



Safety Information Sheet for Medical Devices

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| | | | |
|---|------------|-------------------------|------------|
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| Revision date: | 06/05/2020 | Supersedes date: | 23/04/2020 |
| Transportation version number: 1.00 (06/05/2020) | | | |

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 Base Paste

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

Identified uses

Medical device; refer to Instructions for Use

Restrictions on Use

For use only by dental professionals

1.3 Details of the supplier of the safety information sheet for medical devices

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

1.4. Emergency telephone number

+44 (0)1344 858 000

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

CLP REGULATION (EC) No 1272/2008

This product is a medical device as defined in Directive 93/42/EEC (MDD) 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:

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 | < 1 |
| Mint flavor | 68917-18-0 | | < 0.5 |
| Mint flavor | 98561-44-5 | 308-804-6 | < 0.5 |

HAZARD STATEMENTS:

| | |
|------|--|
| 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:

| | |
|-------------|--|
| 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/international regulations. |
|------|--|

Notes on labelling

H319 not assigned per test data.

2.3. Other hazards

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

SECTION 3: Composition/information on ingredients

| Ingredient | CAS Nbr | EC No. | % by Wt | Classification |
|--|-------------|-----------|---------|--|
| Polyether | 110531-92-5 | | 40 - 60 | Eye Irrit. 2, H319 |
| Fatty acids ester | 67701-27-3 | 266-945-8 | 10 - 30 | Substance not classified as hazardous |
| Polyether acetate | 91825-26-2 | | 1 - 20 | Substance not classified as hazardous |
| Aromatic hydrocarbon | 26898-17-9 | 248-097-0 | 1 - 10 | Aquatic Chronic 1, H410, M=1 |
| Diatomaceous earth (respirable cristobalite fraction 1-<10%) | 68855-54-9 | 272-489-0 | < 10 | STOT RE 2, H373 |
| Laurylimidazole (REACH Reg. No.:01-2120068170-65) | 4303-67-7 | 224-314-4 | < 1 | Aquatic Acute 1, H400, M=100; Aquatic Chronic 1, H410, M=10; Acute Tox. 4, H302; Eye Irrit. 2, H319; Skin Sens. 1A, H317 |
| Mint flavor | 98561-44-5 | 308-804-6 | < 0.5 | Asp. Tox. 1, H304; Skin Irrit. 2, H315; Skin Sens. 1, H317 |
| Mint flavor | 68917-18-0 | | < 0.5 | 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

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 respirable dust):2.4 mg/m ³ ;TWA(as inhalable dust):6 mg/m ³ | |
| Quartz | 68855-54-9 | UK HSC | TWA(respirable):0.1 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 | Multicolor |
| Specific Physical Form: | Paste |
| Odor | Minty |
| pH | <i>No data available.</i> |
| Boiling point/boiling range | <i>Not applicable.</i> |
| Melting point | <i>No data available.</i> |
| Flammability (solid, gas) | Not classified |
| Explosive properties | Not classified |
| Oxidising properties | Not classified |
| Flash point | Flash point > 93 °C (200 °F) |
| Autoignition temperature | <i>No data available.</i> |
| Flammable Limits(LEL) | <i>Not applicable.</i> |
| Flammable Limits(UEL) | <i>Not applicable.</i> |
| Relative density | 1 - 1.2 [Ref Std: WATER=1] |
| Water solubility | Nil |
| Viscosity | <i>No data available.</i> |
| Density | <i>No data available.</i> |

9.2. Other information

| | |
|-------------------------------|---------------------------|
| EU Volatile Organic Compounds | <i>No data available.</i> |
| Percent volatile | <i>Not applicable.</i> |

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

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.

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 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 |
| Fatty acids ester | Dermal | Rabbit | LD50 > 2,000 mg/kg |
| Fatty acids ester | Ingestion | Rat | LD50 > 2,000 mg/kg |
| Polyether acetate | Dermal | Professional judgement | LD50 estimated to be > 5,000 mg/kg |
| Polyether acetate | 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 |
| Diatomaceous earth (respirable cristobalite fraction 1-<10%) | Dermal | Professional judgement | LD50 estimated to be > 5,000 mg/kg |
| Diatomaceous earth (respirable) | Inhalation-Dust/Mist (4 hours) | Rat | LC50 > 2.7 mg/l |

| | | | |
|--|-----------|--------|--------------------|
| cristobalite fraction 1-<10%) | | | |
| Diatomaceous earth (respirable cristobalite fraction 1-<10%) | Ingestion | Rat | LD50 > 2,000 mg/kg |
| 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 |
| Diatomaceous earth (respirable cristobalite fraction 1-<10%) | In vitro data | No significant irritation |
| Laurylimidazole | Rabbit | Mild irritant |
| Mint flavor | Rabbit | Mild irritant |
| Mint flavor | Not available | Irritant |

Serious Eye Damage/Irritation

| Name | Species | Value |
|--|---------------|---------------------------|
| Overall product | In vitro data | No significant irritation |
| 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 | Not available | 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 |
| Polyether acetate | 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 |
| Laurylimidazole | In Vitro | Not mutagenic |

Carcinogenicity

| Name | Route | Species | Value |
|--|------------|------------------|---------------|
| 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 |
|--|------------|---|--|---------|-----------------------|-----------------------|
| 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

| Name | Value |
|-------------|-------------------|
| Mint flavor | 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.

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 | | | |
| 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 |
| Polyether acetate | 91825-26-2 | | Data not available or insufficient for classification | | | |
| Aromatic hydrocarbon | 26898-17-9 | Water flea | Experimental | 48 hours | EC50 | >100 mg/l |
| Aromatic hydrocarbon | 26898-17-9 | Zebra Fish | Experimental | 96 hours | Lethal Level 50% | >100 mg/l |
| Aromatic hydrocarbon | 26898-17-9 | Diatom | Experimental | 72 hours | NOEC | >100 mg/l |
| Aromatic hydrocarbon | 26898-17-9 | Water flea | Experimental | 21 days | NOEC | 0.03 mg/l |
| Diatomaceous earth (respirable cristobalite fraction 1-<10%) | 68855-54-9 | | Data not available or insufficient for classification | | | |
| 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 | 68917-18-0 | | Data not available or insufficient for classification | | | |
| Mint flavor | 98561-44-5 | | 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 available or insufficient | | | N/A | |
| Fatty acids ester | 67701-27-3 | Estimated Biodegradation | 28 days | BOD | 79 % BOD/ThBOD | OECD 301F - Manometric respirometry |
| Polyether acetate | 91825-26-2 | Data not available or insufficient | | | N/A | |
| Aromatic hydrocarbon | 26898-17-9 | Experimental Biodegradation | 28 days | BOD | 0 % BOD/ThBOD | OECD 301C - MITI test (I) |
| Diatomaceous earth (respirable cristobalite fraction 1-<10%) | 68855-54-9 | Data not available or insufficient | | | N/A | |
| Laurylimidazole | 4303-67-7 | Experimental Biodegradation | 28 days | CO2 evolution | 2-3 % weight | OECD 301B - Modified sturm or CO2 |
| Mint flavor | 98561-44-5 | Data not available or insufficient | | | N/A | |
| Mint flavor | 68917-18-0 | Data not available or insufficient | | | N/A | |

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 |
| Fatty acids ester | 67701-27-3 | Estimated Bioconcentration | | Bioaccumulation factor | 7.4 | Other methods |
| Polyether acetate | 91825-26-2 | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| Aromatic hydrocarbon | 26898-17-9 | Experimental BCF-Carp | 60 days | Bioaccumulation factor | 23000 | OECD 305E - Bioaccumulation flow-through fish test |
| Diatomaceous earth (respirable cristobalite fraction 1-<10%) | 68855-54-9 | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| Laurylimidazole | 4303-67-7 | Estimated Bioconcentration | | Bioaccumulation factor | 3090 | Estimated: Bioconcentration factor |
| Mint flavor | 98561-44-5 | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| Mint flavor | 68917-18-0 | 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

IMDG: UN3077; Environmentally Hazardous Substance, Solid, N.O.S (Laurylimidazole, Aromatic hydrocarbon); 9; III; EMS: FA, SF; Marine Pollutant: Laurylimidazole, Aromatic hydrocarbon. (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
ADR: UN3077; Environmentally Hazardous Substance, Solid, N.O.S (Laurylimidazole, Aromatic hydrocarbon); 9; III; (-); M7.

IATA: UN3077; Environmentally Hazardous Substance, Solid, N.O.S (Laurylimidazole, Aromatic hydrocarbon); 9; III.

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. |
| 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. |
| H373 | May cause damage to organs through prolonged or repeated exposure. |
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |
| H411 | Toxic to aquatic life with long lasting effects. |

Revision information:

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: | 16-2742-1 | Version number: | 1.00 |
| Revision date: | 06/05/2020 | Supersedes date: | Initial issue. |
| Transportation version number: 1.00 (06/05/2020) | | | |

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 Catalyst

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) 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:

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

Reproductive Toxicity, Category 2 - Repr. 2; H361

Specific Target Organ Toxicity-Repeated Exposure, Category 1 - STOT RE 1; H372

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) |

Pictograms



Ingredients:

| Ingredient | CAS Nbr | EC No. | % by Wt |
|----------------|------------|-----------|---------|
| Sulfonium salt | 72140-65-9 | 276-380-9 | 10 - 30 |

HAZARD STATEMENTS:

| | |
|-------|---|
| H317 | May cause an allergic skin reaction. |
| H361f | Suspected of damaging fertility. |
| H372 | Causes damage to organs through prolonged or repeated exposure: blood or blood-forming organs respiratory system sensory organs |

PRECAUTIONARY STATEMENTS

Prevention:

P280E Wear protective gloves.

Response:

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

Notes on labelling

Silicosis and P260 do 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 | 30 - 50 | Substance not classified as hazardous |
| Silane treated silica | 68909-20-6 | 272-697-1 | 10 - 30 | Substance with an occupational exposure limit |
| Diatomaceous earth (respirable cristobalite fraction 1-<10%) | 68855-54-9 | 272-489-0 | 10 - 30 | STOT RE 2, H373 |

| | | | | |
|----------------|------------|-----------|---------|--|
| Sulfonium salt | 72140-65-9 | 276-380-9 | 10 - 30 | Acute Tox. 4, H302; Skin Sens. 1B, H317; Repr. 2, H361f; STOT RE 1, H372 |
| 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 respirable dust):2.4 mg/m ³ ;TWA(as inhalable dust):6 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 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

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 | <i>No data available.</i> |
| Boiling point/boiling range | <i>Not applicable.</i> |
| Melting point | <i>No data available.</i> |
| Flammability (solid, gas) | Not classified |
| Explosive properties | Not classified |
| Oxidising properties | Not classified |
| Flash point | Flash point > 93 °C (200 °F) |
| Autoignition temperature | <i>No data available.</i> |
| Flammable Limits(LEL) | <i>Not applicable.</i> |
| Flammable Limits(UEL) | <i>Not applicable.</i> |
| Relative density | 1.1 - 1.4 [Ref Std: WATER=1] |
| Water solubility | Negligible |
| Viscosity | <i>No data available.</i> |
| Density | <i>No data available.</i> |

9.2. Other information

| | |
|--------------------------------------|---------------------------|
| EU Volatile Organic Compounds | <i>No data available.</i> |
| Percent volatile | <i>Not applicable.</i> |

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 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

May be harmful if swallowed.

Gastrointestinal irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhoea. May cause additional health effects (see below).

Additional Health Effects:

Prolonged or repeated exposure may cause target organ effects:

Ocular effects: Signs/symptoms may include blurred or significantly impaired vision. Bone marrow effects: Signs/symptoms may include generalised weakness, pallor of the skin, fatty infiltration of the bone marrow, decreases in the numbers of circulating blood cells, increased susceptibility to infection. Respiratory effects: Signs/symptoms may include cough, shortness of breath, chest tightness, wheezing, increased heart rate, bluish coloured skin (cyanosis), sputum production, changes in lung function tests, and respiratory failure.

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 | Ingestion | | No data available; calculated ATE2,000 - 5,000 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 |
| Sulfonium salt | Dermal | Rat | LD50 > 2,000 mg/kg |
| Sulfonium salt | Ingestion | Rat | LD50 300-2,000 mg/kg |
| Diatomaceous earth (respirable cristobalite) | Dermal | Professional judgement | LD50 estimated to be > 5,000 mg/kg |

| | | | |
|--|--------------------------------|------------------------|------------------------------------|
| fraction 1-<10%) | | | |
| 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 |

ATE = acute toxicity estimate

Skin Corrosion/Irritation

| Name | Species | Value |
|--|---------------|---------------------------|
| Silane treated silica | Rabbit | No significant irritation |
| Sulfonium salt | Rabbit | Mild irritant |
| Diatomaceous earth (respirable cristobalite fraction 1-<10%) | In vitro data | No significant irritation |

Serious Eye Damage/Irritation

| Name | Species | Value |
|--|---------|---------------------------|
| Silane treated silica | Rabbit | No significant irritation |
| Sulfonium salt | Rabbit | Mild irritant |
| Diatomaceous earth (respirable cristobalite fraction 1-<10%) | Rabbit | Mild irritant |

Skin Sensitisation

| Name | Species | Value |
|--|------------------|----------------|
| Silane treated silica | Human and animal | Not classified |
| Sulfonium salt | Mouse | Sensitising |
| Diatomaceous earth (respirable cristobalite fraction 1-<10%) | 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 |
|--|----------|--|
| Silane treated silica | In Vitro | Not mutagenic |
| Sulfonium salt | 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 |

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 (respirable cristobalite fraction 1-<10%) | Inhalation | Human and animal | Carcinogenic. |

Reproductive Toxicity

Reproductive and/or Developmental Effects

| Name | Route | Value | Species | Test result | Exposure Duration |
|-----------------------|-----------|--|---------|-----------------------|----------------------------|
| Silane treated silica | Ingestion | Not classified for female reproduction | Rat | NOAEL 509 mg/kg/day | 1 generation |
| Silane treated silica | Ingestion | Not classified for male reproduction | Rat | NOAEL 497 mg/kg/day | 1 generation |
| Silane treated silica | Ingestion | Not classified for development | Rat | NOAEL 1,350 mg/kg/day | during organogenesis |
| Sulfonium salt | Ingestion | Not classified for development | Rat | NOAEL 100 mg/kg/day | prematuring into lactation |

| | | | | | |
|----------------|-----------|------------------------------|-----|--------------------|--------------------------|
| Sulfonium salt | Ingestion | Toxic to female reproduction | Rat | NOAEL 30 mg/kg/day | preparing into lactation |
| Sulfonium salt | Ingestion | Toxic to male reproduction | Rat | NOAEL 30 mg/kg/day | 30 days |

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 |
|--|------------|--|---|---------|-----------------------|-----------------------|
| Silane treated silica | Inhalation | respiratory system silicosis | Not classified | Human | NOAEL Not available | occupational exposure |
| 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 through prolonged or repeated exposure | Rat | NOAEL 30 mg/kg/day | 30 days |
| Sulfonium salt | Ingestion | eyes | May cause damage to organs through 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 |
| 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 |
|----------|-------|----------|------|----------|---------------|-------------|
|----------|-------|----------|------|----------|---------------|-------------|

| | | | | | | |
|--|------------|-------------|---|----------|--------------------------------|------------|
| 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 |
| Diatomaceous earth (respirable cristobalite fraction 1-<10%) | 68855-54-9 | | Data not available or insufficient for classification | | | |
| Silane treated silica | 68909-20-6 | Algae | Estimated | 72 hours | EC50 | >100 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 |
| 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 |
| Diatomaceous earth (respirable cristobalite fraction 1-<10%) | 68855-54-9 | Data not availbl-insufficient | | | N/A | |
| Silane treated silica | 68909-20-6 | Data not availbl-insufficient | | | N/A | |
| Sulfonium salt | 72140-65-9 | Experimental Hydrolysis | | Hydrolytic half-life | 2.08 hours (t 1/2) | Other methods |
| 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 |
| 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 |
| Silane treated silica | 68909-20-6 | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| Sulfonium salt | 72140-65-9 | Experimental Bioconcentration | | Log Kow | ≤0.75 | Other methods |
| 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

ADR/IMDG/IATA: Not restricted for transport.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****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.

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: | 35-4551-4 | Version number: | 1.00 |
| Revision date: | 06/05/2020 | Supersedes date: | Initial issue. |
| Transportation version number: 1.00 (06/05/2020) | | | |

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™ Polyether Adhesive - New Formulation

Product Identification Numbers

70-2011-4442-8

7100059327

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

Identified uses

Medical device; refer to Instructions for Use

Restrictions on Use

For use only by dental professionals.

1.3 Details of the supplier of the safety information sheet for medical devices

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

1.4. Emergency telephone number

+44 (0)1344 858 000

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

CLP REGULATION (EC) No 1272/2008

This product is a medical device as defined in Directive 93/42/EEC (MDD) 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:

Flammable Liquid, Category 2 - Flam. Liq. 2; H225

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

Specific Target Organ Toxicity-Single Exposure, Category 3 - STOT SE 3; H336

For full text of H phrases, see Section 16.

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

DANGER.

Symbols:

GHS02 (Flame) |GHS07 (Exclamation mark) |

Pictograms**Ingredients:**

| Ingredient | CAS Nbr | EC No. | % by Wt |
|---------------|----------|-----------|---------|
| Ethyl acetate | 141-78-6 | 205-500-4 | 40 - 70 |

HAZARD STATEMENTS:

| | |
|------|-------------------------------------|
| H225 | Highly flammable liquid and vapour. |
| H319 | Causes serious eye irritation. |
| H336 | May cause drowsiness or dizziness. |

PRECAUTIONARY STATEMENTS**Prevention:**

| | |
|-------|--|
| P210A | Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. |
| P261A | Avoid breathing vapours. |

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. |
| P370 + P378G | In case of fire: Use a fire fighting agent suitable for flammable liquids such as dry chemical or carbon dioxide to extinguish. |

SUPPLEMENTAL INFORMATION:**Supplemental Hazard Statements:**

| | |
|--------|---|
| EUH066 | Repeated exposure may cause skin dryness or cracking. |
|--------|---|

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 |
|---------------|------------|-----------|---------|---|
| Ethyl acetate | 141-78-6 | 205-500-4 | 40 - 70 | Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336; EUH066 |
| Silicon resin | 68440-70-0 | | 40 - 60 | 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

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. Do not induce vomiting. Get immediate medical attention.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

In case of fire: Use a fire fighting agent suitable for flammable liquids such as dry chemical or carbon dioxide to extinguish.

5.2. Special hazards arising from the substance or mixture

Closed containers exposed to heat from fire may build pressure and explode.

5.3. Advice for fire-fighters

Water may not effectively extinguish fire; however, it should be used to keep fire-exposed containers and surfaces cool and prevent explosive rupture. 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. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Use only non-sparking tools. 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. Warning! A motor could be an ignition source and could cause flammable gases or vapours in the spill area to burn or explode. 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

Contain spill. Cover spill area with a fire-extinguishing foam. Working from around the edges of the spill inward, cover with bentonite, vermiculite, or commercially available inorganic absorbent material. Mix in sufficient absorbent until it appears dry. Remember, adding an absorbent material does not remove a physical, health, or environmental hazard. Collect as much of the spilled material as possible using non-sparking tools. Place in a metal container approved for transportation by appropriate authorities. Clean up residue with an appropriate solvent selected by a qualified and authorized person. Ventilate the area with fresh air. Read and follow safety precautions on the solvent label and SIS. 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 |
|---------------|----------|--------|---|---------------------|
| Ethyl acetate | 141-78-6 | UK HSC | TWA:734 mg/m ³ (200 ppm);STEL:1468 mg/m ³ (400 ppm) | |

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 | Liquid. |
| Colour | Red |
| Specific Physical Form: | Viscous. |
| Odor | Characteristic Organic solvent |
| pH | <i>No data available.</i> |
| Boiling point/boiling range | 76.1 °C |
| Melting point | <i>No data available.</i> |
| Flammability (solid, gas) | Not applicable. |
| Explosive properties | Not classified |
| Oxidising properties | Not classified |
| Flash point | -3.9 °C [<i>Test Method: Closed Cup</i>] |
| Autoignition temperature | <i>No data available.</i> |
| Flammable Limits(LEL) | 1.2 % |
| Flammable Limits(UEL) | 11.5 % |
| Relative density | > 0.9 [<i>Ref Std: WATER=1</i>] |
| Water solubility | Nil |
| Viscosity | approximately 0.25 Pa-s |
| Density | approximately 0.9 g/cm ³ |

9.2. Other information

| | |
|--------------------------------------|---------------------------|
| EU Volatile Organic Compounds | <i>No data available.</i> |
| Molecular weight | <i>No data available.</i> |
| Percent volatile | <i>No data available.</i> |

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

Sparks and/or flames.

Heat.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

| <u>Substance</u> | <u>Condition</u> |
|------------------|-----------------------------|
| Carbon monoxide | Oxidation, heat or reaction |
| Carbon dioxide. | Oxidation, heat or reaction |

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

Respiratory tract irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain. May cause additional health effects (see below).

Skin contact

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

Eye contact

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

Ingestion

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

Toxicological Data

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

Acute Toxicity

| Name | Route | Species | Value |
|-----------------|-----------------------------|---------|--|
| Overall product | Ingestion | | No data available; calculated ATE >5,000 mg/kg |
| Ethyl acetate | Dermal | Rabbit | LD50 > 18,000 mg/kg |
| Ethyl acetate | Inhalation-Vapour (4 hours) | Rat | LC50 70.5 mg/l |
| Ethyl acetate | Ingestion | Rat | LD50 5,620 mg/kg |

ATE = acute toxicity estimate

Skin Corrosion/Irritation

| Name | Species | Value |
|---------------|---------|--------------------|
| Ethyl acetate | Rabbit | Minimal irritation |

Serious Eye Damage/Irritation

| Name | Species | Value |
|---------------|---------|---------------|
| Ethyl acetate | Rabbit | Mild irritant |

Skin Sensitisation

| Name | Species | Value |
|---------------|------------|----------------|
| Ethyl acetate | Guinea pig | 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 |
|---------------|----------|---------------|
| Ethyl acetate | In Vitro | Not mutagenic |
| Ethyl acetate | In vivo | Not mutagenic |

Carcinogenicity

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

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**

| Name | Route | Target Organ(s) | Value | Species | Test result | Exposure Duration |
|---------------|------------|-----------------------------------|--|---------|---------------------|-------------------|
| Ethyl acetate | Inhalation | central nervous system depression | May cause drowsiness or dizziness | Human | NOAEL Not available | |
| Ethyl acetate | Inhalation | respiratory irritation | Some positive data exist, but the data are not sufficient for classification | Human | NOAEL Not available | |
| Ethyl acetate | Ingestion | central nervous system depression | May cause drowsiness or dizziness | Human | NOAEL Not available | |

Specific Target Organ Toxicity - repeated exposure

| Name | Route | Target Organ(s) | Value | Species | Test result | Exposure Duration |
|---------------|------------|--|----------------|---------|-----------------------|-------------------|
| Ethyl acetate | Inhalation | endocrine system liver nervous system | Not classified | Rat | NOAEL 0.043 mg/l | 90 days |
| Ethyl acetate | Inhalation | hematopoietic system | Not classified | Rabbit | LOAEL 16 mg/l | 40 days |
| Ethyl acetate | Ingestion | hematopoietic system liver kidney and/or bladder | Not classified | Rat | NOAEL 3,600 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 |
|---------------|------------|-------------|---|----------|---------------|-------------|
| Ethyl acetate | 141-78-6 | Crustacea | Experimental | 48 hours | EC50 | 165 mg/l |
| Ethyl acetate | 141-78-6 | Fish | Experimental | 96 hours | LC50 | 212.5 mg/l |
| Ethyl acetate | 141-78-6 | Green Algae | Experimental | 72 hours | NOEC | >100 mg/l |
| Ethyl acetate | 141-78-6 | Water flea | Experimental | 21 days | NOEC | 2.4 mg/l |
| Silicon resin | 68440-70-0 | | Data not available or insufficient for classification | | | |

12.2. Persistence and degradability

| Material | CAS Nbr | Test type | Duration | Study Type | Test result | Protocol |
|---------------|------------|-------------------------------|----------|-------------------------------|-------------------|---------------------------|
| Ethyl acetate | 141-78-6 | Experimental Photolysis | | Photolytic half-life (in air) | 20.0 days (t 1/2) | Other methods |
| Ethyl acetate | 141-78-6 | Experimental Biodegradation | 14 days | BOD | 94 % BOD/ThBOD | OECD 301C - MITI test (I) |
| Silicon resin | 68440-70-0 | Data not availbl-insufficient | | | N/A | |

12.3 : Bioaccumulative potential

| Material | Cas No. | Test type | Duration | Study Type | Test result | Protocol |
|---------------|------------|---|----------|------------|-------------|---------------|
| Ethyl acetate | 141-78-6 | Experimental Bioconcentration | | Log Kow | 0.68 | Other methods |
| Silicon resin | 68440-70-0 | 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

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**

| | |
|--------|---|
| EUH066 | Repeated exposure may cause skin dryness or cracking. |
| H225 | Highly flammable liquid and vapour. |
| H319 | Causes serious eye irritation. |
| H336 | May cause drowsiness or dizziness. |

Revision information:

Revision information not available

The product to which this Safety Information Sheet applies is classified as a medical device according to the EU Medical Device Regulation EU 2017/745. x000D

Medical devices which are invasive or used in direct physical contact with the human body are exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). x000D

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

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