



## 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™ PERMADYNE Light Body Consistency Base / PERMADYNE PENTA L Base

#### Product Identification Numbers

LE-F100-2616-9      LE-FSFD-3001-0

#### 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.

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	10 - 17
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.  
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	60 - 80	Eye Irrit. 2, H319
Fatty acids ester	(CAS-No.) 67701-27-3 (EC-No.) 266-945-8	1 - 20	Substance not classified as hazardous
Aromatic hydrocarbon	(CAS-No.) 53585-53-8 (EC-No.) 258-649-2	10 - 17	Asp. Tox. 1, H304 Repr. 1B, H360FD Aquatic Acute 1, H400,M=10 Aquatic Chronic 1, H410,M=10
Polyglycol	(CAS-No.) 9003-11-6	< 5	Substance not classified as hazardous
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	(CAS-No.) 68855-54-9 (EC-No.) 272-489-0	< 5	STOT RE 2, H373
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,M=1 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
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Silicon dioxide	68855-54-9	UK HSC	TWA(as respirable dust):2.4 mg/m <sup>3</sup> ;TWA(as inhalable dust):6 mg/m <sup>3</sup>
Quartz	68855-54-9	UK HSC	TWA(respirable):0.1 mg/m <sup>3</sup>

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	Orange
Odor	Characteristic Odour
Melting point/freezing point	<i>No data available.</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	<i>No data available.</i>

### 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.

### Carcinogenicity:

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

Contains a chemical or chemicals which can cause cancer.

### Toxicological Data

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

### Acute Toxicity

Name	Route	Species	Value
Overall product	Dermal		No data available; calculated ATE >5,000 mg/kg
Overall product	Ingestion		No data available; calculated ATE >5,000 mg/kg
Polyether	Dermal	Professional judgement	LD50 Not applicable
Polyether	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
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
Polyglycol	Dermal	Professional judgement	LD50 estimated to be > 5,000 mg/kg
Polyglycol	Ingestion	Rat	LD50 5,700 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
Aromatic hydrocarbon	Rabbit	Mild irritant
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	In vitro data	No significant irritation
Laurylimidazole	Rabbit	Mild irritant
Limonene	Rabbit	Mild irritant

### Serious Eye Damage/Irritation

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

Laurylimidazole	In vitro data	Severe irritant
Limonene	Rabbit	Mild irritant

### Skin Sensitisation

Name	Species	Value
Polyether	Guinea pig	Not classified
Aromatic hydrocarbon	Guinea pig	Not classified
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	Mouse	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
Aromatic hydrocarbon	In Vitro	Not mutagenic
Aromatic hydrocarbon	In vivo	Not mutagenic
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	In Vitro	Some positive data exist, but the data are not sufficient for classification
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	prematuring 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	prematuring & 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
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
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
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
Fatty acids ester	67701-27-3	Green algae	Estimated	72 hours	EC50	>100 mg/l

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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
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	68855-54-9		Data not available or insufficient for classification			N/A
Polyglycol	9003-11-6		Data not available or insufficient for classification			N/A
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	
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
Diatomaceous earth (respirable cristobalite fraction 1-<10%)	68855-54-9	Data not availbl-insufficient			N/A	
Polyglycol	9003-11-6	Data not availbl-insufficient			N/A	
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

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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
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
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
Polyglycol	9003-11-6	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
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

Not hazardous for transportation.

	Ground Transport (ADR)	Air Transport (IATA)	Marine Transport (IMDG)

<b>14.1 UN number</b>	No data available.	No Data Available	No Data Available
<b>14.2 UN proper shipping name</b>	No data available.	No Data Available	No Data Available
<b>14.3 Transport hazard class(es)</b>	No data available.	No Data Available	No Data Available
<b>14.4 Packing group</b>	No data available.	No Data Available	No Data Available
<b>14.5 Environmental hazards</b>	No data available.	No Data Available	No Data Available
<b>14.6 Special precautions for user</b>	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.
<b>14.7 Transport in bulk according to Annex II of Marpol 73/78 and IBC Code</b>	No data available.	No Data Available	No Data Available
<b>Control Temperature</b>	No data available.	No Data Available	No Data Available
<b>Emergency Temperature</b>	No data available.	No Data Available	No Data Available
<b>ADR Tunnel Code</b>	No data available.	Not Applicable	No Data Available
<b>ADR Classification Code</b>	No data available.	No Data Available	No Data Available
<b>ADR Transport Category</b>	No data available.	No Data Available	No Data Available
<b>ADR Multiplier</b>	No data available.	No Data Available	No Data Available
<b>IMDG Segregation Code</b>	No data available.	No Data Available	No Data Available
<b>Transport not Permitted</b>	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**

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](http://www.3M.com/uk)**