



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.

Document group:	18-9356-9	Version number:	2.00
Revision date:	27/07/2020	Supersedes date:	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™ Vinyl Polysiloxane Impression Material Regular Body (7322)

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:

18-4003-2, 18-4009-9

TRANSPORTATION INFORMATION

ADR/IATA/IMDG: Not restricted for transport.

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.

Document group:	18-4003-2	Version number:	1.00
Revision date:	23/04/2020	Supersedes date:	Initial issue.
Transportation version number: 1.00 (23/04/2020)			

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

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

1.1. Product identifier

3M™ Express™ Regular Body Wash Base

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

Identified uses

Medical device; refer to Instructions for Use

Restrictions on Use

For use only by dental professionals

1.3 Details of the supplier of the safety information sheet for medical devices

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

1.4. Emergency telephone number

+44 (0)1344 858 000

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

CLP REGULATION (EC) No 1272/2008

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

CLASSIFICATION:

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

For full text of H phrases, see Section 16.

2.2. Label elements**CLP REGULATION (EC) No 1272/2008****HAZARD STATEMENTS:**

H412 Harmful to aquatic life with long lasting effects.

PRECAUTIONARY STATEMENTS**Disposal:**

P501 Dispose of contents/container in accordance with applicable local/regional/national/international regulations.

Notes on labelling

H372 does not apply. Material is a paste, 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
Quartz	14808-60-7	238-878-4	45 - 55	STOT RE 1, H372
Vinyl siloxanes	68083-19-2		25 - 35	Substance not classified as hazardous
Hydrogen silicone	68037-59-2		1 - 10	Substance not classified as hazardous
Silane treated silica	67762-90-7		1 - 10	Substance with an occupational exposure limit
Pigment	1345-16-0	310-193-6	< 5	Substance with an occupational exposure limit
Silicon oil	63148-62-9		< 5	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.

Ingredient	CAS Nbr	Agency	Limit type	Additional comments
Cobalt compounds	1345-16-0	UK HSC	TWA(as Co):0.1 mg/m ³	Respiratory Sensitizer
Quartz	14808-60-7	UK HSC	TWA(respirable):0.1 mg/m ³	

Silicon dioxide 67762-90-7 UK HSC TWA(as inhalable dust):6 mg/m³;TWA(as respirable dust):2.4 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

Purple

Specific Physical Form:

Paste

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

Flash point > 93 °C (200 °F)

Autoignition temperature

Not applicable.

Flammable Limits(LEL)

Not applicable.

Flammable Limits(UEL)

Not applicable.

Relative density

1.45 [Ref Std: WATER=1]

Water solubility

Nil

Viscosity

130,000 - 200,000 mPa-s

Density 1.4 - 1.5 g/cm³

9.2. Other information

EU Volatile Organic Compounds	<i>No data available.</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

None known.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

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

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

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

11.1 Information on Toxicological effects

Signs and Symptoms of Exposure

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

Inhalation

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

Skin contact

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

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
Vinyl siloxanes	Dermal	Rabbit	LD50 > 15,440 mg/kg
Vinyl siloxanes	Ingestion	Rat	LD50 > 15,440 mg/kg
Hydrogen silicone	Dermal	Rabbit	LD50 > 2,000 mg/kg
Hydrogen silicone	Ingestion	Rat	LD50 > 2,000 mg/kg
Silane treated silica	Dermal	Rabbit	LD50 > 5,000 mg/kg
Silane treated silica	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Silane treated silica	Ingestion	Rat	LD50 > 5,110 mg/kg
Silicon oil	Dermal	Rabbit	LD50 > 19,400 mg/kg
Silicon oil	Ingestion	Rat	LD50 > 17,000 mg/kg
Pigment	Dermal		LD50 estimated to be > 5,000 mg/kg
Pigment	Ingestion	Rat	LD50 > 10,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Quartz	Professional judgement	No significant irritation
Vinyl siloxanes	Rabbit	No significant irritation
Hydrogen silicone	Rabbit	No significant irritation
Silane treated silica	Rabbit	No significant irritation
Silicon oil	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Vinyl siloxanes	Rabbit	Mild irritant
Hydrogen silicone	Rabbit	Mild irritant
Silane treated silica	Rabbit	No significant irritation
Silicon oil	Rabbit	No significant irritation

Skin Sensitisation

Name	Species	Value
Hydrogen silicone	Guinea pig	Not classified
Silane treated silica	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
Hydrogen silicone	In Vitro	Not mutagenic
Silane treated silica	In Vitro	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
Quartz	Inhalation	Human and animal	Carcinogenic.
Silane treated silica	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
Silane treated silica	Ingestion	Not classified for female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
Silane treated silica	Ingestion	Not classified for male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Silane treated silica	Ingestion	Not classified for development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis

Target Organ(s)

Specific Target Organ Toxicity - single exposure

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

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Quartz	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
Silane treated silica	Inhalation	respiratory system silicosis	Not classified	Human	NOAEL Not available	occupational exposure

Aspiration Hazard

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

Please contact the address or phone number listed on the first page of the SIS for additional toxicological information on this material and/or its components.

The product was evaluated by a toxicologist to be safe for its intended use.

SECTION 12: Ecological information

The information below may not agree with the EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 12 are based on UN GHS calculation rules and classifications derived from 3M assessments.

12.1. Toxicity

No product test data available.

Material	CAS #	Organism	Type	Exposure	Test endpoint	Test result
Quartz	14808-60-7	Green Algae	Estimated	72 hours	EC50	440 mg/l
Quartz	14808-60-7	Zebra Fish	Estimated	96 hours	LC50	5,000 mg/l
Quartz	14808-60-7	Water flea	Estimated	48 hours	EC50	7,600 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			
Hydrogen silicone	68037-59-2		Data not available or insufficient for classification			
Silane treated silica	67762-90-7		Data not available or insufficient for classification			
Silicon oil	63148-62-9		Data not available or insufficient for classification			

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Quartz	14808-60-7	Data not availbl-insufficient			N/A	
Vinyl siloxanes	68083-19-2	Data not availbl-insufficient			N/A	
Hydrogen silicone	68037-59-2	Data not availbl-insufficient			N/A	
Silane treated silica	67762-90-7	Data not availbl-insufficient			N/A	
Pigment	1345-16-0	Data not availbl-insufficient			N/A	
Silicon oil	63148-62-9	Data not availbl-insufficient			N/A	

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
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
Hydrogen silicone	68037-59-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silane treated silica	67762-90-7	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Pigment	1345-16-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silicon oil	63148-62-9	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)

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/IATA/IMDG: 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**

H372 Causes damage to organs through prolonged or repeated exposure.
H412 Harmful to aquatic life with long lasting effects.

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



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.

Document group:	18-4009-9	Version number:	1.00
Revision date:	23/04/2020	Supersedes date:	Initial issue.
Transportation version number: 1.00 (23/04/2020)			

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

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

1.1. Product identifier

3M™ Express™ Regular Body Wash Catalyst

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

Identified uses

Medical device; refer to Instructions for Use

Restrictions on Use

For use only by dental professionals

1.3 Details of the supplier of the safety information sheet for medical devices

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

1.4. Emergency telephone number

+44 (0)1344 858 000

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

CLP REGULATION (EC) No 1272/2008

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

CLASSIFICATION:

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 paste, 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
Quartz	14808-60-7	238-878-4	50 - 60	STOT RE 1, H372
Vinyl siloxanes	68083-19-2		40 - 50	Substance not classified as hazardous
Silane treated silica	67762-90-7		1 - 5	Substance with an occupational exposure limit
Pigment	1345-16-0	310-193-6	< 0.5	Substance with an occupational exposure limit

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.

Ingredient	CAS Nbr	Agency	Limit type	Additional comments
Cobalt compounds	1345-16-0	UK HSC	TWA(as Co):0.1 mg/m ³	Respiratory Sensitizer
Quartz	14808-60-7	UK HSC	TWA(respirable):0.1 mg/m ³	
Silicon dioxide	67762-90-7	UK HSC	TWA(as inhalable dust):6 mg/m ³ ;TWA(as respirable dust):2.4 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**

Appearance	
Physical state	Solid.
Colour	Purple
Specific Physical Form:	Paste
Odor	Characteristic Odour
pH	<i>Not applicable.</i>
Boiling point/boiling range	<i>Not applicable.</i>
Melting point	<i>No data available.</i>
Flammability (solid, gas)	Not classified
Explosive properties	Not classified
Oxidising properties	Not classified
Flash point	Flash point > 93 °C (200 °F)
Autoignition temperature	<i>No data available.</i>
Flammable Limits(LEL)	<i>Not applicable.</i>
Flammable Limits(UEL)	<i>Not applicable.</i>
Relative density	1.45 [Ref Std: WATER=1]
Water solubility	Nil
Viscosity	<i>No data available.</i>
Density	1.4 - 1.5 g/cm ³

9.2. Other information

EU Volatile Organic Compounds	<i>No data available.</i>
Molecular weight	<i>No data available.</i>
Percent volatile	<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

None known.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

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

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

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

11.1 Information on Toxicological effects**Signs and Symptoms of Exposure**

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

Inhalation

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

Skin contact

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

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
Vinyl siloxanes	Dermal	Rabbit	LD50 > 15,440 mg/kg
Vinyl siloxanes	Ingestion	Rat	LD50 > 15,440 mg/kg
Silane treated silica	Dermal	Rabbit	LD50 > 5,000 mg/kg
Silane treated silica	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Silane treated silica	Ingestion	Rat	LD50 > 5,110 mg/kg
Pigment	Dermal		LD50 estimated to be > 5,000 mg/kg
Pigment	Ingestion	Rat	LD50 > 10,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Quartz	Professional judgement	No significant irritation
Vinyl siloxanes	Rabbit	No significant irritation
Silane treated silica	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Vinyl siloxanes	Rabbit	Mild irritant
Silane treated silica	Rabbit	No significant irritation

Skin Sensitisation

Name	Species	Value
Silane treated silica	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
Silane treated silica	In Vitro	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
Quartz	Inhalation	Human and animal	Carcinogenic.
Silane treated silica	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
Silane treated silica	Ingestion	Not classified for female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
Silane treated silica	Ingestion	Not classified for male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Silane treated silica	Ingestion	Not classified for development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis

Target Organ(s)

Specific Target Organ Toxicity - single exposure

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

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Quartz	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
Silane treated silica	Inhalation	respiratory system silicosis	Not classified	Human	NOAEL Not available	occupational exposure

Aspiration Hazard

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

Please contact the address or phone number listed on the first page of the SIS for additional toxicological information on this material and/or its components.

The product was evaluated by a toxicologist to be safe for its intended use.

SECTION 12: Ecological information

The information below may not agree with the EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 12 are based on UN GHS calculation rules and classifications derived from 3M assessments.

12.1. Toxicity

No product test data available.

Material	CAS #	Organism	Type	Exposure	Test endpoint	Test result
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			
Silane treated silica	67762-90-7		Data not available or insufficient for classification			

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Quartz	14808-60-7	Data not availbl-insufficient			N/A	
Vinyl siloxanes	68083-19-2	Data not availbl-insufficient			N/A	
Silane treated silica	67762-90-7	Data not availbl-insufficient			N/A	
Pigment	1345-16-0	Data not availbl-insufficient			N/A	

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
----------	---------	-----------	----------	------------	-------------	----------

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
Silane treated silica	67762-90-7	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Pigment	1345-16-0	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

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

12.6. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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

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

EU waste code (product as sold)

180106* Chemicals consisting of or containing dangerous substances.

EU waste code (product container after use)

180107 Chemicals other than those mentioned in 18 01 06

SECTION 14: Transportation information

ADR/IATA/IMDG: 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

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