



Safety Information Sheet for Medical Devices

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Document group:	16-2600-1	Version number:	2.00
Revision date:	27/07/2020	Supersedes date:	20/07/2020

Transportation version number: 1.00 (27/07/2020)

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™ Impregum™ F, Refill (31710, 31712, 31722, 31723)

Product Identification Numbers

70-2011-1595-6

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 by dental professionals 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. 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:

16-2599-5, 16-2598-7

TRANSPORTATION INFORMATION

70-2011-1595-6

Component 1

ADR/RID: UN3077, NOT RESTRICTED AS PER SPECIAL PROVISION 375, ENVIRONMENTALLY HAZARDOUS SUBSTANCE EXEMPTION, DIBENZYL TOLUENE, 1-DODECYLIMIDAZOLE REQUIRED, III, --.

IMDG-CODE: UN3077, NOT RESTRICTED AS PER IMDG CODE 2.10.2.7, MARINE POLLUTANT EXCEPTION, DIBENZYL TOLUENE, 1-DODECYLIMIDAZOLE REQUIRED, III, IMDG-Code segregation code: NONE, EMS: --.

ICAO/IATA: UN3077, NOT RESTRICTED AS PER SPECIAL PROVISION A197, ENVIRONMENTALLY HAZARDOUS SUBSTANCE EXEMPTION, DIBENZYL TOLUENE, 1-DODECYLIMIDAZOLE REQUIRED, III.

Component 2

ADR/RID: UN3077, NOT RESTRICTED AS PER SPECIAL PROVISION 375, ENVIRONMENTALLY HAZARDOUS SUBSTANCE EXEMPTION, (CITRIC ESTER), III, --.

IMDG-CODE: UN3077, NOT RESTRICTED AS PER IMDG CODE 2.10.2.7, MARINE POLLUTANT EXCEPTION, (CITRIC ESTER), III, IMDG-Code segregation code: NONE, EMS: --.

ICAO/IATA: UN3077, NOT RESTRICTED AS PER SPECIAL PROVISION A197, ENVIRONMENTALLY HAZARDOUS SUBSTANCE EXEMPTION, (CITRIC ESTER), III.

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:	16-2598-7	Version number:	2.00
Revision date:	29/06/2021	Supersedes date:	23/10/2019

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™ Impregum™ F Base (31503, 31504)

Product Identification Numbers

70-2011-3764-6	70-2011-3766-1	UU-0098-0446-7	UU-0104-3643-2
7000129148	7000055130	7100196212	7100215415

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

The health and environmental classifications of this material have been derived using the calculation method, except in cases where test data are available or the physical form impacts classification. Classification(s) based on test data or physical form are noted below, if applicable.

The aspiration hazard classification is not required due to the product's physical form.

The silicosis target organ toxicity classification is not applied because there is no potential for inhalation exposure.

This product is a medical device as defined in Directive 93/42/EEC (MDD) respectively Regulation (EU) 2017/745 (MDR), which is invasive or used in direct physical contact with the human body, and therefore is exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). Although not required, the classification and label information, as applicable, is provided below.

CLASSIFICATION:

Serious Eye Damage/Eye Irritation, Category 2 - Eye Irrit. 2; H319

Skin Sensitization, Category 1A - Skin Sens. 1A; H317

Reproductive Toxicity, Category 1B - Repr. 1B; H360

Hazardous to the Aquatic Environment (Acute), Category 1 - Aquatic Acute 1; H400

Hazardous to the Aquatic Environment (Chronic), Category 1 - Aquatic Chronic 1; H410

For full text of H phrases, see Section 16.

2.2. Label elements

CLP REGULATION (EC) No 1272/2008

SIGNAL WORD

DANGER.

Symbols

GHS07 (Exclamation mark) | GHS08 (Health Hazard) | GHS09 (Environment) |

Pictograms



Ingredients:

Ingredient	CAS Nbr	EC No.	% by Wt
Aromatic hydrocarbon	53585-53-8	258-649-2	5 - 15
Limonene	5989-27-5	227-813-5	< 0.2
Laurylimidazole	4303-67-7	224-314-4	< 1

HAZARD STATEMENTS:

H319	Causes serious eye irritation.
H317	May cause an allergic skin reaction.
H360FD	May damage fertility. May damage the unborn child.
H410	Very toxic to aquatic life with long lasting effects.

PRECAUTIONARY STATEMENTS

Prevention:

P201	Obtain special instructions before use.
P273	Avoid release to the environment.
P280E	Wear protective gloves.

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.
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P308 + P313

IF exposed or concerned: Get medical advice/attention.

P333 + P313

If skin irritation or rash occurs: Get medical advice/attention.

SUPPLEMENTAL INFORMATION:**Supplemental Precautionary Statements:**

Restricted to professional users.

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**3.1. Substances**

Not applicable

3.2. Mixtures

Ingredient	Identifier(s)	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Polyether	(CAS-No.) 110531-92-5	50 - 70	Eye Irrit. 2, H319
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	(CAS-No.) 68855-54-9 (EC-No.) 272-489-0	10 - 30	STOT RE 2, H373
Fatty acids ester	(CAS-No.) 67701-27-3 (EC-No.) 266-945-8	10 - 20	Substance not classified as hazardous
Aromatic hydrocarbon	(CAS-No.) 53585-53-8 (EC-No.) 258-649-2	5 - 15	Asp. Tox. 1, H304 Repr. 1B, H360FD Aquatic Acute 1, H400,M=10 Aquatic Chronic 1, H410,M=10
Limonene	(CAS-No.) 5989-27-5 (EC-No.) 227-813-5	< 0.2	Flam. Liq. 3, H226 Skin Irrit. 2, H315 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Acute 1, H400,M=1 Aquatic Chronic 1, H410 Aquatic Chronic 1, H410,M=1 Nota C Asp. Tox. 1, H304
Laurylimidazole (REACH Reg. No.:01-2120068170-65)	(CAS-No.) 4303-67-7 (EC-No.) 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

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

Eye contact

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

If swallowed

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

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

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

5.2. Special hazards arising from the substance or mixture

None inherent in this product.

Hazardous Decomposition or By-Products**Substance**

Carbon monoxide
Carbon dioxide.
Irritant vapours or gases.

Condition

During combustion.
During combustion.
During combustion.

5.3. Advice for fire-fighters

Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

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

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

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

SECTION 7: Handling and storage

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

SECTION 8: Exposure controls/personal protection**8.1 Control parameters**

Occupational exposure limits

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

Ingredient	CAS Nbr	Agency	Limit type	Additional comments
Silicon dioxide	68855-54-9	UK HSC	TWA(as respirable dust):2.4 mg/m ³ ;TWA(as inhalable dust):6 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

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**

Physical state	Solid.
Specific Physical Form:	Paste
Colour	Grey
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	Flash point > 93 °C (200 °F)
Autoignition temperature	<i>No data available.</i>
Relative density	> 1 [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 g/cm ³ - 1.2 g/cm ³

9.2. Other information

9.2.2 Other safety characteristics

EU Volatile Organic Compounds

No data available.

Evaporation rate

Not applicable.

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

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

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

The information below may not agree with the EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 11 are based on UN GHS calculation rules and classifications derived from internal hazard assessments.

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Signs and Symptoms of Exposure

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

Inhalation

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

Skin contact

Mild Skin Irritation: Signs/symptoms may include localised redness, swelling, itching, and dryness. Allergic skin reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, and itching.

Eye contact

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:**Reproductive/Developmental Toxicity:**

Contains a chemical or chemicals which can cause birth defects or other reproductive harm.

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
Polyether	Dermal	Professional judgement	LD50 Not applicable
Polyether	Ingestion	Rat	LD50 > 2,000 mg/kg
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 2.7 mg/l
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Ingestion	Rat	LD50 > 2,000 mg/kg
Aromatic hydrocarbon	Dermal	Rat	LD50 > 2,000 mg/kg
Aromatic hydrocarbon	Ingestion	Rat	LD50 > 10,360 mg/kg
Fatty acids ester	Dermal	Rabbit	LD50 > 2,000 mg/kg
Fatty acids ester	Ingestion	Rat	LD50 > 2,000 mg/kg
Laurylimidazole	Ingestion	Rat	LD50 641 mg/kg
Limonene	Inhalation-Vapour (4 hours)	Mouse	LC50 > 3.14 mg/l
Limonene	Dermal	Rabbit	LD50 > 5,000 mg/kg
Limonene	Ingestion	Rat	LD50 4,400 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Polyether	Rabbit	No significant irritation
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	In vitro data	No significant irritation
Aromatic hydrocarbon	Rabbit	Mild irritant
Laurylimidazole	Rabbit	Mild irritant
Limonene	Rabbit	Mild irritant

Serious Eye Damage/Irritation

Name	Species	Value
Polyether	Rabbit	Moderate irritant
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Rabbit	Mild irritant
Aromatic hydrocarbon	Rabbit	No significant irritation
Laurylimidazole	In vitro data	Severe irritant
Limonene	Rabbit	Mild irritant

Skin Sensitisation

Name	Species	Value
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Polyether	Guinea pig	Not classified
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Mouse	Not classified
Aromatic hydrocarbon	Guinea pig	Not classified
Laurylimidazole	Mouse	Sensitising
Limonene	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 (respirable cristobalite fraction 1-<10%)	In Vitro	Some positive data exist, but the data are not sufficient for classification
Aromatic hydrocarbon	In Vitro	Not mutagenic
Aromatic hydrocarbon	In vivo	Not mutagenic
Laurylimidazole	In Vitro	Not mutagenic
Limonene	In Vitro	Not mutagenic
Limonene	In vivo	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Inhalation	Human and animal	Carcinogenic.
Limonene	Ingestion	Rat	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
Aromatic hydrocarbon	Ingestion	Toxic to male reproduction	Rat	NOAEL 250 mg/kg/day	28 days
Aromatic hydrocarbon	Ingestion	Toxic to female reproduction	Rat	NOAEL 250 mg/kg/day	premating into lactation
Aromatic hydrocarbon	Ingestion	Toxic to development	Rabbit	LOAEL 10 mg/kg/day	during gestation
Limonene	Ingestion	Not classified for female reproduction	Rat	NOAEL 750 mg/kg/day	premating & during gestation
Limonene	Ingestion	Not classified for development	Multiple animal species	NOAEL 591 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
Aromatic hydrocarbon	Inhalation	respiratory irritation	Some positive data exist, but the data are not sufficient for classification	similar health hazards	NOAEL not available	
Limonene	Ingestion	nervous system	Not classified		NOAEL Not available	

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
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Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Inhalation	silicosis	Causes damage to organs through prolonged or repeated exposure	Human	NOAEL Not available	occupational exposure
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Ingestion	hematopoietic system eyes kidney and/or bladder	Not classified	Rat	NOAEL 3,738 mg/kg/day	90 days
Aromatic hydrocarbon	Ingestion	liver kidney and/or bladder heart skin endocrine system gastrointestinal tract bone, teeth, nails, and/or hair hematopoietic system immune system muscles nervous system eyes respiratory system vascular system	Not classified	Rat	NOAEL 500 mg/kg/day	120 days
Limonene	Ingestion	kidney and/or bladder	Not classified	Rat	LOAEL 75 mg/kg/day	103 weeks
Limonene	Ingestion	liver	Not classified	Mouse	NOAEL 1,000 mg/kg/day	103 weeks
Limonene	Ingestion	heart endocrine system bone, teeth, nails, and/or hair hematopoietic system immune system muscles nervous system respiratory system	Not classified	Rat	NOAEL 600 mg/kg/day	103 weeks

Aspiration Hazard

Name	Value
Aromatic hydrocarbon	Aspiration hazard
Limonene	Aspiration hazard

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 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			N/A
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	68855-54-9		Data not available or insufficient for classification			N/A
Fatty acids ester	67701-27-3	Green algae	Estimated	72 hours	EC50	>100 mg/l

Fatty acids ester	67701-27-3	Water flea	Estimated	48 hours	EC50	>100 mg/l
Fatty acids ester	67701-27-3	Zebra Fish	Estimated	96 hours	LC50	>100 mg/l
Fatty acids ester	67701-27-3	Green algae	Estimated	72 hours	NOEC	100 mg/l
Fatty acids ester	67701-27-3	Water flea	Estimated	21 days	NOEC	100 mg/l
Aromatic hydrocarbon	53585-53-8	Bacteria	Experimental	4.92 hours	EC10	>1,000 mg/l
Aromatic hydrocarbon	53585-53-8	Copepods	Experimental	48 hours	LC50	>0.0206 mg/l
Aromatic hydrocarbon	53585-53-8	Green algae	Experimental	96 hours	EC50	0.019 mg/l
Aromatic hydrocarbon	53585-53-8	Water flea	Experimental	48 hours	EC50	>0.029 mg/l
Aromatic hydrocarbon	53585-53-8	Zebra Fish	Experimental	96 hours	No tox obs at lmt of water sol	>100 mg/l
Aromatic hydrocarbon	53585-53-8	Green algae	Experimental	96 hours	EC10	0.006 mg/l
Aromatic hydrocarbon	53585-53-8	Water flea	Experimental	21 days	NOEC	0.03 mg/l
Limonene	5989-27-5	Fathead minnow	Experimental	96 hours	LC50	0.702 mg/l
Limonene	5989-27-5	Green Algae	Experimental	72 hours	EC50	0.32 mg/l
Limonene	5989-27-5	Water flea	Experimental	48 hours	EC50	0.307 mg/l
Limonene	5989-27-5	Green Algae	Experimental	72 hours	EC10	0.174 mg/l
Limonene	5989-27-5	Water flea	Experimental	21 days	NOEC	0.08 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	EC10	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 (respirable cristobalite fraction 1-<10%)	68855-54-9	Data not availbl-insufficient			N/A	
Fatty acids ester	67701-27-3	Estimated Biodegradation	28 days	BOD	79 % BOD/ThBOD	OECD 301F - Manometric respirometry
Aromatic hydrocarbon	53585-53-8	Experimental Biodegradation	28 days	BOD	0.5 % BOD/ThBOD	OECD 301D - Closed bottle test
Limonene	5989-27-5	Experimental Biodegradation	14 days	BOD	98 % BOD/ThBOD	OECD 301C - MITI test (I)
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 (respirable cristobalite fraction 1-<10%)	68855-54-9	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

Fatty acids ester	67701-27-3	Estimated Bioconcentration		Bioaccumulation factor	7.4	Non-standard method
Aromatic hydrocarbon	53585-53-8	Experimental BCF-Carp	56 days	Bioaccumulation factor	6300	OECD 305E - Bioaccumulation flow-through fish test
Limonene	5989-27-5	Estimated Bioconcentration		Bioaccumulation factor	2100	Estimated: Bioconcentration factor
Laurylimidazole	4303-67-7	Estimated Bioconcentration		Bioaccumulation factor	3090	Estimated: Bioconcentration factor

12.4. Mobility in soil

Material	Cas No.	Test type	Study Type	Test result	Protocol
Fatty acids ester	67701-27-3	Estimated Mobility in Soil	Koc	10,000,000,000 l/kg	Episuite™
Aromatic hydrocarbon	53585-53-8	Experimental Mobility in Soil	Koc	35,300 l/kg	OECD 121 Estim. of Koc by HPLC

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. Endocrine disrupting properties

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

12.7. 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

Excepted quantity

	Ground Transport (ADR)	Air Transport (IATA)	Marine Transport (IMDG)
14.1 UN number	UN3077	UN3077	UN3077
14.2 UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (AROMATIC HYDROCARBON; LAURYLIMIDAZOLE)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (AROMATIC HYDROCARBON; LAURYLIMIDAZOLE)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (AROMATIC HYDROCARBON; LAURYLIMIDAZOLE)

14.3 Transport hazard class(es)	9	9	9
14.4 Packing group	III	III	III
14.5 Environmental hazards	Not Environmentally Hazardous	Not applicable	Not a Marine Pollutant
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 Tunnel Code	(-)	Not applicable.	Not applicable.
ADR Classification Code	M7	Not applicable.	Not applicable.
ADR Transport Category	4	Not applicable.	Not applicable.
ADR Multiplier	0	0	0
IMDG Segregation Code	Not applicable.	Not applicable.	NONE

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

H226	Flammable liquid and vapour.
H302	Harmful if swallowed.
H304	May be fatal if swallowed and enters airways.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H360FD	May damage fertility. May damage the unborn child.
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.

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



Safety Information Sheet for Medical Devices

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Document group:	16-2599-5	Version number:	1.00
Revision date:	23/10/2019	Supersedes date:	Initial issue.
Transportation version number: 1.00 (23/10/2019)			

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™ IMPREGUM F Catalyst

Product Identification Numbers

70-2011-3070-8	70-2011-3763-8	70-2011-3765-3	UU-0098-0445-9	UU-0098-0509-2
7000129147	7000055129	7100196211	7100196275	

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 in approved indications.

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:

Skin Sensitization, Category 1B - Skin Sens. 1B; H317

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) |

Pictograms**Ingredients:**

Ingredient	CAS Nbr	EC No.	% by Wt
Sulfonium salt	72140-65-9	276-380-9	20 - 40

HAZARD STATEMENTS:

H317 May cause an allergic skin reaction.

PRECAUTIONARY STATEMENTS**Prevention:**

P280E Wear protective gloves.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

Notes on labelling

H373 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
Citric acid ester	77-90-7	201-067-0	20 - 40	Substance not classified as hazardous
Sulfonium salt	72140-65-9	276-380-9	20 - 40	Acute Tox. 4, H302; Skin Sens. 1B, H317; Repr. 2, H361f; STOT RE 1, H372

Silane treated silica	68909-20-6	272-697-1	10 - 30	Substance with a Community level exposure limit in the workplace
Diatomaceous earth	68855-54-9	272-489-0	1 - 20	STOT RE 2, H373
Polyglycol	9003-11-6		1 - 10	Substance not classified as hazardous

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

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation

Remove person to fresh air. If you feel unwell, get medical attention.

Skin contact

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

Eye contact

No need for first aid is anticipated.

If swallowed

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

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

None inherent in this product.

Hazardous Decomposition or By-Products

Substance

Carbon monoxide.
Carbon dioxide.
Irritant vapours or gases.

Condition

During combustion.
During combustion.
During combustion.

5.3. Advice for fire-fighters

Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Evacuate area. Ventilate the area with fresh air. For large spill, or spills in confined spaces, provide mechanical ventilation to disperse or exhaust vapours, in accordance with good industrial hygiene practice. Refer to other

sections of this SIS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

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

SECTION 7: Handling and storage

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

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

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

Ingredient	CAS Nbr	Agency	Limit type	Additional comments
Silicon dioxide	68855-54-9	UK HSC	TWA(as inhalable dust):6 mg/m ³ ;TWA(as respirable dust):2.4 mg/m ³	
Quartz	68855-54-9	UK HSC	TWA(respirable):0.1 mg/m ³	
Silicon dioxide	68909-20-6	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

Dark Red

Specific Physical Form:

Paste

Odor

Slight Acrid

pH*Not applicable.***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 - 1.4 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

None known.

Condition

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

The information below may not agree with the EU material classification in Section 2 and/or the ingredient classifications in Section 3 if specific ingredient classifications are mandated by a competent authority. In addition, statements and data presented in Section 11 are based on UN GHS calculation rules and classifications derived from 3M assessments.

11.1 Information on Toxicological effects

Signs and Symptoms of Exposure

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

Inhalation

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

Skin contact

Mild Skin Irritation: Signs/symptoms may include localised redness, swelling, itching, and dryness. Allergic skin reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, and itching.

Eye contact

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

Ingestion

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	Ingestion	Rat	LD50 > 2,000 mg/kg
Sulfonium salt	Dermal	Rat	LD50 > 2,000 mg/kg
Sulfonium salt	Ingestion	Rat	LD50 300-2,000 mg/kg
Citric acid ester	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Citric acid ester	Ingestion	Rat	LD50 > 25,000 mg/kg
Silane treated silica	Dermal	Rabbit	LD50 > 5,000 mg/kg

Silane treated silica	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 0.691 mg/l
Silane treated silica	Ingestion	Rat	LD50 > 5,110 mg/kg
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
Polyglycol	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Polyglycol	Ingestion	Rat	LD50 5,700 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Sulfonium salt	Rabbit	Mild irritant
Silane treated silica	Rabbit	No significant irritation
Diatomaceous earth	In vitro data	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Sulfonium salt	Rabbit	Mild irritant
Silane treated silica	Rabbit	No significant irritation
Diatomaceous earth	Rabbit	Mild irritant

Skin Sensitisation

Name	Species	Value
Sulfonium salt	Mouse	Sensitising
Silane treated silica	Human and animal	Not classified
Diatomaceous earth	Mouse	Not classified

Respiratory Sensitisation

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

Germ Cell Mutagenicity

Name	Route	Value
Sulfonium salt	In Vitro	Not mutagenic
Silane treated silica	In Vitro	Not mutagenic
Diatomaceous earth	In Vitro	Some positive data exist, but the data are not sufficient for classification

Carcinogenicity

Name	Route	Species	Value
Silane treated silica	Not specified.	Mouse	Some positive data exist, but the data are not sufficient for classification
Diatomaceous earth	Inhalation	Human and animal	Carcinogenic.

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test result	Exposure Duration
Sulfonium salt	Ingestion	Not classified for development	Rat	NOAEL 100 mg/kg/day	premating into lactation
Sulfonium salt	Ingestion	Toxic to female reproduction	Rat	NOAEL 30 mg/kg/day	premating into lactation
Sulfonium salt	Ingestion	Toxic to male reproduction	Rat	NOAEL 30 mg/kg/day	30 days
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

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Sulfonium salt	Ingestion	respiratory system	Not classified	Rat	NOAEL 300 mg/kg	

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test result	Exposure Duration
Sulfonium salt	Ingestion	bone marrow	Causes damage to organs through prolonged or repeated exposure	Rat	NOAEL 10 mg/kg/day	30 days
Sulfonium salt	Ingestion	respiratory system	May cause damage to organs though prolonged or repeated exposure	Rat	NOAEL 30 mg/kg/day	30 days
Sulfonium salt	Ingestion	eyes	May cause damage to organs though prolonged or repeated exposure	Rat	NOAEL 100 mg/kg/day	30 days
Sulfonium salt	Ingestion	hematopoietic system liver immune system kidney and/or bladder	Not classified	Rat	NOAEL 300 mg/kg/day	30 days
Sulfonium salt	Ingestion	gastrointestinal tract	Not classified	Rat	NOAEL 30 mg/kg/day	30 days
Sulfonium salt	Ingestion	auditory system heart skin endocrine system bone, teeth, nails, and/or hair muscles nervous system vascular system	Not classified	Rat	NOAEL 300 mg/kg/day	30 days
Silane treated silica	Inhalation	respiratory system silicosis	Not classified	Human	NOAEL Not available	occupational exposure
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 bladder	Not classified	Rat	NOAEL 3,738 mg/kg/day	90 days

Aspiration Hazard

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

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

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

SECTION 12: Ecological information

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

12.1. Toxicity

No product test data available.

Material	CAS #	Organism	Type	Exposure	Test endpoint	Test result
Citric acid ester	77-90-7	Bluegill	Experimental	96 hours	LC50	>=38 mg/l
Citric acid ester	77-90-7	Green algae	Experimental	72 hours	EC50	74.4 mg/l
Citric acid ester	77-90-7	Water flea	Experimental	48 hours	EC50	7.82 mg/l
Citric acid ester	77-90-7	Green algae	Experimental	72 hours	NOEC	4.65 mg/l
Citric acid ester	77-90-7	Water flea	Experimental	21 days	NOEC	>1.11 mg/l
Sulfonium salt	72140-65-9	Green Algae	Estimated	72 hours	No tox obs at lmt of water sol	>100 mg/l
Sulfonium salt	72140-65-9	Water flea	Estimated	48 hours	No tox obs at lmt of water sol	>100 mg/l
Sulfonium salt	72140-65-9	Zebra Fish	Estimated	96 hours	No tox obs at lmt of water sol	>100 mg/l
Sulfonium salt	72140-65-9	Green Algae	Estimated	72 hours	No tox obs at lmt of water sol	>100 mg/l
Silane treated silica	68909-20-6	Algae	Estimated	72 hours	EC50	>100 mg/l
Diatomaceous earth	68855-54-9		Data not available or insufficient for classification			
Polyglycol	9003-11-6		Data not available or insufficient for classification			

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Citric acid ester	77-90-7	Experimental Biodegradation	28 days	BOD	48 % weight	Other methods
Sulfonium salt	72140-65-9	Experimental Hydrolysis		Hydrolytic half-life	2.08 hours (t 1/2)	Other methods
Silane treated silica	68909-20-6	Data not availbl-insufficient			N/A	
Diatomaceous earth	68855-54-9	Data not availbl-insufficient			N/A	
Polyglycol	9003-11-6	Data not availbl-insufficient			N/A	

12.3 : Bioaccumulative potential

Material	Cas No.	Test type	Duration	Study Type	Test result	Protocol
Citric acid ester	77-90-7	Estimated Bioconcentration		Bioaccumulation factor	5.1	Estimated: Bioconcentration factor
Sulfonium salt	72140-65-9	Experimental Bioconcentration		Log Kow	≤0.75	Other methods
Silane treated silica	68909-20-6	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
Polyglycol	9003-11-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

12.4. Mobility in soil

Please contact manufacturer for more details

12.5. Results of the PBT and vPvB assessment

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

12.6. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose of contents/ container in accordance with the local/regional/national/international regulations.

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

EU waste code (product as sold)

180106* Chemicals consisting of or containing dangerous substances.

SECTION 14: Transportation information

70-2011-3070-8, 70-2011-3763-8, 70-2011-3765-3

Not hazardous for transportation

UU-0098-0445-9

UU-0098-0509-2

SECTION 15: Regulatory information

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

Global inventory status

Contact the manufacturer for more information

SECTION 16: Other information

List of relevant H statements

H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H361f	Suspected of damaging fertility.
H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.

Revision information:

Revision information not available

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

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