# Safety Information Sheet for Medical Devices

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| | | | |
|---|---|---|---|
| **Document group:** | 19-2467-9 | **Version number:** | 1.00 |
| **Revision date:** | 29/04/2020 | **Supersedes date:** | Initial issue. |

**Transportation version number:** 1.00 (29/04/2020)

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™ Penta™ Soft Quick Base

**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 Ireland Limited, The Iveagh Building, The Park, Carrickmines, Dublin 18. |
| **Telephone:** | +353 1 280 3555 |
| **E Mail:** | tox.uk@mmm.com |
| **Website:** | www.3M.com |

**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) 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
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**

**Ingredients:**

| Ingredient | CAS Nbr | EC No. | % by Wt |
|---|---|---|---|
| Laurylimidazole | 4303-67-7 | 224-314-4 | < 0.8 |
| Mint flavor | 90063-97-1 | 290-058-5 | < 0.5 |

**HAZARD STATEMENTS:**

| | |
|---|---|
| H319 | Causes serious eye irritation. |
| H317 | May cause an allergic skin reaction. |
| H400 | Very toxic to aquatic life. |
| H411 | Toxic to aquatic life with long lasting effects. |

**PRECAUTIONARY STATEMENTS**

**Prevention:**

| | |
|---|---|
| P280E | Wear protective gloves. |
| 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. |
| P333 + P313 | If skin irritation or rash occurs: Get medical advice/attention. |

**Disposal:**

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

**Notes on labelling**

H373 not applied based on physical form.

**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 - 60 | Eye Irrit. 2, H319 |
| Fatty acids ester | 67701-27-3 | 266-945-8 | 10 - 20 | Substance not classified as hazardous |
| Aromatic hydrocarbon | 26898-17-9 | 248-097-0 | 5 - 20 | Aquatic Chronic 1, H410,M=1 |
| Diatomaceous earth (respirable cristobalite fraction 1-<10%) (REACH Reg. No.:01-2119488518-22) | 68855-54-9 | 272-489-0 | 1 - 10 | STOT RE 1, H372 |
| Cristobalite | 14464-46-1 | 238-455-4 | 1 - 10 | STOT RE 1, H372 |
| Sulfoneamide | 80-39-7 | 201-275-1 | 1 - 5 | Acute Tox. 4, H302; Aquatic Chronic 3, H412 |
| Pigment | 1345-05-7 | 215-715-5 | < 2 | Substance not classified as hazardous |
| Laurylimidazole | 4303-67-7 | 224-314-4 | < 0.8 | Aquatic Acute 1, H400,M=100; Aquatic Chronic 1, H410,M=10 Acute Tox. 4, H302; Eye Irrit. 2, H319; Skin Sens. 1A, H317 |
| Mint flavor | 90063-97-1 | 290-058-5 | < 0.5 | Aquatic Chronic 2, H411 Acute Tox. 4, H302; Eye Irrit. 2, H319; Skin Sens. 1B, 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 | 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**
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 |
|---|---|---|---|---|
| Quartz | 14464-46-1 | UK HSC | TWA(respirable):0.1 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.

*Applicable Norms/Standards*
Use eye protection conforming to EN 166

**Skin/hand protection**
See Section 7.1 for additional information on skin protection.

**Respiratory protection**
None required.

## SECTION 9: Physical and chemical properties

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

| | |
|---|---|
| **Appearance** | |
| **Physical state** | Solid. |
| **Colour** | Blue |
| **Specific Physical Form:** | Paste |
| **Odor** | 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** | *Not applicable.* |
| **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** | *Not applicable.* |

## SECTION 10: Stability and reactivity

**10.1 Reactivity**
This material is considered to be non reactive under normal use conditions

**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**
May be harmful in contact with skin. Contact with the skin during product use is not expected to result in significant irritation. 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**
May be harmful if swallowed.
Gastrointestinal irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhoea.

**Additional Health Effects:**

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

Contains a chemical or chemicals which can cause cancer.

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

**Acute Toxicity**

| Name | Route | Species | Value |
|---|---|---|---|
| Overall product | Dermal | | No data available; calculated ATE2,000 - 5,000 mg/kg |
| Overall product | Ingestion | | No data available; calculated ATE2,000 - 5,000 mg/kg |
| Polyether | Dermal | Professional judgement | LD50 Not applicable |
| Polyether | Ingestion | Rat | LD50 > 2,000 mg/kg |
| Fatty acids ester | Dermal | Rabbit | LD50 > 2,000 mg/kg |
| Fatty acids ester | 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 |
| Cristobalite | Dermal | | LD50 estimated to be > 5,000 mg/kg |
| Cristobalite | Ingestion | | LD50 estimated to be > 5,000 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 |
| Sulfoneamide | Dermal | Rabbit | LD50 > 5,000 mg/kg |
| Sulfoneamide | Ingestion | similar compounds | LD50 estimated to be 300 - 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 |
| Mint flavor | Dermal | Rabbit | LD50 > 5,000 mg/kg |
| Mint flavor | Ingestion | Rat | LD50 1,240 mg/kg |

ATE = acute toxicity estimate

**Skin Corrosion/Irritation**

| Name | Species | Value |
|---|---|---|
| Polyether | Rabbit | No significant irritation |
| Cristobalite | Professional judgement | No significant irritation |
| Diatomaceous earth (respirable cristobalite fraction 1-<10%) | In vitro data | No significant irritation |
| Laurylimidazole | Rabbit | Mild irritant |
| Mint flavor | Rabbit | Mild irritant |

**Serious Eye Damage/Irritation**

| Name | Species | Value |
|---|---|---|
| Polyether | Rabbit | Moderate irritant |
| Diatomaceous earth (respirable cristobalite fraction 1-<10%) | Rabbit | Mild irritant |
| Laurylimidazole | In vitro data | Severe irritant |
| Mint flavor | In vitro data | Severe irritant |

**Skin Sensitisation**

| Name | Species | Value |
|---|---|---|
| Polyether | Guinea pig | Not classified |

| | | |
|---|---|---|
| Diatomaceous earth (respirable cristobalite fraction 1-<10%) | Mouse | Not classified |
| Laurylimidazole | Mouse | Sensitising |
| Mint flavor | Guinea pig | 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 |
| Cristobalite | In Vitro | Some positive data exist, but the data are not sufficient for classification |
| Cristobalite | In vivo | Some positive data exist, but the data are not sufficient for classification |
| 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 |

**Carcinogenicity**

| Name | Route | Species | Value |
|---|---|---|---|
| Cristobalite | Inhalation | Human and animal | Carcinogenic. |
| Diatomaceous earth (respirable cristobalite fraction 1-<10%) | 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 |
|---|---|---|---|---|---|---|
| Cristobalite | Inhalation | silicosis | Causes damage to organs through prolonged or repeated exposure | Human | NOAEL Not available | occupational exposure |
| 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 |

**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 | | | |
| 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 |
| 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 |
| Cristobalite | 14464-46-1 | | Data not available or insufficient for classification | | | |
| Diatomaceous earth (respirable cristobalite fraction 1-<10%) | 68855-54-9 | | Data not available or insufficient for classification | | | |
| Sulfoneamide | 80-39-7 | Crustacea other | Estimated | 48 hours | EC50 | >=1,000 mg/l |
| Sulfoneamide | 80-39-7 | Rainbow trout | Estimated | 96 hours | LC50 | >=80 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 |
| Mint flavor | 90063-97-1 | | Data not available or insufficient for classification | | | |

### 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 | |
| Aromatic hydrocarbon | 26898-17-9 | Experimental Biodegradation | 28 days | BOD | 0 % BOD/ThBOD | OECD 301C - MITI test (I) |
| Fatty acids ester | 67701-27-3 | Estimated Biodegradation | 28 days | BOD | 79 % BOD/ThBOD | OECD 301F - Manometric respirometry |
| Cristobalite | 14464-46-1 | Data not availbl-insufficient | | | N/A | |
| Diatomaceous earth (respirable cristobalite fraction 1-<10%) | 68855-54-9 | Data not availbl-insufficient | | | N/A | |
| Sulfoneamide | 80-39-7 | Estimated Biodegradation | 28 days | BOD | 25 % weight | OECD 301C - MITI test (I) |

| | | | | | | |
|---|---|---|---|---|---|---|
| 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 |
| Mint flavor | 90063-97-1 | Data not availbl-insufficient | | | NA | |

**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 |
| Aromatic hydrocarbon | 26898-17-9 | Experimental BCF-Carp | 60 days | Bioaccumulation factor | 23000 | OECD 305E - Bioaccumulation flow-through fish test |
| Fatty acids ester | 67701-27-3 | Estimated Bioconcentration | | Bioaccumulation factor | 7.4 | Other methods |
| Cristobalite | 14464-46-1 | 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 |
| Sulfoneamide | 80-39-7 | Estimated Bioconcentration | | Log Kow | 1.87 | 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 |
| Mint flavor | 90063-97-1 | 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

ADR: UN3077; Environmentally Hazardous Substance, Solid, N.O.S (Laurylimidazole, Aromatic hydrocarbon, Mint flavor); 9; III; (-); M7.
IATA: UN3077; Environmentally Hazardous Substance, Solid, N.O.S (Laurylimidazole, Aromatic hydrocarbon, Mint flavor); 9; III.
IMDG: UN3077; Environmentally Hazardous Substance, Solid, N.O.S (Laurylimidazole, Aromatic hydrocarbon, Mint flavor); 9; III; EMS: FA, SF; Marine Pollutant: Laurylimidazole, Aromatic hydrocarbon, Mint flavor. (ENG)
Exemption: For vessels containing a net quantity of 5 l or a net mass of 5 kg or less per single or inner packaging ,

special provision 375 (ADR), exemption per 2.10.2.7 (IMDG) or special provision A197 (IATA) may be applied, if applicable

## 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**

| | |
|---|---|
| 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. |
| 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. |
| H412 | Harmful 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 Ireland Safety Information Sheets are available at www.3M.com**