



Safety Information Sheet for Medical Devices

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Transportation version number: 1.00 (27/07/2020)

A safety data sheet is not required for this Product. This Safety Information Sheet has been created on a voluntary basis.

IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

3M™ Express™ Standard Putty (7312)

Product Identification Numbers

70-2005-5213-4

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 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

This product is a kit or a multipart product which consists of multiple, independently packaged components. Safety Information Sheet for Medical Devices for each of these components is included. Please do not separate the component Safety Information Sheet for Medical Devices from this cover page. The document numbers of the Safety Information Sheet for Medical Devices for components of this product are:

18-3613-9, 18-4188-1

TRANSPORTATION INFORMATION

70-2005-5213-4

Not hazardous for transportation

KIT LABEL

2.1. Classification of the substance or mixture

Please refer to Kit Components

Revision information:

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



Safety Information Sheet for Medical Devices

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Document group:	18-3613-9	Version number:	1.01
Revision date:	17/03/2023	Supersedes date:	07/01/2020

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™ Express™ STD-Putty Catalyst

Product Identification Numbers

LE-F100-0069-4

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

The retained CLP Regulation (EU) No 1272/2008 as amended for Great Britain

This product is a medical device as defined in Directive 93/42/EEC (MDD) respectively Regulation SI 2002 No 618, as amended (UK MDR 2002), 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 the retained CLP Regulation (EC) No. 1272/2008, as amended for Great Britain (Article 1, paragraph 5). Although not required, the classification and label information, as applicable, is provided below.

CLASSIFICATION:

This material is not classified as hazardous according to Regulation (EC) No. 1272/2008, as amended for Great Britain, on

classification, labelling, and packaging of substances and mixtures.

2.2. Label elements

The retained CLP Regulation (EU) No 1272/2008 as amended for Great Britain

Not applicable

H372 does not apply. Material is a putty, with no potential for inhalation exposure.

2.3. Other hazards

For information on hazards and safe use, please consider the corresponding sections of this document.
This material does not contain any substances that are assessed to be a PBT or vPvB

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Ingredient	Identifier(s)	%	Classification according to Regulation (EC) No. 1272/2008 [CLP], as amended for GB
Limestone	(CAS-No.) 1317-65-3 (EC-No.) 215-279-6	20 - 40	Substance with a national occupational exposure limit
Quartz	(CAS-No.) 14808-60-7 (EC-No.) 238-878-4	30 - 40	STOT RE 1, H372
Vinyl siloxanes	(CAS-No.) 68083-19-2	15 - 25	Substance not classified as hazardous
Mineral oil	(CAS-No.) 8042-47-5 (EC-No.) 232-455-8	5 - 15	Asp. Tox. 1, H304

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

No need for first aid is anticipated. If symptoms develop, remove the affected person to fresh air. Get medical attention.

Skin contact

Wash with soap and water. If signs/symptoms develop, get medical attention.

Eye contact

Flush with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. If signs/symptoms persist, get medical attention.

If swallowed

Rinse mouth. If you feel unwell, get medical attention.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

In case of fire: Use a fire fighting agent suitable for ordinary combustible material such as water or foam to extinguish.

5.2. Special hazards arising from the substance or mixture

None inherent in this product.

Hazardous Decomposition or By-Products**Substance**

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**

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

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue. 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**

If a component is disclosed in section 3 but does not appear in the table below, an occupational exposure limit is not available for the component.

Ingredient	CAS Nbr	Agency	Limit type	Additional comments
Limestone	1317-65-3	UK HSC	TWA(respirable):4 mg/m ³ ;TWA(as respirable dust):4 mg/m ³ ;TWA(Inhalable):10 mg/m ³ ;TWA(as inhalable dust):10 mg/m ³	
Quartz	14808-60-7	UK HSC	TWA(respirable):0.1 mg/m ³	

UK HSC : UK Health and Safety Commission

TWA: Time-Weighted-Average

STEL: Short Term Exposure Limit

CEIL: Ceiling

Biological limit values

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

8.2. Exposure controls

8.2.1. Engineering controls

No engineering controls required.

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:	Putty
Colour	Off-White
Odor	Slight Odor, Characteristic Odour
Melting point/freezing point	<i>No data available.</i>
Boiling point/boiling range	<i>Not applicable.</i>
Flammability (solid, gas)	Not classified
Flammable Limits(LEL)	<i>Not applicable.</i>
Flammable Limits(UEL)	<i>Not applicable.</i>
Flash point	<i>Not applicable.</i>
Autoignition temperature	<i>No data available.</i>
Relative density	2.5 [Ref Std: WATER=1]
pH	<i>substance/mixture is non-soluble (in water)</i>
Kinematic Viscosity	<i>Not applicable.</i>
Water solubility	Nil
Density	<i>No data available.</i>

9.2. Other information**9.2.2 Other safety characteristics**

EU Volatile Organic Compounds	<i>No data available.</i>
Evaporation rate	<i>Not applicable.</i>
Molecular weight	<i>No data available.</i>
Percent volatile	<i>No data available.</i>

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

Heat.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products**Substance**

None known.

Condition

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

The information below may not agree with the 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 hazard classes as defined in the retained CLP Regulation (EU) No 1272/2008, as amended for Great Britain.**Signs and Symptoms of Exposure**

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation

This product may have a characteristic odour; however, no adverse health effects are anticipated.

Skin contact

Contact with the skin during product use is not expected to result in significant irritation.

Eye contact

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

Ingestion

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

Additional Health Effects:**Carcinogenicity:**

Exposures needed to cause the following health effect(s) are not expected during normal, intended use:

Contains a chemical or chemicals which can cause cancer.

Toxicological Data

If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

Acute Toxicity

Name	Route	Species	Value
------	-------	---------	-------

Overall product	Ingestion		No data available; calculated ATE >5,000 mg/kg
Limestone	Dermal	Rat	LD50 > 2,000 mg/kg
Limestone	Inhalation-Dust/Mist (4 hours)	Rat	LC50 3 mg/l
Limestone	Ingestion	Rat	LD50 6,450 mg/kg
Quartz	Dermal		LD50 estimated to be > 5,000 mg/kg
Quartz	Ingestion		LD50 estimated to be > 5,000 mg/kg
Vinyl siloxanes	Dermal	Rabbit	LD50 > 15,440 mg/kg
Vinyl siloxanes	Ingestion	Rat	LD50 > 15,440 mg/kg
Mineral oil	Dermal	Rabbit	LD50 > 2,000 mg/kg
Mineral oil	Ingestion	Rat	LD50 > 5,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Limestone	Rabbit	No significant irritation
Quartz	Professional judgement	No significant irritation
Vinyl siloxanes	Rabbit	No significant irritation
Mineral oil	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Limestone	Rabbit	No significant irritation
Vinyl siloxanes	Rabbit	Mild irritant
Mineral oil	Rabbit	Mild irritant

Skin Sensitisation

Name	Species	Value
Mineral oil	Guinea pig	Not classified

Respiratory Sensitisation

For the component/components, either no data is currently available or the data is not sufficient for classification.

Germ Cell Mutagenicity

Name	Route	Value
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
Mineral oil	In Vitro	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
Quartz	Inhalation	Human and animal	Carcinogenic.
Mineral oil	Dermal	Mouse	Not carcinogenic
Mineral oil	Inhalation	Multiple animal species	Not carcinogenic

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
Limestone	Ingestion	Not classified for development	Rat	NOAEL 625 mg/kg/day	premating & during gestation
Mineral oil	Ingestion	Not classified for female reproduction	Rat	NOAEL 4,350 mg/kg/day	13 weeks

Mineral oil	Ingestion	Not classified for male reproduction	Rat	NOAEL 4,350 mg/kg/day	13 weeks
Mineral oil	Ingestion	Not classified for development	Rat	NOAEL 4,350 mg/kg/day	during gestation

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Limestone	Inhalation	respiratory system	Not classified	Rat	NOAEL 0.812 mg/l	90 minutes

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Limestone	Inhalation	respiratory system	Not classified	Human	NOAEL Not available	occupational exposure
Quartz	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
Mineral oil	Ingestion	hematopoietic system	Not classified	Rat	NOAEL 1,381 mg/kg/day	90 days
Mineral oil	Ingestion	liver immune system	Not classified	Rat	NOAEL 1,336 mg/kg/day	90 days

Aspiration Hazard

Name	Value
Mineral oil	Aspiration hazard

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.

11.2. Information on other hazards

This material does not contain any substances that are assessed to be an endocrine disruptor for human health.

SECTION 12: Ecological information

The information below may not agree with the 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
Limestone	1317-65-3	Green algae	Estimated	72 hours	EC50	>100 mg/l
Limestone	1317-65-3	Rainbow trout	Estimated	96 hours	LC50	>100 mg/l
Limestone	1317-65-3	Water flea	Estimated	48 hours	EC50	>100 mg/l
Limestone	1317-65-3	Green algae	Estimated	72 hours	EC10	>100 mg/l
Quartz	14808-60-7	Green algae	Estimated	72 hours	EC50	440 mg/l
Quartz	14808-60-7	Water flea	Estimated	48 hours	EC50	7,600 mg/l

Quartz	14808-60-7	Zebra Fish	Estimated	96 hours	LC50	5,000 mg/l
Quartz	14808-60-7	Green algae	Estimated	72 hours	NOEC	60 mg/l
Vinyl siloxanes	68083-19-2	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Mineral oil	8042-47-5	Water flea	Analogous Compound	48 hours	EL50	>100 mg/l
Mineral oil	8042-47-5	Bluegill	Experimental	96 hours	LL50	>100 mg/l
Mineral oil	8042-47-5	Green algae	Analogous Compound	72 hours	NOEL	100 mg/l
Mineral oil	8042-47-5	Water flea	Analogous Compound	21 days	NOEL	>100 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Limestone	1317-65-3	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Quartz	14808-60-7	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Vinyl siloxanes	68083-19-2	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Mineral oil	8042-47-5	Experimental Biodegradation	28 days	CO2 evolution	0 %CO2 evolution/THCO2 evolution	OECD 301B - Modified sturm or CO2

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Limestone	1317-65-3	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
Vinyl siloxanes	68083-19-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Mineral oil	8042-47-5	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

12.4. Mobility in soil

No test data available.

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

This material does not contain any substances that are assessed to be an endocrine disruptor for environmental effects

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose of contents/ container in accordance with the local/regional/national/international regulations.

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

EU waste code (product as sold)

180107

Chemicals other than those mentioned in 18 01 06

SECTION 14: Transportation information

Not hazardous for transportation.

	Ground Transport (ADR)	Air Transport (IATA)	Marine Transport (IMDG)
14.1 UN number	No data available.	No data available.	No data available.
14.2 UN proper shipping name	No data available.	No data available.	No data available.
14.3 Transport hazard class(es)	No data available.	No data available.	No data available.
14.4 Packing group	No data available.	No data available.	No data available.
14.5 Environmental hazards	No data available.	No data available.	No data available.
14.6 Special precautions for user	Please refer to the other sections of the SDS for further information.	Please refer to the other sections of the SDS for further information.	Please refer to the other sections of the SDS for further information.
14.7 Transport in bulk according to Annex II of Marpol 73/78 and IBC Code	No data available.	No data available.	No data available.
Control Temperature	No data available.	No data available.	No data available.
Emergency Temperature	No data available.	No data available.	No data available.
ADR Classification Code	No data available.	No data available.	No data available.
IMDG Segregation Code	No data available.	No data available.	No data available.

Please contact the address or phone number listed on the first page of the SDS for additional information on the transport/shipment of the material by rail (RID) or inland waterways (ADN).

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****Carcinogenicity**

Contact the manufacturer for more information

Global inventory status

Contact the manufacturer for more information

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

H304 May be fatal if swallowed and enters airways.
H372 Causes damage to organs through prolonged or repeated exposure.

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 Safety Information Sheets for Great Britain are available at www.3M.com/uk



Safety Information Sheet for Medical Devices

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Document group:	18-4188-1	Version number:	2.00
Revision date:	23/03/2023	Supersedes date:	07/01/2020

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™ Express™ STD-Putty Base

Product Identification Numbers

LE-F100-0077-0

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

The retained CLP Regulation (EU) No 1272/2008 as amended for Great Britain

The health and environmental classifications of this material have been derived using the calculation method, except in cases where test data are available or the physical form impacts classification. Classification(s) based on test data or physical form are noted below, if applicable.

The silicosis target organ toxicity classification is not applied because there is no potential for inhalation exposure.

This product is a medical device as defined in Directive 93/42/EEC (MDD) respectively Regulation SI 2002 No 618, as amended (UK MDR 2002), 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 the retained CLP Regulation (EC) No. 1272/2008, as

amended for Great Britain (Article 1, paragraph 5). Although not required, the classification and label information, as applicable, is provided below.

CLASSIFICATION:

Hazardous to the Aquatic Environment (Chronic), Category 3 - Aquatic Chronic 3; H412

This material is not classified as hazardous according to Regulation (EC) No. 1272/2008, as amended for Great Britain, on classification, labelling, and packaging of substances and mixtures.

For full text of H phrases, see Section 16.

2.2. Label elements

The retained CLP Regulation (EU) No 1272/2008 as amended for Great Britain

Not applicable

HAZARD STATEMENTS:

H412 Harmful to aquatic life with long lasting effects.

1% of the mixture consists of components of unknown acute oral toxicity.

Contains 20% of components with unknown hazards to the aquatic environment.

2.3. Other hazards

For information on hazards and safe use, please consider the corresponding sections of this document. Contains a substance that meets the criteria for PBT according to Regulation (EC) No 1907/2006, Annex XIII, as amended by UK REACH Regulations SI 2019/758. Contains a substance that meets the criteria for vPvB according to Regulation (EC) No 1907/2006, Annex XIII, as amended by UK REACH Regulations SI 2019/758.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Ingredient	Identifier(s)	%	Classification according to Regulation (EC) No. 1272/2008 [CLP], as amended for GB
Limestone	(CAS-No.) 1317-65-3 (EC-No.) 215-279-6	20 - 40	Substance with a national occupational exposure limit
Quartz	(CAS-No.) 14808-60-7 (EC-No.) 238-878-4	30 - 40	STOT RE 1, H372
Vinyl siloxane	(CAS-No.) 68083-19-2	10 - 25	Substance not classified as hazardous
Mineral oil	(CAS-No.) 8042-47-5 (EC-No.) 232-455-8	< 10	Asp. Tox. 1, H304
Methyl Hydrogen Silicone Fluid	Trade Secret	< 2	Substance not classified as hazardous
Octamethylcyclotetrasiloxane	(CAS-No.) 556-67-2 (EC-No.) 209-136-7	< 0.1	Repr. 2, H361f Aquatic Chronic 1, H410,M=10 Flam. Liq. 3, H226

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

For information on ingredient occupational exposure limits or PBT or vPvB status, see sections 8 and 12 of this SIS

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation

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

Skin contact

Wash with soap and water. If signs/symptoms develop, get medical attention.

Eye contact

Flush with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. If signs/symptoms persist, get medical attention.

If swallowed

Rinse mouth. If you feel unwell, get medical attention.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

In case of fire: Use a fire fighting agent suitable for ordinary combustible material such as water or foam to extinguish.

5.2. Special hazards arising from the substance or mixture

None inherent in this product.

Hazardous Decomposition or By-Products

<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

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

If a component is disclosed in section 3 but does not appear in the table below, an occupational exposure limit is not available for the component.

Ingredient	CAS Nbr	Agency	Limit type	Additional comments
Limestone	1317-65-3	UK HSC	TWA(respirable):4 mg/m ³ ;TWA(as respirable dust):4 mg/m ³ ;TWA(Inhalable):10 mg/m ³ ;TWA(as inhalable dust):10 mg/m ³	
Quartz	14808-60-7	UK HSC	TWA(respirable):0.1 mg/m ³	

UK HSC : UK Health and Safety Commission

TWA: Time-Weighted-Average

STEL: Short Term Exposure Limit

CEIL: Ceiling

Biological limit values

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

8.2. Exposure controls

8.2.1. Engineering controls

Use in a well-ventilated area.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

Select and use eye/face protection to prevent contact based on the results of an exposure assessment. The following eye/face protection(s) are recommended:
Safety glasses with side shields.

Applicable Norms/Standards

Use eye protection conforming to EN 166

Skin/hand protection

See Section 7.1 for additional information on skin protection.

Respiratory protection

None required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid.
Specific Physical Form:	Putty
Colour	Light Brown, Off-White
Odor	Slight Odor, Characteristic Odour
Melting point/freezing point	<i>No data available.</i>
Boiling point/boiling range	<i>Not applicable.</i>
Flammability (solid, gas)	Not classified
Flammable Limits(LEL)	<i>Not applicable.</i>

Flammable Limits(UEL)	<i>Not applicable.</i>
Flash point	<i>Not applicable.</i>
Autoignition temperature	<i>No data available.</i>
Relative density	2.5 [Ref Std:WATER=1]
pH	<i>substance/mixture is non-soluble (in water)</i>
Kinematic Viscosity	<i>Not applicable.</i>
Water solubility	Nil
Density	2.5 g/cm3

9.2. Other information

9.2.2 Other safety characteristics

EU Volatile Organic Compounds	<i>No data available.</i>
Evaporation rate	<i>Not applicable.</i>
Molecular weight	<i>No data available.</i>
Percent volatile	<i>No data available.</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

<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 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 hazard classes as defined in the retained CLP Regulation (EU) No 1272/2008, as amended for Great Britain.

Signs and Symptoms of Exposure

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation

This product may have a characteristic odour; however, no adverse health effects are anticipated.

Skin contact

Contact with the skin during product use is not expected to result in significant irritation.

Eye contact

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

Ingestion

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

Additional Health Effects:**Carcinogenicity:**

Exposures needed to cause the following health effect(s) are not expected during normal, intended use:

Contains a chemical or chemicals which can cause cancer.

Toxicological Data

If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

Acute Toxicity

Name	Route	Species	Value
Overall product	Ingestion		No data available; calculated ATE >5,000 mg/kg
Limestone	Dermal	Rat	LD50 > 2,000 mg/kg
Limestone	Inhalation-Dust/Mist (4 hours)	Rat	LC50 3 mg/l
Limestone	Ingestion	Rat	LD50 6,450 mg/kg
Quartz	Dermal		LD50 estimated to be > 5,000 mg/kg
Quartz	Ingestion		LD50 estimated to be > 5,000 mg/kg
Vinyl siloxane	Dermal	Rabbit	LD50 > 15,440 mg/kg
Vinyl siloxane	Ingestion	Rat	LD50 > 15,440 mg/kg
Mineral oil	Dermal	Rabbit	LD50 > 2,000 mg/kg
Mineral oil	Ingestion	Rat	LD50 > 5,000 mg/kg
Octamethylcyclotetrasiloxane	Dermal	Rat	LD50 > 2,400 mg/kg
Octamethylcyclotetrasiloxane	Inhalation-Dust/Mist (4 hours)	Rat	LC50 36 mg/l
Octamethylcyclotetrasiloxane	Ingestion	Rat	LD50 > 5,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Limestone	Rabbit	No significant irritation
Quartz	Professional judgement	No significant irritation
Vinyl siloxane	Rabbit	No significant irritation
Mineral oil	Rabbit	No significant irritation
Octamethylcyclotetrasiloxane	Rabbit	Minimal irritation

Serious Eye Damage/Irritation

Name	Species	Value
Limestone	Rabbit	No significant irritation
Vinyl siloxane	Rabbit	Mild irritant
Mineral oil	Rabbit	Mild irritant
Octamethylcyclotetrasiloxane	Rabbit	No significant irritation

Skin Sensitisation

Name	Species	Value
Mineral oil	Guinea pig	Not classified
Octamethylcyclotetrasiloxane	Human and animal	Not classified

Respiratory Sensitisation

For the component/components, either no data is currently available or the data is not sufficient for classification.

Germ Cell Mutagenicity

Name	Route	Value
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
Mineral oil	In Vitro	Not mutagenic
Octamethylcyclotetrasiloxane	In Vitro	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
Quartz	Inhalation	Human and animal	Carcinogenic.
Mineral oil	Dermal	Mouse	Not carcinogenic
Mineral oil	Inhalation	Multiple animal species	Not carcinogenic

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
Limestone	Ingestion	Not classified for development	Rat	NOAEL 625 mg/kg/day	premating & during gestation
Mineral oil	Ingestion	Not classified for female reproduction	Rat	NOAEL 4,350 mg/kg/day	13 weeks
Mineral oil	Ingestion	Not classified for male reproduction	Rat	NOAEL 4,350 mg/kg/day	13 weeks
Mineral oil	Ingestion	Not classified for development	Rat	NOAEL 4,350 mg/kg/day	during gestation
Octamethylcyclotetrasiloxane	Inhalation	Not classified for male reproduction	Rat	NOAEL 8.5 mg/l	2 generation
Octamethylcyclotetrasiloxane	Ingestion	Toxic to female reproduction	Rabbit	NOAEL 50 mg/kg/day	during organogenesis
Octamethylcyclotetrasiloxane	Inhalation	Toxic to female reproduction	Rat	NOAEL 3.6 mg/l	2 generation

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Limestone	Inhalation	respiratory system	Not classified	Rat	NOAEL 0.812 mg/l	90 minutes

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Limestone	Inhalation	respiratory system	Not classified	Human	NOAEL Not available	occupational exposure
Quartz	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
Mineral oil	Ingestion	hematopoietic system	Not classified	Rat	NOAEL 1,381 mg/kg/day	90 days
Mineral oil	Ingestion	liver immune system	Not classified	Rat	NOAEL 1,336 mg/kg/day	90 days

Octamethylcyclotetrasiloxane	Dermal	hematopoietic system	Not classified	Rabbit	NOAEL 960 mg/kg/day	3 weeks
Octamethylcyclotetrasiloxane	Inhalation	liver	Not classified	Rat	NOAEL 8.5 mg/l	13 weeks
Octamethylcyclotetrasiloxane	Inhalation	endocrine system immune system kidney and/or bladder	Not classified	Rat	NOAEL 8.5 mg/l	2 generation
Octamethylcyclotetrasiloxane	Inhalation	hematopoietic system	Not classified	Rat	NOAEL 8.5 mg/l	13 weeks
Octamethylcyclotetrasiloxane	Ingestion	liver	Not classified	Rat	NOAEL 1,600 mg/kg/day	2 weeks

Aspiration Hazard

Name	Value
Mineral oil	Aspiration hazard

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.

11.2. Information on other hazards

This material does not contain any substances that are assessed to be an endocrine disruptor for human health.

SECTION 12: Ecological information

The information below may not agree with the 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
Limestone	1317-65-3	Green algae	Estimated	72 hours	EC50	>100 mg/l
Limestone	1317-65-3	Rainbow trout	Estimated	96 hours	LC50	>100 mg/l
Limestone	1317-65-3	Water flea	Estimated	48 hours	EC50	>100 mg/l
Limestone	1317-65-3	Green algae	Estimated	72 hours	EC10	>100 mg/l
Quartz	14808-60-7	Green algae	Estimated	72 hours	EC50	440 mg/l
Quartz	14808-60-7	Water flea	Estimated	48 hours	EC50	7,600 mg/l
Quartz	14808-60-7	Zebra Fish	Estimated	96 hours	LC50	5,000 mg/l
Quartz	14808-60-7	Green algae	Estimated	72 hours	NOEC	60 mg/l
Vinyl siloxane	68083-19-2	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Mineral oil	8042-47-5	Water flea	Analogous Compound	48 hours	EL50	>100 mg/l
Mineral oil	8042-47-5	Bluegill	Experimental	96 hours	LL50	>100 mg/l
Mineral oil	8042-47-5	Green algae	Analogous Compound	72 hours	NOEL	100 mg/l
Mineral oil	8042-47-5	Water flea	Analogous Compound	21 days	NOEL	>100 mg/l
Methyl Hydrogen Silicone Fluid	Trade Secret	N/A	Data not available or insufficient for classification	N/A	N/A	N/A

Octamethylcyclotetrasiloxane	556-67-2	Blackworm	Experimental	28 days	NOEC	0.73 mg/kg (Dry Weight)
Octamethylcyclotetrasiloxane	556-67-2	Midge	Experimental	14 days	LC50	>170 mg/kg (Dry Weight)
Octamethylcyclotetrasiloxane	556-67-2	Mysid Shrimp	Experimental	96 hours	LC50	>0.0091 mg/l
Octamethylcyclotetrasiloxane	556-67-2	Rainbow trout	Experimental	96 hours	LC50	>0.022 mg/l
Octamethylcyclotetrasiloxane	556-67-2	Water flea	Experimental	48 hours	EC50	>0.015 mg/l
Octamethylcyclotetrasiloxane	556-67-2	Rainbow trout	Experimental	93 days	NOEC	0.0044 mg/l
Octamethylcyclotetrasiloxane	556-67-2	Water flea	Experimental	21 days	NOEC	0.015 mg/l
Octamethylcyclotetrasiloxane	556-67-2	Activated sludge	Experimental	3 hours	EC50	>10,000 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Limestone	1317-65-3	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Quartz	14808-60-7	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Vinyl siloxane	68083-19-2	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Mineral oil	8042-47-5	Experimental Biodegradation	28 days	CO2 evolution	0 %CO2 evolution/THCO2 evolution	OECD 301B - Modified sturm or CO2
Methyl Hydrogen Silicone Fluid	Trade Secret	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Octamethylcyclotetrasiloxane	556-67-2	Experimental Biodegradation	29 days	CO2 evolution	3.7 %CO2 evolution/THCO2 evolution	OECD 310 CO2 Headspace
Octamethylcyclotetrasiloxane	556-67-2	Experimental Photolysis		Photolytic half-life (in air)	31 days (t 1/2)	
Octamethylcyclotetrasiloxane	556-67-2	Experimental Hydrolysis		Hydrolytic half-life (pH 7)	69.3-144 hours (t 1/2)	OECD 111 Hydrolysis func of pH

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Limestone	1317-65-3	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
Vinyl siloxane	68083-19-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Mineral oil	8042-47-5	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Methyl Hydrogen Silicone Fluid	Trade Secret	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Octamethylcyclotetrasiloxane	556-67-2	Experimental BCF - Fish	28 days	Bioaccumulation factor	12400	40CFR 797.1520-Fish Bioaccumm
Octamethylcyclotetrasiloxane	556-67-2	Experimental Bioconcentration		Log Kow	6.49	OECD 123 log Kow slow stir

12.4. Mobility in soil

Material	Cas No.	Test type	Study Type	Test result	Protocol
Octamethylcyclotetrasiloxane	556-67-2	Experimental Mobility in Soil	Koc	16,600 l/kg	OECD 106 Adsp-Desb Batch Equil

12.5. Results of the PBT and vPvB assessment

Ingredient	CAS Nbr	PBT/vPvB status
Octamethylcyclotetrasiloxane	556-67-2	Meets UK REACH PBT criteria
Octamethylcyclotetrasiloxane	556-67-2	Meets UK REACH vPvB criteria

12.6. Other adverse effects

This material does not contain any substances that are assessed to be an endocrine disruptor for environmental effects

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose of contents/ container in accordance with the local/regional/national/international regulations.

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

EU waste code (product as sold)

180107 Chemicals other than those mentioned in 18 01 06

SECTION 14: Transportation information

Not hazardous for transportation.

	Ground Transport (ADR)	Air Transport (IATA)	Marine Transport (IMDG)
14.1 UN number	No data available.	No data available.	No data available.
14.2 UN proper shipping name	No data available.	No data available.	No data available.
14.3 Transport hazard class(es)	No data available.	No data available.	No data available.
14.4 Packing group	No data available.	No data available.	No data available.
14.5 Environmental hazards	No data available.	No data available.	No data available.
14.6 Special precautions for user	Please refer to the other sections of the SDS for further information.	Please refer to the other sections of the SDS for further information.	Please refer to the other sections of the SDS for further information.
14.7 Transport in bulk according to Annex II of Marpol 73/78 and IBC Code	No data available.	No data available.	No data available.
Control Temperature	No data available.	No data available.	No data available.
Emergency Temperature	No data available.	No data available.	No data available.
ADR Classification Code	No data available.	No data available.	No data available.
IMDG Segregation	No data available.	No data available.	No data available.

Code			
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Please contact the address or phone number listed on the first page of the SDS for additional information on the transport/shipment of the material by rail (RID) or inland waterways (ADN).

SECTION 15: Regulatory information

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

Carcinogenicity

Contact the manufacturer for more information

Global inventory status

Contact the manufacturer for more information

SECTION 16: Other information

List of relevant H statements

H226	Flammable liquid and vapour.
H304	May be fatal if swallowed and enters airways.
H361f	Suspected of damaging fertility.
H372	Causes damage to organs through prolonged or repeated exposure.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful 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 Safety Information Sheets for Great Britain are available at www.3M.com/uk