



## Safety Information Sheet for Medical Devices

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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 Quick 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 Ireland Limited, The Iveagh Building, The Park, Carrickmines, Dublin 18.  
**Telephone:** +353 1 280 3555  
**E Mail:** tox.uk@mmm.com  
**Website:** www.3M.com

#### 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	15 - 25

### 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-forming 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 based on the nature of this product, no inhalation is expected.

## 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	35 - 50	Substance not classified as hazardous
Silane treated silica	68909-20-6	272-697-1	20 - 30	Substance with an occupational exposure limit
Sulfonium salt	72140-65-9	276-380-9	15 - 25	Acute Tox. 4, H302; Skin Sens. 1B, H317; Repr. 2, H361f; STOT

				RE 1, H372
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	68855-54-9	272-489-0	10 - 20	STOT RE 2, H373
Polyglycol	9003-11-6		1 - 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

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

#### Eye contact

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

#### If swallowed

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

## SECTION 5: Fire-fighting measures

### 5.1. Extinguishing media

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

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

None inherent in this product.

### Hazardous Decomposition or By-Products

#### Substance

Carbon monoxide

Carbon dioxide.

Irritant vapours or gases.

#### Condition

During combustion.

During combustion.

During combustion.

### 5.3. Advice for fire-fighters

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/m <sup>3</sup> ;TWA(as inhalable dust):6 mg/m <sup>3</sup>	
Quartz	68855-54-9	UK HSC	TWA(respirable):0.1 mg/m <sup>3</sup>	
Silicon dioxide	68909-20-6	UK HSC	TWA(as respirable dust):2.4 mg/m <sup>3</sup> ;TWA(as inhalable dust):6 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

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

<b>Appearance</b>	
<b>Physical state</b>	Solid.
<b>Colour</b>	Dark Red
<b>Specific Physical Form:</b>	Paste
<b>Odor</b>	Slight Acrid
<b>pH</b>	<i>No data available.</i>
<b>Boiling point/boiling range</b>	<i>Not applicable.</i>
<b>Melting point</b>	<i>No data available.</i>
<b>Flammability (solid, gas)</b>	Not classified
<b>Explosive properties</b>	Not classified
<b>Oxidising properties</b>	Not classified
<b>Flash point</b>	Flash point > 93 °C (200 °F)
<b>Autoignition temperature</b>	<i>No data available.</i>
<b>Flammable Limits(LEL)</b>	<i>Not applicable.</i>
<b>Flammable Limits(UEL)</b>	<i>Not applicable.</i>
<b>Relative density</b>	> 1 [Ref Std: WATER=1]
<b>Water solubility</b>	Negligible
<b>Viscosity</b>	<i>No data available.</i>
<b>Density</b>	1.1 g/cm <sup>3</sup> - 1.5 g/cm <sup>3</sup>

### 9.2. Other information

<b>EU Volatile Organic Compounds</b>	<i>No data available.</i>
<b>Percent volatile</b>	<i>Not applicable.</i>

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

This material may be reactive with certain agents under certain conditions - see the remaining headings in this section

### 10.2 Chemical stability

Stable.

### 10.3 Possibility of hazardous reactions

Hazardous polymerisation will not occur.

### 10.4 Conditions to avoid

Heat.

### 10.5 Incompatible materials

Strong acids.  
Strong bases.  
Strong oxidising agents.

### 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

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.

#### 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 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 fraction 1-<10%)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
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	prematuring into lactation
Sulfonium salt	Ingestion	Toxic to female reproduction	Rat	NOAEL 30 mg/kg/day	prematuring 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
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
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	68855-54-9		Data not available or insufficient for classification			
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
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
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	68855-54-9	Data not availbl-insufficient			N/A	
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
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
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
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.   

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).   

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