Safety Information Sheet for Medical Devices

Document group:	16-2740-5	**Version number:**	3.00
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Transportation version number: 1.00 (06/05/2020)

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™ Impregum™ Penta™ Soft Base Paste

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:
Skin Sensitization, Category 1A - Skin Sens. 1A; H317
Hazardous to the Aquatic Environment (Acute), Category 1 - Aquatic Acute 1; H400
Hazardous to the Aquatic Environment (Chronic), Category 2 - Aquatic Chronic 2; H411

For full text of H phrases, see Section 16.

2.2. Label elements
CLP REGULATION (EC) No 1272/2008

SIGNAL WORD
WARNING.

Symbols:
GHS07 (Exclamation mark) |GHS09 (Environment) |

Pictograms

Ingredients:

Ingredient	CAS Nbr	EC No.	% by Wt
Laurylimidazole	4303-67-7	224-314-4	< 1
Mint flavor	68917-18-0		< 0.5
Mint flavor	98561-44-5	308-804-6	< 0.5

HAZARD STATEMENTS:

H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.

PRECAUTIONARY STATEMENTS

Prevention:

P280E	Wear protective gloves.
P273	Avoid release to the environment.

Response:

P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.

Disposal:

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

Notes on labelling

H319 not assigned per test data.

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
Polyether	110531-92-5		40 - 60	Eye Irrit. 2, H319
Fatty acids ester	67701-27-3	266-945-8	10 - 30	Substance not classified as hazardous
Polyether acetate	91825-26-2		1 - 20	Substance not classified as hazardous
Aromatic hydrocarbon	26898-17-9	248-097-0	1 - 10	Aquatic Chronic 1, H410,M=1
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	68855-54-9	272-489-0	< 10	STOT RE 2, H373
Laurylimidazole (REACH Reg. No.:01-2120068170-65)	4303-67-7	224-314-4	< 1	Aquatic Acute 1, H400,M=100; Aquatic Chronic 1, H410,M=10 Acute Tox. 4, H302; Eye Irrit. 2, H319; Skin Sens. 1A, H317
Mint flavor	98561-44-5	308-804-6	< 0.5	Asp. Tox. 1, H304; Skin Irrit. 2, H315; Skin Sens. 1, H317
Mint flavor	68917-18-0		< 0.5	Acute Tox. 4, H302; Eye Irrit. 2, H319; Skin Sens. 1B, H317

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
Immediately wash with soap and water. Remove contaminated clothing and wash before reuse. If signs/symptoms develop, get medical attention.

Eye contact
No need for first aid is anticipated.

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	Condition
Carbon monoxide	During combustion.
Carbon dioxide.	During combustion.
Irritant vapours or gases.	During combustion.

5.3. Advice for fire-fighters

Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Evacuate area. Ventilate the area with fresh air. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapours, in accordance with good industrial hygiene practice. Refer to other sections of this 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
Silicon dioxide	68855-54-9	UK HSC	TWA(as respirable dust):2.4 mg/m3;TWA(as inhalable dust):6 mg/m3	
Quartz	68855-54-9	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	Multicolor
Specific Physical Form:	Paste
Odor	Minty
pH	*No data available.*
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	*No data available.*
Flammable Limits(LEL)	*Not applicable.*
Flammable Limits(UEL)	*Not applicable.*
Relative density	1 - 1.2 [*Ref Std:*WATER=1]
Water solubility	Nil
Viscosity	*No data available.*
Density	*No data available.*

9.2. Other information

EU Volatile Organic Compounds	*No data available.*
Percent volatile	*Not applicable.*

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
Strong acids.
Strong bases.
Strong oxidising agents.

10.6 Hazardous decomposition products

Substance	Condition
None known.	

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

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

11.1 Information on Toxicological effects

Signs and Symptoms of Exposure

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

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

Skin contact
Allergic skin reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, and itching.

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

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

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	Dermal		No data available; calculated ATE >5,000 mg/kg
Overall product	Ingestion		No data available; calculated ATE >5,000 mg/kg
Polyether	Dermal	Professional judgement	LD50 Not applicable
Polyether	Ingestion	Rat	LD50 > 2,000 mg/kg
Fatty acids ester	Dermal	Rabbit	LD50 > 2,000 mg/kg
Fatty acids ester	Ingestion	Rat	LD50 > 2,000 mg/kg
Polyether acetate	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Polyether acetate	Ingestion	Rat	LD50 > 2,000 mg/kg
Aromatic hydrocarbon	Dermal	Rabbit	LD50 > 2,000 mg/kg
Aromatic hydrocarbon	Ingestion	Rat	LD50 > 10,360 mg/kg
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Diatomaceous earth (respirable	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 2.7 mg/l

cristobalite fraction 1-<10%)			
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Ingestion	Rat	LD50 > 2,000 mg/kg
Laurylimidazole	Ingestion	Rat	LD50 641 mg/kg
Mint flavor	Dermal	Rabbit	LD50 > 5,000 mg/kg
Mint flavor	Ingestion	Rat	LD50 1,240 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Polyether	Rabbit	No significant irritation
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	In vitro data	No significant irritation
Laurylimidazole	Rabbit	Mild irritant
Mint flavor	Rabbit	Mild irritant
Mint flavor	Not available	Irritant

Serious Eye Damage/Irritation

Name	Species	Value
Overall product	In vitro data	No significant irritation
Polyether	Rabbit	Moderate irritant
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Rabbit	Mild irritant
Laurylimidazole	In vitro data	Severe irritant
Mint flavor	In vitro data	Severe irritant

Skin Sensitisation

Name	Species	Value
Polyether	Guinea pig	Not classified
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Mouse	Not classified
Laurylimidazole	Mouse	Sensitising
Mint flavor	Not available	Sensitising
Mint flavor	Guinea pig	Sensitising

Respiratory Sensitisation

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

Germ Cell Mutagenicity

Name	Route	Value
Polyether	In Vitro	Not mutagenic
Polyether acetate	In Vitro	Not mutagenic
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	In Vitro	Some positive data exist, but the data are not sufficient for classification
Laurylimidazole	In Vitro	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Inhalation	Human and animal	Carcinogenic.

Reproductive Toxicity

Reproductive and/or Developmental Effects

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

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
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Ingestion	hematopoietic system | eyes | kidney and/or bladder	Not classified	Rat	NOAEL 3,738 mg/kg/day	90 days

Aspiration Hazard

Name	Value
Mint flavor	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
Polyether	110531-92-5		Data not available or insufficient for classification			
Fatty acids ester	67701-27-3	Green algae	Estimated	72 hours	EC50	>100 mg/l
Fatty acids ester	67701-27-3	Water flea	Estimated	48 hours	EC50	>100 mg/l
Fatty acids ester	67701-27-3	Zebra Fish	Estimated	96 hours	LC50	>100 mg/l
Fatty acids ester	67701-27-3	Green algae	Estimated	72 hours	NOEC	>100 mg/l
Fatty acids ester	67701-27-3	Water flea	Estimated	21 days	NOEC	>100 mg/l
Polyether acetate	91825-26-2		Data not available or insufficient for classification			
Aromatic hydrocarbon	26898-17-9	Water flea	Experimental	48 hours	EC50	>100 mg/l
Aromatic hydrocarbon	26898-17-9	Zebra Fish	Experimental	96 hours	Lethal Level 50%	>100 mg/l
Aromatic hydrocarbon	26898-17-9	Diatom	Experimental	72 hours	NOEC	>100 mg/l
Aromatic hydrocarbon	26898-17-9	Water flea	Experimental	21 days	NOEC	0.03 mg/l
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	68855-54-9		Data not available or insufficient for classification			
Laurylimidazole	4303-67-7	Green Algae	Experimental	72 hours	EC50	0.00557 mg/l

Laurylimidazole	4303-67-7	Water flea	Experimental	48 hours	EC50	>100 mg/l
Laurylimidazole	4303-67-7	Green algae	Experimental	72 hours	Effect Concentration 10%	0.0021 mg/l
Mint flavor	68917-18-0		Data not available or insufficient for classification			
Mint flavor	98561-44-5		Data not available or insufficient for classification			

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Polyether	110531-92-5	Data not availbl-insufficient			N/A	
Fatty acids ester	67701-27-3	Estimated Biodegradation	28 days	BOD	79 % BOD/ThBOD	OECD 301F - Manometric respirometry
Polyether acetate	91825-26-2	Data not availbl-insufficient			N/A	
Aromatic hydrocarbon	26898-17-9	Experimental Biodegradation	28 days	BOD	0 % BOD/ThBOD	OECD 301C - MITI test (I)
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	68855-54-9	Data not availbl-insufficient			N/A	
Laurylimidazole	4303-67-7	Experimental Biodegradation	28 days	CO2 evolution	2-3 % weight	OECD 301B - Modified sturm or CO2
Mint flavor	98561-44-5	Data not availbl-insufficient			N/A	
Mint flavor	68917-18-0	Data not availbl-insufficient			N/A	

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Polyether	110531-92-5	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Fatty acids ester	67701-27-3	Estimated Bioconcentration		Bioaccumulation factor	7.4	Other methods
Polyether acetate	91825-26-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Aromatic hydrocarbon	26898-17-9	Experimental BCF-Carp	60 days	Bioaccumulation factor	23000	OECD 305E - Bioaccumulation flow-through fish test
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	68855-54-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Laurylimidazole	4303-67-7	Estimated Bioconcentration		Bioaccumulation factor	3090	Estimated: Bioconcentration factor
Mint flavor	98561-44-5	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Mint flavor	68917-18-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

12.4. Mobility in soil

Please contact manufacturer for more details

12.5. Results of the PBT and vPvB assessment

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.

SECTION 14: Transportation information

IMDG: UN3077; Environmentally Hazardous Substance, Solid, N.O.S (Laurylimidazole, Aromatic hydrocarbon); 9; III; EMS: FA, SF; Marine Pollutant: Laurylimidazole, Aromatic hydrocarbon. (ENG)
Exemption: For vessels containing a net quantity of 5 l or a net mass of 5 kg or less per single or inner packaging , special provision 375 (ADR), exemption per 2.10.2.7 (IMDG) or special provision A197 (IATA) may be applied, if applicable
ADR: UN3077; Environmentally Hazardous Substance, Solid, N.O.S (Laurylimidazole, Aromatic hydrocarbon); 9; III; (-); M7.
IATA: UN3077; Environmentally Hazardous Substance, Solid, N.O.S (Laurylimidazole, Aromatic hydrocarbon); 9; III.

SECTION 15: Regulatory information

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

Global inventory status
Contact the manufacturer for more information

SECTION 16: Other information

List of relevant H statements

H302	Harmful if swallowed.
H304	May be fatal if swallowed and enters airways.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic 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 United Kingdom Safety Information Sheets are available at www.3M.com/uk

Safety Information Sheet for Medical Devices

Document group:	16-2742-1	**Version number:**	1.00
Revision date:	06/05/2020	**Supersedes date:**	Initial issue.

Transportation version number: 1.00 (06/05/2020)

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™ Impregum™ Penta™ Soft 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 in approved indications.

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:
Skin Sensitization, Category 1B - Skin Sens. 1B; H317
Reproductive Toxicity, Category 2 - Repr. 2; H361
Specific Target Organ Toxicity-Repeated Exposure, Category 1 - STOT RE 1; H372

For full text of H phrases, see Section 16.

2.2. Label elements
CLP REGULATION (EC) No 1272/2008

SIGNAL WORD
DANGER.

Symbols:
GHS07 (Exclamation mark) | GHS08 (Health Hazard) |

Pictograms

Ingredients:

Ingredient	CAS Nbr	EC No.	% by Wt
Sulfonium salt	72140-65-9	276-380-9	10 - 30

HAZARD STATEMENTS:

H317	May cause an allergic skin reaction.
H361f	Suspected of damaging fertility.
H372	Causes damage to organs through prolonged or repeated exposure: blood or blood-formi organs | respiratory system | sensory organs |

PRECAUTIONARY STATEMENTS

Prevention:

P280E	Wear protective gloves.

Response:

P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.

Notes on labelling

Silicosis and P260 do 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
Citric acid ester	77-90-7	201-067-0	30 - 50	Substance not classified as hazardous
Silane treated silica	68909-20-6	272-697-1	10 - 30	Substance with an occupational exposure limit
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	68855-54-9	272-489-0	10 - 30	STOT RE 2, H373

Sulfonium salt	72140-65-9	276-380-9	10 - 30	Acute Tox. 4, H302; Skin Sens. 1B, H317; Repr. 2, H361f; STOT RE 1, H372
Polyglycol	9003-11-6		1 - 10	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
Immediately wash with soap and water. Remove contaminated clothing and wash before reuse. If signs/symptoms develop, get medical attention.

Eye contact
No need for first aid is anticipated.

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	Condition
Carbon monoxide	During combustion.
Carbon dioxide.	During combustion.
Irritant vapours or gases.	During combustion.

5.3. Advice for fire-fighters
Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Evacuate area. Ventilate the area with fresh air. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapours, in accordance with good industrial hygiene practice. Refer to other sections of this 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
Silicon dioxide	68855-54-9	UK HSC	TWA(as respirable dust):2.4 mg/m3;TWA(as inhalable dust):6 mg/m3	
Quartz	68855-54-9	UK HSC	TWA(respirable):0.1 mg/m3	
Silicon dioxide	68909-20-6	UK HSC	TWA(as respirable dust):2.4 mg/m3;TWA(as inhalable dust):6 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	Dark Red
Specific Physical Form:	Paste
Odor	Slight Acrid
pH	*No data available.*
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	*No data available.*
Flammable Limits(LEL)	*Not applicable.*
Flammable Limits(UEL)	*Not applicable.*
Relative density	1.1 - 1.4 [*Ref Std:*WATER=1]
Water solubility	Negligible
Viscosity	*No data available.*
Density	*No data available.*

9.2. Other information

EU Volatile Organic Compounds	*No data available.*
Percent volatile	*Not applicable.*

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
Strong acids.
Strong bases.
Strong oxidising agents.

10.6 Hazardous decomposition products

Substance	**Condition**
None known.	

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

The information below may not agree with the EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition,

statements and data presented in Section 11 are based on UN GHS calculation rules and classifications derived from 3M assessments.

11.1 Information on Toxicological effects

Signs and Symptoms of Exposure

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

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

Skin contact
Mild Skin Irritation: Signs/symptoms may include localised redness, swelling, itching, and dryness. Allergic skin reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, and itching.

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

Ingestion
May be harmful if swallowed.
Gastrointestinal irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhoea. May cause additional health effects (see below).

Additional Health Effects:

Prolonged or repeated exposure may cause target organ effects:
Ocular effects: Signs/symptoms may include blurred or significantly impaired vision. Bone marrow effects: Signs/symptoms may include generalised weakness, pallor of the skin, fatty infiltration of the bone marrow, decreases in the numbers of circulating blood cells, increased susceptibility to infection. Respiratory effects: Signs/symptoms may include cough, shortness of breath, chest tightness, wheezing, increased heart rate, bluish coloured skin (cyanosis), sputum production, changes in lung function tests, and respiratory failure.

Reproductive/Developmental Toxicity:
Contains a chemical or chemicals which can cause birth defects or other reproductive harm.

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 ATE2,000 - 5,000 mg/kg
Citric acid ester	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Citric acid ester	Ingestion	Rat	LD50 > 25,000 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
Sulfonium salt	Dermal	Rat	LD50 > 2,000 mg/kg
Sulfonium salt	Ingestion	Rat	LD50 300-2,000 mg/kg
Diatomaceous earth (respirable cristobalite	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg

fraction 1-<10%)			
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 2.7 mg/l
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Ingestion	Rat	LD50 > 2,000 mg/kg
Polyglycol	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Polyglycol	Ingestion	Rat	LD50 5,700 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silane treated silica	Rabbit	No significant irritation
Sulfonium salt	Rabbit	Mild irritant
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	In vitro data	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Silane treated silica	Rabbit	No significant irritation
Sulfonium salt	Rabbit	Mild irritant
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Rabbit	Mild irritant

Skin Sensitisation

Name	Species	Value
Silane treated silica	Human and animal	Not classified
Sulfonium salt	Mouse	Sensitising
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Mouse	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
Silane treated silica	In Vitro	Not mutagenic
Sulfonium salt	In Vitro	Not mutagenic
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	In Vitro	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
Silane treated silica	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Inhalation	Human and animal	Carcinogenic.

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
Sulfonium salt	Ingestion	Not classified for development	Rat	NOAEL 100 mg/kg/day	premating into lactation

Sulfonium salt	Ingestion	Toxic to female reproduction	Rat	NOAEL 30 mg/kg/day	premating into lactation
Sulfonium salt	Ingestion	Toxic to male reproduction	Rat	NOAEL 30 mg/kg/day	30 days

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Sulfonium salt	Ingestion	respiratory system	Not classified	Rat	NOAEL 300 mg/kg	

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Silane treated silica	Inhalation	respiratory system | silicosis	Not classified	Human	NOAEL Not available	occupational exposure
Sulfonium salt	Ingestion	bone marrow	Causes damage to organs through prolonged or repeated exposure	Rat	NOAEL 10 mg/kg/day	30 days
Sulfonium salt	Ingestion	respiratory system	May cause damage to organs though prolonged or repeated exposure	Rat	NOAEL 30 mg/kg/day	30 days
Sulfonium salt	Ingestion	eyes	May cause damage to organs though prolonged or repeated exposure	Rat	NOAEL 100 mg/kg/day	30 days
Sulfonium salt	Ingestion	hematopoietic system | liver | immune system | kidney and/or bladder	Not classified	Rat	NOAEL 300 mg/kg/day	30 days
Sulfonium salt	Ingestion	gastrointestinal tract	Not classified	Rat	NOAEL 30 mg/kg/day	30 days
Sulfonium salt	Ingestion	auditory system | heart | skin | endocrine system | bone, teeth, nails, and/or hair | muscles | nervous system | vascular system	Not classified	Rat	NOAEL 300 mg/kg/day	30 days
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Ingestion	hematopoietic system | eyes | kidney and/or bladder	Not classified	Rat	NOAEL 3,738 mg/kg/day	90 days

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

Citric acid ester	77-90-7	Bluegill	Experimental	96 hours	LC50	>=38 mg/l
Citric acid ester	77-90-7	Green algae	Experimental	72 hours	EC50	74.4 mg/l
Citric acid ester	77-90-7	Water flea	Experimental	48 hours	EC50	7.82 mg/l
Citric acid ester	77-90-7	Green algae	Experimental	72 hours	NOEC	4.65 mg/l
Citric acid ester	77-90-7	Water flea	Experimental	21 days	NOEC	>1.11 mg/l
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	68855-54-9		Data not available or insufficient for classification			
Silane treated silica	68909-20-6	Algae	Estimated	72 hours	EC50	>100 mg/l
Sulfonium salt	72140-65-9	Green Algae	Estimated	72 hours	No tox obs at lmt of water sol	>100 mg/l
Sulfonium salt	72140-65-9	Water flea	Estimated	48 hours	No tox obs at lmt of water sol	>100 mg/l
Sulfonium salt	72140-65-9	Zebra Fish	Estimated	96 hours	No tox obs at lmt of water sol	>100 mg/l
Sulfonium salt	72140-65-9	Green Algae	Estimated	72 hours	No tox obs at lmt of water sol	>100 mg/l
Polyglycol	9003-11-6		Data not available or insufficient for classification			

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Citric acid ester	77-90-7	Experimental Biodegradation	28 days	BOD	48 % weight	Other methods
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	68855-54-9	Data not availbl-insufficient			N/A	
Silane treated silica	68909-20-6	Data not availbl-insufficient			N/A	
Sulfonium salt	72140-65-9	Experimental Hydrolysis		Hydrolytic half-life	2.08 hours (t 1/2)	Other methods
Polyglycol	9003-11-6	Data not availbl-insufficient			N/A	

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Citric acid ester	77-90-7	Estimated Bioconcentration		Bioaccumulation factor	5.1	Estimated: Bioconcentration factor
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	68855-54-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silane treated silica	68909-20-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Sulfonium salt	72140-65-9	Experimental Bioconcentration		Log Kow	≤0.75	Other methods
Polyglycol	9003-11-6	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.

SECTION 14: Transportation information

ADR/IMDG/IATA: Not restricted for transport.

SECTION 15: Regulatory information

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

Global inventory status
Contact the manufacturer for more information

SECTION 16: Other information

List of relevant H statements

H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H361f	Suspected of damaging fertility.
H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause 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