalation	respiratory system silicosis	All data are negative	Human	NOAEL Not available	occupational exposure
Tridymite	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
Quartz	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure

Aspiration Hazard

Name	Value

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 Nbr	Organism	Type	Exposure	Test endpoint	Test result
Silica, vitreous	60676-86-0	Common Carp	Experimental	72 hours	LC50	>10,000 mg/l
CI Pig Yellow 109	5045-40-9		Data not available or insufficient for classification			
COBALT TITANATE GREEN SPINEL	68186-85-6		Data not available or insufficient for classification			
Cristobalite	14464-46-1		Data not available or insufficient for classification			
Dimethyl siloxane, reaction product with silica	67762-90-7		Data not available or insufficient for classification			
Quartz	14808-60-7		Data not available or insufficient for classification			
Siloxanes and silicones, di-Me	63148-62-9		Data not available or insufficient for classification			
Siloxanes and silicones, Di-Me, vinyl group-terminated	68083-19-2		Data not available or insufficient for classification			
Tridymite	15468-32-3		Data not available or insufficient for classification			

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Siloxanes and silicones, di-Me	63148-62-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

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Dimethyl siloxane, reaction product with silica	67762-90-7	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
COBALT TITANATE GREEN SPINEL	68186-85-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silica, vitreous	60676-86-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
CI Pig Yellow 109	5045-40-9	Estimated Biodegradation	28 days	BOD	2 % weight	OECD 301C - MITI test (I)
Quartz	14808-60-7	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Tridymite	15468-32-3	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Cristobalite	14464-46-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Siloxanes and silicones, Di-Me, vinyl group-terminated	68083-19-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

12.3 : Bioaccumulative potential

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Siloxanes and silicones, di-Me	63148-62-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Dimethyl siloxane, reaction product with silica	67762-90-7	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
COBALT TITANATE GREEN SPINEL	68186-85-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silica, vitreous	60676-86-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
CI Pig Yellow 109	5045-40-9	Estimated Bioconcentration		Bioaccumulation factor	21	Estimated: Bioconcentration factor

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		on				
Quartz	14808-60-7	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Tridymite	15468-32-3	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Cristobalite	14464-46-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Siloxanes and silicones, Di-Me, vinyl group-terminated	68083-19-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

12.4. Mobility in soil

Please contact manufacturer for more details

12.5. Results of the PBT and vPvB assessment

No information available at this time, contact manufacturer for more details

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

Incinerate in a permitted waste incineration facility. Combustion products will include halogen acid (HCl/HF/HBr). Facility must be capable of handling halogenated materials. As a disposal alternative, utilize an acceptable permitted waste disposal facility. If no other disposal options are available, waste product may be placed in a landfill properly designed for industrial waste.

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.

EU waste code (product container after use)

180107 Chemicals other than those mentioned in 18 01 06

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****Carcinogenicity**

<u>Ingredient</u>	<u>CAS Nbr</u>	<u>Classification</u>	<u>Regulation</u>
Cristobalite	14464-46-1	Grp. 1: Carcinogenic to humans	International Agency for Research on Cancer
Quartz	14808-60-7	Grp. 1: Carcinogenic to humans	International Agency for Research on Cancer

Global inventory status

All applicable chemical ingredients in this material are listed on the European Inventory of Existing Chemical Substances (EINECS), or are exempt polymers whose monomers are listed on EINECS. Contact 3M for more information. The components of this material are in compliance with the China "Measures on Environmental Management of New Chemical Substance". Certain restrictions may apply. Contact the selling division for additional information. The components of this product are in compliance with the new substance notification requirements of CEPA.

15.2. Chemical Safety Assessment

Not applicable

SECTION 16: Other information**List of relevant H statements**

H372 Causes damage to organs through prolonged or repeated exposure.

List of relevant R-phrases

R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation.

Revision information:

No revision information is available.

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