



## Safety Data Sheet

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<b>Document group:</b>	31-6686-5	<b>Version number:</b>	2.00
<b>Revision date:</b>	31/05/2015	<b>Supersedes date:</b>	21/05/2014
<b>Transportation version number:</b>	1.00 (21/05/2014)		

This Safety Data Sheet has been prepared in accordance with the REACH Regulation (EC) 1907/2006 and its modifications.

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

#### 1.1. Product identifier

3M™ ESPE™ IMPRINT™ 4 PENTA™ SUPER QUICK HEAVY Catalyst

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

##### Identified uses

Dental Product

##### 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

### SECTION 2: Hazard identification

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

CLP REGULATION (EC) No 1272/2008

##### CLASSIFICATION:

This product is a medical device as defined in Directive 93/42/EEC (MDD), 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).

##### Dangerous substances(67/548/EEC)/preparations(1999/45/EC) directive

#### 2.2. Label elements

CLP REGULATION (EC) No 1272/2008

Not applicable

**Dangerous substances(67/548/EEC)/preparations(1999/45/EC) directive**

Not applicable

**Notes on labelling**

This product is exempt from labelling per Directive 1999/45/EC as it is defined as a medical device according to Directive 93/42/EEC and is invasive or comes into contact with the human body.

**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	EU Inventory	% by Wt	Classification
Nepheline syenite	37244-96-5		60 - 70	
Siloxanes and silicones, Di-Me, vinyl group-terminated	68083-19-2		15 - 25	
Siloxanes and silicones, di-Me	63148-62-9		5 - 15	
Dimethyl siloxane, reaction product with silica	67762-90-7		1 - 5	

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

Please refer to section 15 for the any applicable Notas that have been applied to the above components

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

**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.

**4.2. Most important symptoms and effects, both acute and delayed**

See Section 11.1 Information on toxicological effects

**4.3. Indication of any immediate medical attention and special treatment required**

Not applicable

**SECTION 5: Fire-fighting measures****5.1. Extinguishing media**

Material will not burn.

## 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

No special protective actions for fire-fighters are anticipated.

## **SECTION 6: Accidental release measures**

### 6.1. Personal precautions, protective equipment and emergency procedures

Ventilate the area with fresh air. Refer to other sections of this SDS 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.

### 6.4. Reference to other sections

Refer to Section 8 and Section 13 for more information

## **SECTION 7: Handling and storage**

### 7.1. Precautions for safe handling

Avoid prolonged or repeated skin contact. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Avoid contact with oxidising agents (eg. chlorine, chromic acid etc.)

### 7.2. Conditions for safe storage including any incompatibilities

Store away from heat. Store away from acids. Store away from strong bases. Store away from oxidising agents. Store away from amines.

### 7.3. Specific end use(s)

See information in Section 7.1 and 7.2 for handling and storage recommendations. See Section 8 for exposure controls and personal protection recommendations.

## **SECTION 8: Exposure controls/personal protection**

### 8.1 Control parameters

#### Occupational exposure limits

No occupational exposure limit values exist for any of the components listed in Section 3 of this Safety Data Sheet.

#### Biological limit values

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

#### Skin/hand protection

See Section 7.1 for additional information on skin protection.

#### Respiratory protection

None required.

## SECTION 9: Physical and chemical properties

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

Physical state	Solid.
Specific Physical Form:	Paste
Appearance/Odour	Slight characteristic odour; white coloured paste
Odour threshold	<i>No data available.</i>
pH	<i>No data available.</i>
Boiling point/boiling range	<i>Not applicable.</i>
Melting point	<i>Not applicable.</i>
Flammability (solid, gas)	Not classified
Explosive properties	Not classified
Oxidising properties	Not classified
Flash point	No flash point
Autoignition temperature	<i>No data available.</i>
Flammable Limits(LEL)	<i>No data available.</i>
Flammable Limits(UEL)	<i>No data available.</i>
Vapour pressure	<i>No data available.</i>
Relative density	1.6 - 1.7 [Ref Std:WATER=1]
Water solubility	Negligible
Solubility- non-water	<i>No data available.</i>
Partition coefficient: n-octanol/water	<i>No data available.</i>
Evaporation rate	<i>Not applicable.</i>
Vapour density	<i>No data available.</i>
Decomposition temperature	<i>No data available.</i>
Viscosity	<i>No data available.</i>
Density	1.6 g/cm <sup>3</sup> - 1.7 g/cm <sup>3</sup>

### 9.2. Other information

Volatile organic compounds (VOC)	<i>Not applicable.</i>
Percent volatile	<i>Not applicable.</i>
VOC less H <sub>2</sub> O & exempt solvents	<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**

Amines.

Strong acids.

Strong bases.

Strong oxidising agents.

#### **10.6 Hazardous decomposition products**

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

May be harmful if swallowed.

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

#### **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.

**3M™ ESPE™ IMPRINT™ 4 PENTA™ SUPER QUICK HEAVY Catalyst****Acute Toxicity**

Name	Route	Species	Value
Overall product	Ingestion		No data available; calculated ATE2,000 - 5,000 mg/kg
Nepheline syenite	Dermal		LD50 estimated to be > 5,000 mg/kg
Nepheline syenite	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
Siloxanes and silicones, Di-Me, vinyl group-terminated	Dermal	Rabbit	LD50 > 15,440 mg/kg
Siloxanes and silicones, Di-Me, vinyl group-terminated	Ingestion	Rat	LD50 > 15,440 mg/kg
Siloxanes and silicones, di-Me	Dermal	Rabbit	LD50 > 19,400 mg/kg
Siloxanes and silicones, di-Me	Ingestion	Rat	LD50 > 17,000 mg/kg
Dimethyl siloxane, reaction product with silica	Dermal	Rabbit	LD50 > 5,000 mg/kg
Dimethyl siloxane, reaction product with silica	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Dimethyl siloxane, reaction product with silica	Ingestion	Rat	LD50 > 5,110 mg/kg

ATE = acute toxicity estimate

**Skin Corrosion/Irritation**

Name	Species	Value
Nepheline syenite	Professional judgement	No significant irritation
Siloxanes and silicones, Di-Me, vinyl group-terminated	Rabbit	No significant irritation
Siloxanes and silicones, di-Me	Rabbit	No significant irritation
Dimethyl siloxane, reaction product with silica	Rabbit	No significant irritation

**Serious Eye Damage/Irritation**

Name	Species	Value
Nepheline syenite	Professional judgement	Mild irritant
Siloxanes and silicones, Di-Me, vinyl group-terminated	Rabbit	Mild irritant
Siloxanes and silicones, di-Me	Rabbit	No significant irritation
Dimethyl siloxane, reaction product with silica	Rabbit	No significant irritation

**Skin Sensitisation**

Name	Species	Value
Dimethyl siloxane, reaction product with silica	Human and animal	Not 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
Dimethyl siloxane, reaction product with silica	In Vitro	Not mutagenic

**Carcinogenicity**

Name	Route	Species	Value
Dimethyl siloxane, reaction product with 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
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**3M™ ESPE™ IMPRINT™ 4 PENTA™ SUPER QUICK HEAVY Catalyst**

					<b>Duration</b>
Dimethyl siloxane, reaction product with silica	Ingestion	Not toxic to female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
Dimethyl siloxane, reaction product with silica	Ingestion	Not toxic to male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Dimethyl siloxane, reaction product with silica	Ingestion	Not toxic to 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**

<b>Name</b>	<b>Route</b>	<b>Target Organ(s)</b>	<b>Value</b>	<b>Species</b>	<b>Test result</b>	<b>Exposure Duration</b>
Dimethyl siloxane, reaction product with silica	Inhalation	respiratory system   silicosis	All data are negative	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 SDS for additional toxicological information on this material and/or its components.**

**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.

<b>Material</b>	<b>CAS Nbr</b>	<b>Organism</b>	<b>Type</b>	<b>Exposure</b>	<b>Test endpoint</b>	<b>Test result</b>
Siloxanes and silicones, Di-Me, vinyl group-terminated	68083-19-2		Data not available or insufficient for classification			
Siloxanes and silicones, di-Me	63148-62-9		Data not available or insufficient for classification			
Nepheline syenite	37244-96-5		Data not available or insufficient for classification			
Dimethyl siloxane, reaction product with silica	67762-90-7		Data not available or insufficient for classification			

**12.2. Persistence and degradability**

<b>Material</b>	<b>CAS Nbr</b>	<b>Test type</b>	<b>Duration</b>	<b>Study Type</b>	<b>Test result</b>	<b>Protocol</b>
Siloxanes and silicones, Di-Me, vinyl group-terminated	68083-19-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Siloxanes and silicones, di-Me	63148-62-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Nepheline syenite	37244-96-5	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Dimethyl siloxane, reaction product with silica	67762-90-7	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

**12.3 : Bioaccumulative potential**

<b>Material</b>	<b>CAS Nbr</b>	<b>Test type</b>	<b>Duration</b>	<b>Study Type</b>	<b>Test result</b>	<b>Protocol</b>
Siloxanes and silicones, Di-Me, vinyl group-terminated	68083-19-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Siloxanes and silicones, di-Me	63148-62-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Nepheline syenite	37244-96-5	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Dimethyl siloxane, reaction product with silica	67762-90-7	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**

No information available at this time, contact manufacturer for more details

**12.6. Other adverse effects**

No information available.



## **SECTION 13: Disposal considerations**

### **13.1 Waste treatment methods**

See Section 11.1 Information on toxicological effects

Dispose of completely cured (or polymerised) material in a permitted industrial waste facility. If no other disposal options are available, waste product that has been completely cured or polymerised may be placed in a landfill properly designed for industrial waste.

The coding of a waste stream is based on the application of the product by the consumer. Since this is out of the control of 3M, no waste code(s) for products after use will be provided. Please refer to the European Waste Code (EWC - 2000/532/EC and amendments) to assign the correct waste code to your waste stream. Ensure national and/or regional regulations are complied with and always use a licensed waste contractor.

### **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**

#### **Global inventory status**

Contact 3M for more information. The components of this material are in compliance with the China "Measures on Environmental Management of New Chemical Substance". Certain restrictions may apply. Contact the selling division for additional information. The components of this product are in compliance with the new substance notification requirements of CEPA.

### **15.2. Chemical Safety Assessment**

Not applicable

## **SECTION 16: Other information**

### **Revision information:**

Revision Changes:

Section 1: Product name information was modified.

Page Heading: Product name information was modified.

Sections 3 and 9: Odour, colour, grade information information was modified.

Section 01: 1.3. Details of the supplier of the safety data sheet heading information was modified.

Section 12: Component ecotoxicity information information was modified.

Section 12: Persistence and Degradability information information was modified.

Section 10: Materials to avoid physical property information was modified.

Section 12: Bioaccumulative potential information information was modified.

Section 2: Other hazards phrase information was modified.

Copyright information was modified.

Section 1: Initial issue message information was modified.

Label: CLP Classification information was modified.

Section 11: Serious Eye Damage/Irritation Table information was modified.

Section 11: Skin Sensitization Table information was modified.

Section 11: Skin Corrosion/Irritation Table information was modified.

Section 5: Hazardous combustion products table information was modified.

Section 5: Fire - Extinguishing media information information was modified.  
Section 5: Fire - Advice for fire fighters information information was modified.  
Section 6: Accidental release personal information information was modified.  
Section 7: Precautions safe handling information information was modified.  
Section 7: Conditions safe storage information was modified.  
Section 8: Personal Protection - Skin/hand information information was modified.  
Section 13: Standard Phrase Category Waste GHS information was modified.  
Section 1: Restrictions on use information information was added.  
Section 1: Restrictions on use header information was added.  
Section 11: Aspiration Hazard text information was added.  
Section 11: Respiratory Sensitization text information was added.  
Section 11: Skin Sensitization table - Name heading information was added.  
Section 11: Skin Sensitization table - Species heading information was added.  
Section 11: Skin Sensitization table - Value heading information was added.  
Section 11: Serious Eye Damage/Irritation table - Name heading information was added.  
Section 11: Serious Eye Damage/Irritation table - Species heading information was added.  
Section 11: Serious Eye Damage/Irritation table - Value heading information was added.  
Section 11: Skin Corrosion/Irritation table - Name heading information was added.  
Section 11: Skin Corrosion/Irritation table - Species heading information was added.  
Section 11: Skin Corrosion/Irritation table - Value heading information was added.  
Section 11: Germ Cell Mutagenicity table - Name heading information was added.  
Section 11: Germ Cell Mutagenicity table - Route heading information was added.  
Section 11: Germ Cell Mutagenicity table - Value heading information was added.  
Section 11: Specific Target Organ Toxicity - repeated exposure table - Name heading information was added.  
Section 11: Specific Target Organ Toxicity - repeated exposure table - Route heading information was added.  
Section 11: Specific Target Organ Toxicity - repeated exposure table - Target Organ(s) heading information was added.  
Section 11: Specific Target Organ Toxicity - repeated exposure table - Value heading information was added.  
Section 11: Specific Target Organ Toxicity - repeated exposure table - Species heading information was added.  
Section 11: Specific Target Organ Toxicity - repeated exposure table - Test Result heading information was added.  
Section 11: Specific Target Organ Toxicity - repeated exposure table - Exposure Duration heading information was added.  
Section 11: Specific Target Organ Toxicity - single exposure text information was added.  
Section 11: Reproductive and/or Developmental Effects table - Name heading information was added.  
Section 11: Reproductive and/or Developmental Effects table - Route heading information was added.  
Section 11: Reproductive and/or Developmental Effects table - Value heading information was added.  
Section 11: Reproductive and/or Developmental Effects table - Species heading information was added.  
Section 11: Reproductive and/or Developmental Effects table - Test Result heading information was added.  
Section 11: Reproductive and/or Developmental Effects text information was added.  
Section 11: Carcinogenicity table - Name heading information was added.  
Section 11: Carcinogenicity table - Route heading information was added.  
Section 11: Carcinogenicity table - Species heading information was added.  
Section 11: Carcinogenicity table - Value heading information was added.  
Section 13: EU waste code (product as sold) heading information was deleted.  
Section 13: EU waste code (product as sold) information information was deleted.  
Prints No Data if Persistence and Degradability information is not present information was deleted.  
Prints No Data if Bioaccumulative potential information is not present information was deleted.  
Section 11: Exposure Duration table heading information was deleted.  
Section 11: Test Result table heading information was deleted.  
Section 2.1: Classification information information was deleted.

DISCLAIMER: The information on this Safety Data Sheet is based on our experience and is correct to the best of our knowledge at the date of publication, but we do not accept any liability for any loss, damage or injury resulting from its use (except as required by law). The information may not be valid for any use not referred to in this Data Sheet or use of the product in combination with other materials. For these reasons, it is important that customers carry out their own test to satisfy themselves as to the suitability of the product for their own intended applications.

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

