Safety Data Sheet

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Document group:	16-2743-9	**Version number:**	5.01
Revision date:	05/05/2015	**Supersedes date:**	05/05/2015

Transportation version number: 1.00 (08/01/2013)

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

IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier
3M™ ESPE™ IMPREGUM PENTA™ SOFT/ IMPREGUM PENTA™ SOFT MB/ IMPREGUM PENTA H DUOSOFT/IMPREGUM PENTA™ SOFT HB

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

Identified uses
Dental product

Restrictions on Use
For professional dentists use only.

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. A Safety Data Sheet for each of these components is included. Please do not separate the component Safety Data Sheets from this cover page. The document numbers of the MSDSs for components of this product are:

16-2742-1, 16-2740-5

TRANSPORTATION INFORMATION

IATA/ADR/IMDG: Not restricted for transport.

KIT LABEL

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.

Revision information:
Revision Changes:
Remark (phrase) information was added.
Kit: Component document group number(s) information was modified.
Section 01: 1.3. Details of the supplier of the safety data sheet heading information was modified.
Section 2: Contains heading information was deleted.
Section 2: Safety phrases heading information was deleted.
Section 1: Product identification numbers heading information was deleted.
Section 1: Product identification numbers information was deleted.
Section 2: Risk phrases heading information was deleted.
Section 15: Symbol information information was deleted.
Kit label ingredient disclosure information information was deleted.
Section 14: Transportation classification information was added.
Section 2: Notes on labelling heading information was added.
Copyright information was modified.
Telephone header information was modified.
Company Telephone information was modified.
Section 1: Identified uses header information was added.
Section 1: Restrictions on use information information was added.
Section 1: Restrictions on use header information was added.
Section 2: 2.2 & 2.3. CLP REGULATION heading information was added.
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Safety Data Sheet

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Document group:	16-2742-1	**Version number:**	9.00
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Transportation version number: 1.00 (08/01/2013)

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™ Impregum™ Penta™ Soft HB 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
Indication of danger
Dangerous for the environment; N; R51/53

For full text of R phrases, see Section 16.

2.2. Label elements
CLP REGULATION (EC) No 1272/2008
Not applicable

Dangerous substances(67/548/EEC)/preparations(1999/45/EC) directive
Not applicable

Dangerous for the environment

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
Tributyl o-acetylcitrate	77-90-7	EINECS 201-067-0	35 - 45	N:R51/53 (Self Classified) Aquatic Chronic 2, H411 (Self Classified)
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	68909-20-6	EINECS 272-697-1	20 - 30	
Sulphonium salt	72140-65-9	EINECS 276-380-9	15 - 25	Eye Irrit. 2, H319 (Self Classified)
Cristobalite	14464-46-1	EINECS 238-455-4	1 - 10	Xn:R48/20 (Self Classified) STOT RE 1, H372 (Self Classified)
Kieselguhr, soda ash flux-calcined	68855-54-9	EINECS 272-489-0	1 - 10	
Polyethylene-polypropylene glycol	9003-11-6		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
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
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. Avoid breathing dust/fume/gas/mist/vapours/spray. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Avoid release to the environment. Avoid contact with oxidising

agents (eg. chlorine, chromic acid etc.) Do not get in eyes.

7.2. Conditions for safe storage including any incompatibilities
Store in a well-ventilated place. Keep container tightly closed. Protect from sunlight. Store away from heat. Store away from acids. Store away from strong bases. Store away from oxidising agents.

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	Dark red colour, slightly acrid odour
Odour threshold	*No data available.*
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	No flash point

Autoignition temperature	*No data available.*
Flammable Limits(LEL)	*Not applicable.*
Flammable Limits(UEL)	*Not applicable.*
Vapour pressure	*Not applicable.*
Relative density	1.1 - 1.4 [*Ref Std:*WATER=1]
Water solubility	Negligible
Solubility- non-water	*No data available.*
Partition coefficient: n-octanol/water	*No data available.*
Evaporation rate	*Not applicable.*
Vapour density	*Not applicable.*
Decomposition temperature	*No data available.*
Viscosity	*No data available.*

9.2. Other information

Volatile organic compounds (VOC)	*Not applicable.*
Percent volatile	*Not applicable.*
VOC less H2O & exempt solvents	*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.

Eye contact
Moderate eye irritation: Signs/symptoms may include redness, swelling, pain, tearing, and blurred or hazy vision.

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

Additional Health Effects:

Single exposure may cause target organ effects:
Central nervous system (CNS) depression: Signs/symptoms may include headache, dizziness, drowsiness, incoordination, nausea, slowed reaction time, slurred speech, giddiness, and unconsciousness.

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
Tributyl o-acetylcitrate	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Tributyl o-acetylcitrate	Ingestion	Rat	LD50 > 25,000 mg/kg
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Dermal	Rabbit	LD50 > 5,000 mg/kg
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Ingestion	Rat	LD50 > 5,110 mg/kg
Sulphonium salt	Dermal	Professional judgement	LD50 estimated to be 2,000 - 5,000 mg/kg
Sulphonium salt	Ingestion	Rat	LD50 > 2,000 mg/kg
Cristobalite	Dermal		LD50 estimated to be > 5,000 mg/kg
Cristobalite	Ingestion		LD50 estimated to be > 5,000 mg/kg
Kieselguhr, soda ash flux-calcined	Dermal	Rabbit	LD50 > 5,000 mg/kg
Kieselguhr, soda ash flux-calcined	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Kieselguhr, soda ash flux-calcined	Ingestion	Rat	LD50 > 5,110 mg/kg
Polyethylene-polypropylene glycol	Dermal	Professional judgeme	LD50 estimated to be > 5,000 mg/kg

		nt	
Polyethylene-polypropylene glycol	Ingestion	Rat	LD50 5,700 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Rabbit	No significant irritation
Sulphonium salt	Rabbit	Mild irritant
Cristobalite	Professional judgement	No significant irritation
Kieselguhr, soda ash flux-calcined	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Rabbit	No significant irritation
Sulphonium salt	similar health hazards	Moderate irritant
Kieselguhr, soda ash flux-calcined	Rabbit	No significant irritation

Skin Sensitisation

Name	Species	Value
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Human and animal	Not sensitizing
Kieselguhr, soda ash flux-calcined	Human and animal	Not sensitizing

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
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	In Vitro	Not mutagenic
Sulphonium salt	In Vitro	Not mutagenic
Cristobalite	In Vitro	Some positive data exist, but the data are not sufficient for classification
Cristobalite	In vivo	Some positive data exist, but the data are not sufficient for classification
Kieselguhr, soda ash flux-calcined	In Vitro	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification
Cristobalite	Inhalation	Human and animal	Carcinogenic.
Kieselguhr, soda ash flux-calcined	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
Silanamine, 1,1,1-trimethyl-N-	Ingestion	Not toxic to female reproduction	Rat	NOAEL 509	1 generation

(trimethylsilyl)-, hydrolysis products with silica				mg/kg/day	
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Ingestion	Not toxic to male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Ingestion	Not toxic to development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis
Kieselguhr, soda ash flux-calcined	Ingestion	Not toxic to female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation
Kieselguhr, soda ash flux-calcined	Ingestion	Not toxic to male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Kieselguhr, soda ash flux-calcined	Ingestion	Not toxic to development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Sulphonium salt	Ingestion	central nervous system depression	May cause drowsiness or dizziness	Rat	LOAEL 2,000 mg/kg	not applicable

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Inhalation	respiratory system | silicosis	All data are negative	Human	NOAEL Not available	occupational exposure
Cristobalite	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
Kieselguhr, soda ash flux-calcined	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.

Material	CAS Nbr	Organism	Type	Exposure	Test endpoint	Test result
Sulphonium salt	72140-65-9		Data not available or insufficient for classification			
Polyethylene-polypropylene	9003-11-6	Atlantic Salmon	Experimental	96 hours	LC50	>1,000 mg/l

glycol						
Polyethylene-polypropylene glycol	9003-11-6	Inland Silverside	Experimental	96 hours	LC50	650 mg/l
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl) -, hydrolysis products with silica	68909-20-6	Algae	Estimated	72 hours	EC50	>100 mg/l
Tributyl o-acetylcitrate	77-90-7	Water flea	Experimental	48 hours	EC50	7.82 mg/l
Cristobalite	14464-46-1		Data not available or insufficient for classification			
Kieselguhr, soda ash flux-calcined	68855-54-9		Data not available or insufficient for classification			

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Sulphonium salt	72140-65-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Polyethylene-polypropylene glycol	9003-11-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl) -, hydrolysis products with silica	68909-20-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Tributyl o-acetylcitrate	77-90-7	Estimated Photolysis		Photolytic half-life (in air)	2.1 days (t 1/2)	Other methods
Tributyl o-acetylcitrate	77-90-7	Experimental Biodegradation	28 days	BOD	48 % weight	Other methods
Cristobalite	14464-46-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Kieselguhr, soda ash flux-calcined	68855-54-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

12.3 : Bioaccumulative potential

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Sulphonium salt	72140-65-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Polyethylene-polypropylene glycol	9003-11-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	68909-20-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Tributyl o-acetylcitrate	77-90-7	Estimated Bioconcentration		Bioaccumulation factor	5.1	Estimated: Bioconcentration factor
Cristobalite	14464-46-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Kieselguhr, soda ash flux-calcined	68855-54-9	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

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

Incinerate in a permitted waste incineration facility.

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 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

Carcinogenicity

Ingredient	CAS Nbr	Classification	Regulation
Cristobalite	14464-46-1	Grp. 1: Carcinogenic to humans	International Agency for Research on Cancer

Global inventory status
Contact 3M for more information.

15.2. Chemical Safety Assessment
Not applicable

SECTION 16: Other information

List of relevant H statements

H319	Causes serious eye irritation.
H372	Causes damage to organs through prolonged or repeated exposure.
H411	Toxic to aquatic life with long lasting effects.

List of relevant R-phrases

R48/20	Harmful: danger of serious damage to health by prolonged exposure through inhalation.
R51/53	Toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

Revision information:
Revision Changes:
Section 01: 1.3. Details of the supplier of the safety data sheet heading information was modified.
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Section 9: Solubility in water text 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:Bioccumulative potential information information was modified.
Section 2: Other hazards phrase information was modified.
Copyright information was modified.
Label: CLP Classification information was modified.
Telephone header information was modified.
Company Telephone information was modified.
Section 11: Acute Toxicity table information was modified.
Section 11: Carcinogenicity Table information was modified.
Section 11: Serious Eye Damage/Irritation Table information was modified.
Section 11: Germ Cell Mutagenicity Table information was modified.
Section 11: Additional Health Effects heading information was modified.
Section 11: Skin Sensitization Table information was modified.
Section 11: Reproductive Toxicity Table information was modified.
Section 11: Skin Corrosion/Irritation Table information was modified.
Section 11: Target Organs - Repeated Table information was modified.
Section 11: Target Organs - Single Table information was modified.