



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.

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

1.1. Product identifier

3M™ Imprint™ 4 Bite Refill (71529)

Product Identification Numbers

70-2011-4202-6 UU-0098-0560-5

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

Identified uses

Medical device; refer to Instructions for Use

Restrictions on Use

For use only by dental professionals.

1.3. Details of the supplier of the safety data sheet

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

1.4. Emergency telephone number

+44 (0)1344 858 000

This product is a kit or a multipart product which consists of multiple, independently packaged components. Safety Information Sheet for Medical Devices for each of these components is included. Please do not separate the component Safety Information Sheet for Medical Devices from this cover page. The document numbers of the Safety Information Sheet for Medical Devices for components of this product are:

33-1547-0, 33-1548-8

TRANSPORTATION INFORMATION

70-2011-4202-6

Not hazardous for transportation

UU-0098-0560-5

ADR/IMDG/IATA: Not restricted for transport.

KIT LABEL

2.1. Classification of the substance or mixture

Please refer to Kit Components

Revision information:

A revision has been performed due to the need to update the safety information for the medical device.



Safety Information Sheet for Medical Devices

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Document group:	33-1547-0	Version number:	2.00
Revision date:	08/05/2023	Supersedes date:	17/10/2019

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™ Imprint™ 4 Bite Base

Product Identification Numbers

LE-F100-1533-3

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
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1.4. Emergency telephone number

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SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

The retained CLP Regulation (EU) No 1272/2008 as amended for Great Britain

The carcinogenicity classification for titanium dioxide is not applicable based on physical form (material is not a powder).

This product is a medical device as defined in Directive 93/42/EEC (MDD) respectively Regulation SI 2002 No 618, as amended (UK MDR 2002), 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 the retained CLP Regulation (EC) No. 1272/2008, as amended for Great Britain (Article 1, paragraph 5). Although not required, the classification and label information, as applicable, is provided below.

CLASSIFICATION:

This material is not classified as hazardous according to Regulation (EC) No. 1272/2008, as amended for Great Britain, on classification, labelling, and packaging of substances and mixtures.

2.2. Label elements**The retained CLP Regulation (EU) No 1272/2008 as amended for Great Britain**

Not applicable

H372 does not apply. Material is a paste, with no potential for inhalation exposure.

2.3. Other hazards

For information on hazards and safe use, please consider the corresponding sections of this document.

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

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Ingredient	Identifier(s)	%	Classification according to Regulation (EC) No. 1272/2008 [CLP], as amended for GB
Silane treated cristobalite	(CAS-No.) None	30 - 50	STOT RE 1, H372
Vinyl siloxanes	(CAS-No.) 68083-19-2	20 - 30	Substance not classified as hazardous
Silane treated silica	(CAS-No.) None	10 - 20	Substance not classified as hazardous
Hydrogen silicone	(CAS-No.) 68037-59-2	1 - 10	Substance not classified as hazardous
Silicon oil	(CAS-No.) 63148-62-9	1 - 10	Substance not classified as hazardous
Silane treated silica	(CAS-No.) 68611-44-9 (EC-No.) 271-893-4	1 - 10	Substance with a national occupational exposure limit
Titanium dioxide	(CAS-No.) 13463-67-7 (EC-No.) 236-675-5	1 - 10	Carc. 2, H351 (inhalation)
Silane treated tridymite	(CAS-No.) None	< 5	STOT RE 1, H372
Silane treated quartz	(CAS-No.) None	< 0.5	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**

No need for first aid is anticipated. If symptoms develop, remove the affected person to fresh air. Get medical attention.

Skin contact

No need for first aid is anticipated.

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**

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
Titanium dioxide	13463-67-7	UK HSC	TWA(respirable):4 mg/m3;TWA(Inhalable):10 mg/m3	
Silicon dioxide	68611-44-9	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

Physical state	Solid.
Specific Physical Form:	Paste
Colour	White
Odor	Characteristic Odour
Melting point/freezing point	<i>Not applicable.</i>
Boiling point/boiling range	<i>Not applicable.</i>
Flammability (solid, gas)	Not classified
Flammable Limits(LEL)	<i>Not applicable.</i>
Flammable Limits(UEL)	<i>Not applicable.</i>
Flash point	No flash point
Autoignition temperature	<i>Not applicable.</i>
Relative density	1.5 - 1.7 [Ref Std:WATER=1]
pH	<i>substance/mixture is non-soluble (in water)</i>
Kinematic Viscosity	<i>No data available.</i>
Water solubility	Negligible
Density	1.5 g/cm3 - 1.7 g/cm3

9.2. Other information

9.2.2 Other safety characteristics

EU Volatile Organic Compounds

No data available.

Evaporation rate

No data available.

Percent volatile

Not applicable.

SECTION 10: Stability and reactivity

10.1 Reactivity

This material is considered to be non reactive under normal use conditions. 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>
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 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 hazard classes as defined in the retained CLP Regulation (EU) No 1272/2008, as amended for Great Britain.

Signs and Symptoms of Exposure

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

Inhalation

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

Skin contact

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

Eye contact

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

Ingestion

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

Additional Health Effects:**Carcinogenicity:**

Exposures needed to cause the following health effect(s) are not expected during normal, intended use:

Contains a chemical or chemicals which can cause cancer.

Toxicological Data

If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

Acute Toxicity

Name	Route	Species	Value
Overall product	Ingestion		No data available; calculated ATE >5,000 mg/kg
Silane treated cristobalite	Dermal		LD50 estimated to be > 5,000 mg/kg
Silane treated cristobalite	Ingestion		LD50 estimated to be > 5,000 mg/kg
Vinyl siloxanes	Dermal	Rabbit	LD50 > 15,440 mg/kg
Vinyl siloxanes	Ingestion	Rat	LD50 > 15,440 mg/kg
Silane treated silica	Dermal	Rabbit	LD50 > 5,000 mg/kg
Silane treated silica	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Silane treated silica	Ingestion	Rat	LD50 > 5,110 mg/kg
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
Hydrogen silicone	Dermal	Rabbit	LD50 > 2,000 mg/kg
Hydrogen silicone	Ingestion	Rat	LD50 > 2,000 mg/kg
Silane treated tridymite	Dermal		LD50 estimated to be > 5,000 mg/kg
Silane treated tridymite	Ingestion		LD50 estimated to be > 5,000 mg/kg
Silicon oil	Dermal	Rabbit	LD50 > 19,400 mg/kg
Silicon oil	Ingestion	Rat	LD50 > 17,000 mg/kg
Titanium dioxide	Dermal	Rabbit	LD50 > 10,000 mg/kg
Titanium dioxide	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 6.82 mg/l
Titanium dioxide	Ingestion	Rat	LD50 > 10,000 mg/kg
Silane treated quartz	Dermal		LD50 estimated to be > 5,000 mg/kg
Silane treated quartz	Ingestion		LD50 estimated to be > 5,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Silane treated cristobalite		No significant irritation
Vinyl siloxanes	Rabbit	No significant irritation
Silane treated silica	Rabbit	No significant irritation
Silane treated silica	Rabbit	No significant irritation
Hydrogen silicone	Rabbit	No significant irritation
Silane treated tridymite		No significant irritation
Silicon oil	Rabbit	No significant irritation
Titanium dioxide	Rabbit	No significant irritation
Silane treated quartz		No significant irritation

Serious Eye Damage/Irritation

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

Skin Sensitisation

Name	Species	Value
Silane treated silica	Human and animal	Not classified
Silane treated silica	Human and animal	Not classified
Hydrogen silicone	Guinea pig	Not classified
Titanium dioxide	Human and animal	Not classified

Respiratory Sensitisation

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

Germ Cell Mutagenicity

Name	Route	Value
Silane treated cristobalite	In Vitro	Some positive data exist, but the data are not sufficient for classification
Silane treated cristobalite	In vivo	Some positive data exist, but the data are not sufficient for classification
Silane treated silica	In Vitro	Not mutagenic
Silane treated silica	In Vitro	Not mutagenic
Hydrogen silicone	In Vitro	Not mutagenic
Silane treated tridymite	In Vitro	Some positive data exist, but the data are not sufficient for classification
Silane treated tridymite	In vivo	Some positive data exist, but the data are not sufficient for classification
Titanium dioxide	In Vitro	Not mutagenic
Titanium dioxide	In vivo	Not mutagenic
Silane treated quartz	In Vitro	Some positive data exist, but the data are not sufficient for classification
Silane treated quartz	In vivo	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
Silane treated cristobalite	Inhalation	Human and animal	Carcinogenic.
Silane treated silica	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification
Silane treated silica	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification
Silane treated tridymite	Inhalation	Human and animal	Carcinogenic.
Titanium dioxide	Ingestion	Multiple animal species	Not carcinogenic
Titanium dioxide	Inhalation	Rat	Carcinogenic.
Silane treated quartz	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
Silane treated silica	Ingestion	Not classified for female reproduction	Rat	NOAEL 509 mg/kg/day	1 generation

Silane treated silica	Ingestion	Not classified for male reproduction	Rat	NOAEL 497 mg/kg/day	1 generation
Silane treated silica	Ingestion	Not classified for development	Rat	NOAEL 1,350 mg/kg/day	during organogenesis

Target Organ(s)

Specific Target Organ Toxicity - single exposure

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

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Silane treated cristobalite	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
Silane treated silica	Inhalation	respiratory system silicosis respiratory system silicosis	Not classified	Human	NOAEL Not available	occupational exposure
Silane treated tridymite	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
Titanium dioxide	Inhalation	respiratory system	Some positive data exist, but the data are not sufficient for classification	Rat	LOAEL 0.01 mg/l	2 years
Titanium dioxide	Inhalation	pulmonary fibrosis	Not classified	Human	NOAEL Not available	occupational exposure
Silane treated quartz	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure

Aspiration Hazard

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

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

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

11.2. Information on other hazards

This material does not contain any substances that are assessed to be an endocrine disruptor for human health.

SECTION 12: Ecological information

The information below may not agree with the 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
Silane treated cristobalite	None	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Vinyl siloxanes	68083-19-2	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Silane treated silica	None	N/A	Data not available or insufficient for	N/A	N/A	N/A

			classification			
Hydrogen silicone	68037-59-2	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Silane treated silica	68611-44-9	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Silicon oil	63148-62-9	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Titanium dioxide	13463-67-7	Activated sludge	Experimental	3 hours	NOEC	≥1,000 mg/l
Titanium dioxide	13463-67-7	Diatom	Experimental	72 hours	EC50	>10,000 mg/l
Titanium dioxide	13463-67-7	Fathead minnow	Experimental	96 hours	LC50	>100 mg/l
Titanium dioxide	13463-67-7	Water flea	Experimental	48 hours	EC50	>100 mg/l
Titanium dioxide	13463-67-7	Diatom	Experimental	72 hours	NOEC	5,600 mg/l
Silane treated tridymite	None	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Silane treated quartz	None	N/A	Data not available or insufficient for classification	N/A	N/A	N/A

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Silane treated cristobalite	None	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Vinyl siloxanes	68083-19-2	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Silane treated silica	None	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Hydrogen silicone	68037-59-2	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Silane treated silica	68611-44-9	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Silicon oil	63148-62-9	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Titanium dioxide	13463-67-7	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Silane treated tridymite	None	Data not availbl-insufficient	N/A	N/A	N/A	N/A
Silane treated quartz	None	Data not availbl-insufficient	N/A	N/A	N/A	N/A

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Silane treated cristobalite	None	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Vinyl siloxanes	68083-19-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silane treated silica	None	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Hydrogen silicone	68037-59-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silane treated silica	68611-44-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silicon oil	63148-62-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Titanium dioxide	13463-67-7	Experimental BCF - Fish	42 days	Bioaccumulation factor	9.6	
Silane treated tridymite	None	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silane treated quartz	None	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

12.4. Mobility in soil

No test data available.

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

This material does not contain any substances that are assessed to be an endocrine disruptor for environmental effects

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)

180107 Chemicals other than those mentioned in 18 01 06

SECTION 14: Transportation information

Not hazardous for transportation.

	Ground Transport (ADR)	Air Transport (IATA)	Marine Transport (IMDG)
14.1 UN number	No data available.	No data available.	No data available.
14.2 UN proper shipping name	No data available.	No data available.	No data available.
14.3 Transport hazard class(es)	No data available.	No data available.	No data available.
14.4 Packing group	No data available.	No data available.	No data available.
14.5 Environmental hazards	No data available.	No data available.	No data available.
14.6 Special precautions for user	Please refer to the other sections of the SDS for further information.	Please refer to the other sections of the SDS for further information.	Please refer to the other sections of the SDS for further information.
14.7 Transport in bulk according to Annex II of Marpol 73/78 and IBC Code	No data available.	No data available.	No data available.
Control Temperature	No data available.	No data available.	No data available.
Emergency Temperature	No data available.	No data available.	No data available.
ADR Classification	No data available.	No data available.	No data available.

Code			
IMDG Segregation Code	No data available.	No data available.	No data available.

Please contact the address or phone number listed on the first page of the SDS for additional information on the transport/shipment of the material by rail (RID) or inland waterways (ADN).

SECTION 15: Regulatory information

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

Carcinogenicity

Contact the manufacturer for more information

Global inventory status

Contact the manufacturer for more information

SECTION 16: Other information

List of relevant H statements

H351i Suspected of causing cancer by inhalation.
H372 Causes damage to organs through prolonged or repeated exposure.

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 Safety Information Sheets for Great Britain are available at www.3M.com/uk



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™ ESPE™ IMPRINT™ 4 BITE Catalyst

Product Identification Numbers

LE-F100-1533-4

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), which is invasive or used in direct physical contact with the human body, and therefore is exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). Although not required, the classification and label information, as applicable, is provided below.

CLASSIFICATION:

This material is not classified as hazardous according to Regulation (EC) No. 1272/2008, as amended, on classification, labelling, and packaging of substances and mixtures.

2.2. Label elements

CLP REGULATION (EC) No 1272/2008

Not applicable

Notes on labelling

H372 does not apply. Material is a paste, with no potential for inhalation exposure.

2.3. Other hazards

For information on hazards and safe use, please consider the corresponding sections of this document.

SECTION 3: Composition/information on ingredients

Ingredient	CAS Nbr	EC No.	% by Wt	Classification
Cristobalite	14464-46-1	238-455-4	50 - 70	STOT RE 1, H372
Vinyl polysiloxanes	68083-19-2		20 - 40	Substance not classified as hazardous
Silicon oil	63148-62-9		1 - 10	Substance not classified as hazardous
Silane teated silica	68611-44-9	271-893-4	1 - 10	Substance with a Community level exposure limit in the workplace
Titanium dioxide	13463-67-7	236-675-5	1 - 10	Substance with a Community level exposure limit in the workplace

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

No need for first aid is anticipated.

Skin contact

Wash with soap and water. If signs/symptoms develop, get medical attention.

Eye contact

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

If swallowed

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

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

None inherent in this product.

Hazardous Decomposition or By-Products**Substance**

Formaldehyde
Carbon monoxide.
Carbon dioxide.
Irritant vapours or gases.

Condition

During combustion.
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**

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
Titanium dioxide	13463-67-7	UK HSC	TWA(Inhalable):10 mg/m ³ ;TWA(respirable):4 mg/m ³	
Quartz	14464-46-1	UK HSC	TWA(respirable):0.1 mg/m ³	
Silicon dioxide	68611-44-9	UK HSC	TWA(as inhalable dust):6 mg/m ³ ;TWA(as respirable dust):2.4 mg/m ³	

UK HSC : UK Health and Safety Commission
TWA: Time-Weighted-Average
STEL: Short Term Exposure Limit
CEIL: Ceiling

Biological limit values

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

8.2. Exposure controls**8.2.1. Engineering controls**

Use in a well-ventilated area.

8.2.2. Personal protective equipment (PPE)**Eye/face protection**

Select and use eye/face protection to prevent contact based on the results of an exposure assessment. The following eye/face protection(s) are recommended:
Safety glasses with side shields.

Applicable Norms/Standards

Use eye protection conforming to EN 166

Skin/hand protection

See Section 7.1 for additional information on skin protection.

Respiratory protection

None required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties**Appearance**

Physical state

Solid.

Colour

Blue

Specific Physical Form:

Paste

Odor

Slight Odor, Characteristic Odour

pH

No data available.

Boiling point/boiling range

Not applicable.

Melting point

Not applicable.

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.

Relative density

1.5 - 1.7 [Ref Std: WATER=1]

Water solubility

Negligible

Viscosity

No data available.

Density

1.5 g/cm³ - 1.7 g/cm³

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

None known.

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

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

Eye contact

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

Ingestion

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

Additional Health Effects:**Carcinogenicity:**

Exposures needed to cause the following health effect(s) are not expected during normal, intended use:

Contains a chemical or chemicals which can cause cancer.

Toxicological Data

If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

Acute Toxicity

Name	Route	Species	Value
Overall product	Ingestion		No data available; calculated ATE >5,000 mg/kg
Cristobalite	Dermal		LD50 estimated to be > 5,000 mg/kg
Cristobalite	Ingestion		LD50 estimated to be > 5,000 mg/kg
Vinyl polysiloxanes	Dermal	Rabbit	LD50 > 15,440 mg/kg
Vinyl polysiloxanes	Ingestion	Rat	LD50 > 15,440 mg/kg
Silane teated silica	Dermal	Rabbit	LD50 > 5,000 mg/kg
Silane teated silica	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Silane teated silica	Ingestion	Rat	LD50 > 5,110 mg/kg
Silicon oil	Dermal	Rabbit	LD50 > 19,400 mg/kg
Silicon oil	Ingestion	Rat	LD50 > 17,000 mg/kg
Titanium dioxide	Dermal	Rabbit	LD50 > 10,000 mg/kg
Titanium dioxide	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 6.82 mg/l
Titanium dioxide	Ingestion	Rat	LD50 > 10,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Cristobalite	Professional judgement	No significant irritation
Vinyl polysiloxanes	Rabbit	No significant irritation
Silane teated silica	Rabbit	No significant irritation
Silicon oil	Rabbit	No significant irritation
Titanium dioxide	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Vinyl polysiloxanes	Rabbit	Mild irritant
Silane teated silica	Rabbit	No significant irritation
Silicon oil	Rabbit	No significant irritation
Titanium dioxide	Rabbit	No significant irritation

Skin Sensitisation

Name	Species	Value
Silane teated silica	Human and animal	Not classified
Titanium dioxide	Human and animal	Not classified

Respiratory Sensitisation

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

Germ Cell Mutagenicity

Name	Route	Value
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
Silane teated silica	In Vitro	Not mutagenic
Titanium dioxide	In Vitro	Not mutagenic
Titanium dioxide	In vivo	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
Cristobalite	Inhalation	Human and animal	Carcinogenic.
Silane teated silica	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification
Titanium dioxide	Ingestion	Multiple animal species	Not carcinogenic
Titanium dioxide	Inhalation	Rat	Carcinogenic.

Reproductive Toxicity**Reproductive and/or Developmental Effects**

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

Target Organ(s)**Specific Target Organ Toxicity - single exposure**

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

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Cristobalite	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
Silane teated silica	Inhalation	respiratory system silicosis	Not classified	Human	NOAEL Not available	occupational exposure
Titanium dioxide	Inhalation	respiratory system	Some positive data exist, but the data are not sufficient for classification	Rat	LOAEL 0.01 mg/l	2 years
Titanium dioxide	Inhalation	pulmonary fibrosis	Not classified	Human	NOAEL Not available	occupational exposure

Aspiration Hazard

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

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

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

SECTION 12: Ecological information

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

12.1. Toxicity

No product test data available.

Material	CAS #	Organism	Type	Exposure	Test endpoint	Test result
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Cristobalite	14464-46-1		Data not available or insufficient for classification			
Vinyl polysiloxanes	68083-19-2		Data not available or insufficient for classification			
Silane teated silica	68611-44-9		Data not available or insufficient for classification			
Silicon oil	63148-62-9		Data not available or insufficient for classification			
Titanium dioxide	13463-67-7	Diatom	Experimental	72 hours	EC50	>10,000 mg/l
Titanium dioxide	13463-67-7	Fathead minnow	Experimental	96 hours	LC50	>100 mg/l
Titanium dioxide	13463-67-7	Water flea	Experimental	48 hours	EC50	>100 mg/l
Titanium dioxide	13463-67-7	Diatom	Experimental	72 hours	NOEC	5,600 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Cristobalite	14464-46-1	Data not availbl-insufficient			N/A	
Vinyl polysiloxanes	68083-19-2	Data not availbl-insufficient			N/A	
Silane teated silica	68611-44-9	Data not availbl-insufficient			n/a	
Silicon oil	63148-62-9	Data not availbl-insufficient			N/A	
Titanium dioxide	13463-67-7	Data not availbl-insufficient			N/A	

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Cristobalite	14464-46-1	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Vinyl polysiloxanes	68083-19-2	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silane teated silica	68611-44-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Silicon oil	63148-62-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Titanium dioxide	13463-67-7	Experimental BCF-Carp	42 days	Bioaccumulation factor	9.6	Other methods

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)

180107 Chemicals other than those mentioned in 18 01 06

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**

Contact the manufacturer for more information

Global inventory status

Contact the manufacturer for more information

SECTION 16: Other information**List of relevant H statements**

H372 Causes damage to organs through prolonged or repeated exposure.

Revision information:

Revision information not available

The product to which this Safety Information Sheet applies is classified as a medical device according to the EU Medical Device Regulation EU 2017/745. _x000D_

Medical devices which are invasive or used in direct physical contact with the human body are exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). _x000D_

The EU Medical Device Regulation does not foresee the use of Safety Data sheets for medical devices which are invasive or used in direct physical contact with the human body, as the safe use of the product is described through the Instructions for Use and /or the labelling for the product. Nevertheless, the 3M Safety Information Sheet is provided as a further service to customers to provide additional toxicology and chemical information on the product. In case of further questions, please contact your 3M representative listed on the Safety Information Sheet.

3M United Kingdom Safety Information Sheets are available at www.3M.com/uk