



## Safety Information Sheet for Medical Devices

Copyright,2020, 3M Company All rights reserved. Copying and/or downloading of this information for the purpose of properly utilizing 3M products is allowed provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from 3M, and (2) neither the copy nor the original is resold or otherwise distributed with the intention of earning a profit thereon.

<b>Document group:</b>	18-4286-3	<b>Version number:</b>	2.00
<b>Revision date:</b>	27/07/2020	<b>Supersedes date:</b>	20/07/2020

**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

<b>Address:</b>	3M United Kingdom PLC, 3M Centre, Cain Road, Bracknell, Berkshire, RG12 8HT.
<b>Telephone:</b>	+44 (0)1344 858 000
<b>E Mail:</b>	tox.uk@mmm.com
<b>Website:</b>	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

Copyright,2020, 3M Company All rights reserved. Copying and/or downloading of this information for the purpose of properly utilizing 3M products is allowed provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from 3M, and (2) neither the copy nor the original is resold or otherwise distributed with the intention of earning a profit thereon.

<b>Document group:</b>	18-3613-9	<b>Version number:</b>	1.00
<b>Revision date:</b>	07/01/2020	<b>Supersedes date:</b>	Initial issue.
<b>Transportation version number:</b> 1.00 (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

<b>Address:</b>	3M United Kingdom PLC, 3M Centre, Cain Road, Bracknell, Berkshire, RG12 8HT.
<b>Telephone:</b>	+44 (0)1344 858 000
<b>E Mail:</b>	tox.uk@mmm.com
<b>Website:</b>	www.3M.com/uk

#### 1.4. Emergency telephone number

+44 (0)1344 858 000

### SECTION 2: Hazard identification

#### 2.1. Classification of the substance or mixture

CLP REGULATION (EC) No 1272/2008

This product is a medical device as defined in Directive 93/42/EEC (MDD) respectively Regulation (EU) 2017/745 (MDR), which is invasive or used in direct physical contact with the human body, and therefore is exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). Although not required, the classification and label information, as applicable, is provided below.

**CLASSIFICATION:**

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

## 2.2. Label elements

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

Not applicable

### Notes on labelling

H372 does not apply since no inhalation exposure.

## 2.3. Other hazards

For information on hazards and safe use, please consider the corresponding sections of this document.

## SECTION 3: Composition/information on ingredients

Ingredient	CAS Nbr	EC No.	% by Wt	Classification
Limestone	1317-65-3	215-279-6	20 - 40	Substance with a Community level exposure limit in the workplace
Quartz	14808-60-7	238-878-4	30 - 40	STOT RE 1, H372
Vinyl siloxanes	68083-19-2		15 - 25	Substance not classified as hazardous
Mineral oil	8042-47-5	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.

#### 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.

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

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****Appearance**

**Physical state**

Solid.

**Colour**

Off-White

**Specific Physical Form:**

Putty

**Odor**

Slight Odor, Characteristic Odour

**pH**

*Not applicable.*

**Boiling point/boiling range**

*Not applicable.*

**Melting point**

*No data available.*

**Flammability (solid, gas)**

Not classified

**Explosive properties**

Not classified

**Oxidising properties**

Not classified

**Flash point**

*Not applicable.*

**Autoignition temperature**

*No data available.*

**Flammable Limits(LEL)**

*Not applicable.*

**Flammable Limits(UEL)**

*Not applicable.*

**Relative density**

2.5 [Ref Std:WATER=1]

**Water solubility**

Nil

**Viscosity**

*Not applicable.*

**Density**

*No data available.*

**9.2. Other information**

**EU Volatile Organic Compounds**

*No data available.*

**Molecular weight**

*No data available.*

**Percent volatile**

*No data available.*

**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

<u>Substance</u>	<u>Condition</u>
None known.	

Refer to section 5.2 for hazardous decomposition products during combustion.

## SECTION 11: Toxicological information

The information below may not agree with the EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 11 are based on UN GHS calculation rules and classifications derived from 3M assessments.

### 11.1 Information on Toxicological effects

#### Signs and Symptoms of Exposure

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

#### Inhalation

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

#### Skin contact

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

#### 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	prematuring & 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.

## 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
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	Effect Concentration 10%	>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		Data not available or insufficient for classification			
Mineral oil	8042-47-5	Water flea	Estimated	48 hours	Effect Level 50%	>100 mg/l
Mineral oil	8042-47-5	Bluegill	Experimental	96 hours	Lethal Level 50%	>100 mg/l
Mineral oil	8042-47-5	Green algae	Estimated	72 hours	No obs Effect Level	>100 mg/l
Mineral oil	8042-47-5	Water flea	Estimated	21 days	No obs Effect Level	>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	
Quartz	14808-60-7	Data not availbl-insufficient			N/A	
Vinyl siloxanes	68083-19-2	Data not availbl-insufficient			N/A	
Mineral oil	8042-47-5	Experimental Biodegradation	28 days	CO2 evolution	0 % weight	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

Please contact manufacturer for more details

## 12.5. Results of the PBT and vPvB assessment

This material does not contain any substances that are assessed to be a PBT or vPvB

## 12.6. Other adverse effects

No information available.

# SECTION 13: Disposal considerations

## 13.1 Waste treatment methods

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

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

### EU waste code (product as sold)

180107 Chemicals other than those mentioned in 18 01 06

# SECTION 14: Transportation information

ADR/IMDG/IATA: Not restricted for transport.

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

Contact the manufacturer for more information

**Global inventory status**

Contact the manufacturer for more information

**SECTION 16: Other information****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:**

Revision information not available

The product to which this Safety Information Sheet applies is classified as a medical device according to the EU Medical Device Regulation EU 2017/745. \_x000D\_

Medical devices which are invasive or used in direct physical contact with the human body are exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). \_x000D\_

The EU Medical Device Regulation does not foresee the use of Safety Data sheets for medical devices which are invasive or used in direct physical contact with the human body, as the safe use of the product is described through the Instructions for Use and /or the labelling for the product. Nevertheless, the 3M Safety Information Sheet is provided as a further service to customers to provide additional toxicology and chemical information on the product. In case of further questions, please contact your 3M representative listed on the Safety Information Sheet.

**3M United Kingdom Safety Information Sheets are available at [www.3M.com/uk](http://www.3M.com/uk)**



## Safety Information Sheet for Medical Devices

Copyright,2020, 3M Company All rights reserved. Copying and/or downloading of this information for the purpose of properly utilizing 3M products is allowed provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from 3M, and (2) neither the copy nor the original is resold or otherwise distributed with the intention of earning a profit thereon.

<b>Document group:</b>	18-4188-1	<b>Version number:</b>	1.00
<b>Revision date:</b>	07/01/2020	<b>Supersedes date:</b>	Initial issue.
<b>Transportation version number:</b>	1.00 (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™ ESPE™ 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

<b>Address:</b>	3M United Kingdom PLC, 3M Centre, Cain Road, Bracknell, Berkshire, RG12 8HT.
<b>Telephone:</b>	+44 (0)1344 858 000
<b>E Mail:</b>	tox.uk@mmm.com
<b>Website:</b>	www.3M.com/uk

#### 1.4. Emergency telephone number

+44 (0)1344 858 000

### SECTION 2: Hazard identification

#### 2.1. Classification of the substance or mixture

CLP REGULATION (EC) No 1272/2008

This product is a medical device as defined in Directive 93/42/EEC (MDD) respectively Regulation (EU) 2017/745 (MDR), which is invasive or used in direct physical contact with the human body, and therefore is exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). Although not required, the classification and label information, as applicable, is provided below.

**CLASSIFICATION:**

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

## 2.2. Label elements

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

Not applicable

### Notes on labelling

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.

## SECTION 3: Composition/information on ingredients

Ingredient	CAS Nbr	EC No.	% by Wt	Classification
Limestone	1317-65-3	215-279-6	20 - 40	Substance with a Community level exposure limit in the workplace
Quartz	14808-60-7	238-878-4	30 - 40	STOT RE 1, H372
Vinyl siloxanes	68083-19-2		10 - 25	Substance not classified as hazardous
Mineral oil	8042-47-5	232-455-8	5 - 15	Asp. Tox. 1, H304
Methyl hydrogen fluid	Trade Secret		< 2	Substance not classified as hazardous

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

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

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

#### Inhalation

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

#### Skin contact

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

#### Eye contact

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

#### If swallowed

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

## SECTION 5: Fire-fighting measures

### 5.1. Extinguishing media

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

**5.2. Special hazards arising from the substance or mixture**

None inherent in this product.

**Hazardous Decomposition or By-Products****Substance**

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. 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.

<b>Ingredient</b>	<b>CAS Nbr</b>	<b>Agency</b>	<b>Limit type</b>	<b>Additional comments</b>
Limestone	1317-65-3	UK HSC	TWA(as inhalable dust):10 mg/m3;TWA(as respirable dust):4 mg/m3;TWA(Inhalable):10 mg/m3;TWA(respirable):4 mg/m3	
Quartz	14808-60-7	UK HSC	TWA(respirable):0.1 mg/m3	

UK HSC : UK Health and Safety Commission

TWA: Time-Weighted-Average

STEL: Short Term Exposure Limit

CEIL: Ceiling

**Biological limit values**

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

## 8.2. Exposure controls

### 8.2.1. Engineering controls

Use in a well-ventilated area.

### 8.2.2. Personal protective equipment (PPE)

#### Eye/face protection

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

#### Applicable Norms/Standards

Use eye protection conforming to EN 166

#### Skin/hand protection

See Section 7.1 for additional information on skin protection.

#### Respiratory protection

None required.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### Appearance

Physical state

Solid.

Colour

Light Brown, Off-White

Specific Physical Form:

Putty

Odor

Slight Odor, Characteristic Odour

pH

*Not applicable.*

Boiling point/boiling range

*Not applicable.*

Melting point

*No data available.*

Flammability (solid, gas)

Not classified

Explosive properties

Not classified

Oxidising properties

Not classified

Flash point

*Not applicable.*

Autoignition temperature

*No data available.*

Flammable Limits(LEL)

*Not applicable.*

Flammable Limits(UEL)

*Not applicable.*

Relative density

2.5 [Ref Std: WATER=1]

Water solubility

Nil

Viscosity

*Not applicable.*

Density

2.5 g/cm<sup>3</sup>

### 9.2. Other information

EU Volatile Organic Compounds

*No data available.*

Molecular weight

*No data available.*

Percent volatile

*No data available.*

## 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 EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 11 are based on UN GHS calculation rules and classifications derived from 3M assessments.

### 11.1 Information on Toxicological effects

#### Signs and Symptoms of Exposure

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

#### Inhalation

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

#### Skin contact

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

#### Eye contact

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

#### Ingestion

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

#### Additional Health Effects:

#### Carcinogenicity:

Exposures needed to cause the following health effect(s) are not expected during normal, intended use:  
Contains a chemical or chemicals which can cause cancer.



**Toxicological Data**

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

**Acute Toxicity**

Name	Route	Species	Value
Overall product	Ingestion		No data available; calculated ATE >5,000 mg/kg
Quartz	Dermal		LD50 estimated to be > 5,000 mg/kg
Quartz	Ingestion		LD50 estimated to be > 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
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	prematuring & 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.

**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
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	Effect Concentration 10%	>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		Data not available or insufficient for classification			
Mineral oil	8042-47-5	Water flea	Estimated	48 hours	Effect Level 50%	>100 mg/l
Mineral oil	8042-47-5	Bluegill	Experimental	96 hours	Lethal Level 50%	>100 mg/l
Mineral oil	8042-47-5	Green algae	Estimated	72 hours	No obs Effect Level	>100 mg/l
Mineral oil	8042-47-5	Water flea	Estimated	21 days	No obs Effect Level	>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	
Quartz	14808-60-7	Data not availbl-insufficient			N/A	
Vinyl siloxanes	68083-19-2	Data not availbl-insufficient			N/A	
Mineral oil	8042-47-5	Experimental Biodegradation	28 days	CO2 evolution	0 % weight	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

Please contact manufacturer for more details

## 12.5. Results of the PBT and vPvB assessment

This material does not contain any substances that are assessed to be a PBT or vPvB

## 12.6. Other adverse effects

No information available.

# SECTION 13: Disposal considerations

## 13.1 Waste treatment methods

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

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

**EU waste code (product as sold)**

180107 Chemicals other than those mentioned in 18 01 06

**SECTION 14: Transportation information**

ADR/IMDG/IATA: Not restricted for transport.

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

Contact the manufacturer for more information

**Global inventory status**

Contact the manufacturer for more information

**SECTION 16: Other information****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:**

Revision information not available

The product to which this Safety Information Sheet applies is classified as a medical device according to the EU Medical Device Regulation EU 2017/745. \_x000D\_ Medical devices which are invasive or used in direct physical contact with the human body are exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). \_x000D\_ The EU Medical Device Regulation does not foresee the use of Safety Data sheets for medical devices which are invasive or used in direct physical contact with the human body, as the safe use of the product is described through the Instructions for Use and /or the labelling for the product. Nevertheless, the 3M Safety Information Sheet is provided as a further service to customers to provide additional toxicology and chemical information on the product. In case of further questions, please contact your 3M representative listed on the Safety Information Sheet.

**3M United Kingdom Safety Information Sheets are available at [www.3M.com/uk](http://www.3M.com/uk)**