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™ IMPREGUM F Base

Product Identification Numbers

70-2011-3764-6	70-2011-3766-1	UU-0098-0446-7
7000129148	7000055130	7100196212

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:
Serious Eye Damage/Eye Irritation, Category 2 - Eye Irrit. 2; H319
Hazardous to the Aquatic Environment (Acute), Category 1 - Aquatic Acute 1; H400
Hazardous to the Aquatic Environment (Chronic), Category 2 - Aquatic Chronic 2; H411

For full text of H phrases, see Section 16.

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

SIGNAL WORD
WARNING.

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

Pictograms

HAZARD STATEMENTS:

H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.

PRECAUTIONARY STATEMENTS

Prevention:

P273	Avoid release to the environment.

Response:

P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Disposal:

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

Notes on labelling

H317 does not apply due to test data.

2.3. Other hazards

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

SECTION 3: Composition/information on ingredients

Ingredient	CAS Nbr	EC No.	% by Wt	Classification
Polyether	110531-92-5		50 - 70	Eye Irrit. 2, H319
Diatomaceous earth	68855-54-9	272-489-0	10 - 30	STOT RE 2, H373
Fatty acid esters	67701-27-3	266-945-8	10 - 20	Substance not classified as hazardous
Aromatic hydrocarbon	26898-17-9	248-097-0	1 - 20	Aquatic Chronic 1, H410,M=1
Diatomaceous earth	68855-54-9	272-489-0	1 - 20	STOT RE 1, H372
Pigment	1345-05-7	215-715-5	< 5	Substance with a Community level exposure limit in the workplace
Laurylimidazole (REACH Reg. No.:01-2120068170-65)	4303-67-7	224-314-4	< 1	Aquatic Acute 1, H400,M=100; Aquatic Chronic 1, H410,M=10 Acute Tox. 4, H302; Eye Irrit. 2, H319; Skin Sens. 1A, H317

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

5.3. Advice for fire-fighters
Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing

apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Evacuate area. Ventilate the area with fresh air. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapours, in accordance with good industrial hygiene practice. Refer to other sections of this SIS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

6.2. Environmental precautions
Avoid release to the environment.

6.3. Methods and material for containment and cleaning up
Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue. Seal the container. Dispose of collected material as soon as possible.

SECTION 7: Handling and storage

Refer to Instructions for Use (IFU) for more information.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits
If a component is disclosed in section 3 but does not appear in the table below, an occupational exposure limit is not available for the component.

Ingredient	CAS Nbr	Agency	Limit type	Additional comments
Barium, soluable compounds	1345-05-7	UK HSC	TWA(as Ba):0.5 mg/m3	
Silicon dioxide	68855-54-9	UK HSC	TWA(as inhalable dust):6 mg/m3;TWA(as respirable dust):2.4 mg/m3	
Quartz	68855-54-9	UK HSC	TWA(respirable):0.1 mg/m3	

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

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

8.2. Exposure controls

8.2.1. Engineering controls
Use in a well-ventilated area.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

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

Safety glasses with side shields.

Skin/hand protection
No protective gloves required. 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	Grey
Specific Physical Form:	Paste
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	Flash point > 93 °C (200 °F)
Autoignition temperature	*No data available.*
Flammable Limits(LEL)	*Not applicable.*
Flammable Limits(UEL)	*Not applicable.*
Relative density	> 1 [*Ref Std:*WATER=1]
Water solubility	Negligible
Viscosity	*No data available.*
Density	1 - 1.2 g/cm3

9.2. Other information

EU Volatile Organic Compounds	*No data available.*
Percent volatile	*No data available.*

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.

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	Rat	LD50 > 2,000 mg/kg
Polyether	Dermal	Professional judgement	LD50 Not applicable
Polyether	Ingestion	Rat	LD50 > 2,000 mg/kg
Aromatic hydrocarbon	Dermal	Rabbit	LD50 > 2,000 mg/kg
Aromatic hydrocarbon	Ingestion	Rat	LD50 > 10,360 mg/kg
Fatty acid esters	Dermal	Rabbit	LD50 > 2,000 mg/kg
Fatty acid esters	Ingestion	Rat	LD50 > 2,000 mg/kg
Diatomaceous earth	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Diatomaceous earth	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 2.7 mg/l
Diatomaceous earth	Ingestion	Rat	LD50 > 2,000 mg/kg
Pigment	Ingestion	Rat	LD50 > 15,000 mg/kg
Pigment	Dermal	similar compounds	LD50 > 1,000 mg/kg

Pigment	Inhalation-Dust/Mist (4 hours)	similar compounds	LC50 > 2.52 mg/l
Laurylimidazole	Ingestion	Rat	LD50 641 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Polyether	Rabbit	No significant irritation
Diatomaceous earth	In vitro data	No significant irritation
Laurylimidazole	Rabbit	Mild irritant

Serious Eye Damage/Irritation

Name	Species	Value
Polyether	Rabbit	Moderate irritant
Diatomaceous earth	Rabbit	Mild irritant
Laurylimidazole	In vitro data	Severe irritant

Skin Sensitisation

Name	Species	Value
Overall product	Guinea pig	Not classified
Polyether	Guinea pig	Not classified
Diatomaceous earth	Mouse	Not classified
Laurylimidazole	Mouse	Sensitising

Respiratory Sensitisation

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

Germ Cell Mutagenicity

Name	Route	Value
Polyether	In Vitro	Not mutagenic
Diatomaceous earth	In Vitro	Some positive data exist, but the data are not sufficient for classification
Laurylimidazole	In Vitro	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
Diatomaceous earth	Inhalation	Human and animal	Carcinogenic.

Reproductive Toxicity

Reproductive and/or Developmental Effects

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

Target Organ(s)

Specific Target Organ Toxicity - single exposure

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

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Diatomaceous earth	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
Diatomaceous earth	Ingestion	hematopoietic system | eyes | kidney and/or	Not classified	Rat	NOAEL 3,738 mg/kg/day	90 days

		bladder				

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
Polyether	110531-92-5		Data not available or insufficient for classification			
Diatomaceous earth	68855-54-9		Data not available or insufficient for classification			
Aromatic hydrocarbon	26898-17-9	Water flea	Experimental	48 hours	EC50	>100 mg/l
Aromatic hydrocarbon	26898-17-9	Zebra Fish	Experimental	96 hours	Lethal Level 50%	>100 mg/l
Aromatic hydrocarbon	26898-17-9	Diatom	Experimental	72 hours	NOEC	>100 mg/l
Aromatic hydrocarbon	26898-17-9	Water flea	Experimental	21 days	NOEC	0.03 mg/l
Diatomaceous earth	68855-54-9		Data not available or insufficient for classification			
Fatty acid esters	67701-27-3	Green algae	Estimated	72 hours	EC50	>100 mg/l
Fatty acid esters	67701-27-3	Water flea	Estimated	48 hours	EC50	>100 mg/l
Fatty acid esters	67701-27-3	Zebra Fish	Estimated	96 hours	LC50	>100 mg/l
Fatty acid esters	67701-27-3	Green algae	Estimated	72 hours	NOEC	>100 mg/l
Fatty acid esters	67701-27-3	Water flea	Estimated	21 days	NOEC	>100 mg/l
Pigment	1345-05-7	Fish other	Estimated	96 hours	LC50	>100 mg/l
Pigment	1345-05-7	Water flea	Estimated	48 hours	EC50	970 mg/l
Laurylimidazole	4303-67-7	Green Algae	Experimental	72 hours	EC50	0.00557 mg/l
Laurylimidazole	4303-67-7	Water flea	Experimental	48 hours	EC50	>100 mg/l
Laurylimidazole	4303-67-7	Green algae	Experimental	72 hours	Effect Concentration 10%	0.0021 mg/l

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Polyether	110531-92-5	Data not availbl-insufficient			N/A	
Diatomaceous earth	68855-54-9	Data not availbl-insufficient			N/A	
Aromatic hydrocarbon	26898-17-9	Experimental Biodegradation	28 days	BOD	0 % BOD/ThBOD	OECD 301C - MITI test (I)
Diatomaceous earth	68855-54-9	Data not availbl-insufficient			N/A	
Fatty acid esters	67701-27-3	Estimated Biodegradation	28 days	BOD	79 % BOD/ThBOD	OECD 301F - Manometric respirometry
Pigment	1345-05-7	Data not availbl-insufficient			N/A	
Laurylimidazole	4303-67-7	Experimental Biodegradation	28 days	CO2 evolution	2-3 % weight	OECD 301B - Modified sturm or CO2

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Polyether	110531-92-5	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Diatomaceous earth	68855-54-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Aromatic hydrocarbon	26898-17-9	Experimental BCF-Carp	60 days	Bioaccumulation factor	23000	OECD 305E - Bioaccumulation flow-through fish test
Diatomaceous earth	68855-54-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Fatty acid esters	67701-27-3	Estimated Bioconcentration		Bioaccumulation factor	7.4	Other methods
Pigment	1345-05-7	Estimated BCF-Carp	56 days	Bioaccumulation factor	<217	Other methods
Laurylimidazole	4303-67-7	Estimated Bioconcentration		Bioaccumulation factor	3090	Estimated: Bioconcentration factor

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

70-2011-3764-6

70-2011-3766-1

UU-0098-0446-7

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.
H319	Causes serious eye irritation.
H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

Revision information:
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