



Safety Information Sheet for Medical Devices

Copyright,2020, 3M Company All rights reserved. Copying and/or downloading of this information for the purpose of properly utilizing 3M products is allowed provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from 3M, and (2) neither the copy nor the original is resold or otherwise distributed with the intention of earning a profit thereon.

| | | | |
|------------------------|------------|-------------------------|------------|
| Document group: | 29-8481-3 | Version number: | 2.00 |
| Revision date: | 27/07/2020 | Supersedes date: | 20/07/2020 |

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

A safety data sheet is not required for this Product. This Safety Information Sheet has been created on a voluntary basis.

IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

3M™ Scotchbond™ Universal Kit (41255, 41256, 41257, 41292)

Product Identification Numbers

70-2011-3900-6 70-2011-3902-2

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 data sheet

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

1.4. Emergency telephone number

+44 (0)1344 858 000

This product is a kit or a multipart product which consists of multiple, independently packaged components. Safety Information Sheet for Medical Devices for each of these components is included. Please do not separate the component Safety Information Sheet for Medical Devices from this cover page. The document numbers of the Safety Information Sheet for Medical Devices for components of this product are:

29-8286-6, 29-8287-4

TRANSPORTATION INFORMATION

70-2011-3900-6, 70-2011-3902-2

Component 1

ADR/RID: DANGEROUS GOODS IN EXCEPTED QUANTITIES, CLASS 3, III, (--).

IMDG-CODE: UN1133, ADHESIVES, 3, III, IMDG-Code segregation code: NONE, Dangerous Goods in excepted Quantities, EMS: FE,SD.

ICAO/IATA: DANGEROUS GOODS IN EXCEPTED QUANTITIES OF CLASS 3,UN1133, III.

Component 2

ADR/RID: DANGEROUS GOODS IN EXCEPTED QUANTITIES, CLASS 8, III, (--).

IMDG-CODE: UN1805, PHOSPHORIC ACID SOLUTION, 8., III, IMDG-Code segregation code: NONE, Dangerous Goods in excepted Quantities, EMS: FA,SB.

ICAO/IATA: DANGEROUS GOODS IN EXCEPTED QUANTITIES OF CLASS 8,UN1805, III.

| |
|------------------|
| KIT LABEL |
|------------------|

2.1. Classification of the substance or mixture

Please refer to Kit Components

Revision information:

A revision has been performed due to the need to update the safety information for the medical device.



Safety Information Sheet for Medical Devices

Copyright, 2019, 3M Company All rights reserved. Copying and/or downloading of this information for the purpose of properly utilising 3M products is allowed provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from 3M, and (2) neither the copy nor the original is resold or otherwise distributed with the intention of earning a profit thereon.

Document group: 29-8286-6 **Version number:** 1.00
Revision date: 16/10/2019 **Supersedes date:** Initial issue.
Transportation version number: 1.00 (16/10/2019)

A safety data sheet is not required for this Product. This Safety Information Sheet has been created on a voluntary basis.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

3M™ ESPE™ Scotchbond™ Universal Etchant

Product Identification Numbers

LE-F100-1014-5 LE-F100-1040-4 70-2011-3906-3

7000055181

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

Identified uses

Medical device; refer to Instructions for Use

Restrictions on Use

For use only by dental professionals

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

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

1.4. Emergency telephone number

+44 (0)1344 858 000

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

CLP REGULATION (EC) No 1272/2008

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

classification and label information, as applicable, is provided below.

CLASSIFICATION:

Substance or Mixture Corrosive to Metals, Category 1 - Met. Corr. 1; H290
 Serious Eye Damage/Eye Irritation, Category 1 - Eye Dam. 1; H318
 Skin Corrosion/Irritation, Category 1B - Skin Corr. 1B; H314

For full text of H phrases, see Section 16.

2.2. Label elements

CLP REGULATION (EC) No 1272/2008

SIGNAL WORD

DANGER.

Symbols:

GHS05 (Corrosion) |

Pictograms



Ingredients:

| Ingredient | CAS Nbr | EC No. | % by Wt |
|-----------------|-----------|-----------|---------|
| Phosphoric acid | 7664-38-2 | 231-633-2 | 30 - 40 |

HAZARD STATEMENTS:

H290 May be corrosive to metals.
 H314 Causes severe skin burns and eye damage.

PRECAUTIONARY STATEMENTS

Prevention:

P280D Wear protective gloves, protective clothing, and eye/face protection.

Response:

P303 + P361 + P353A IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water shower.
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P310 Immediately call a POISON CENTRE or doctor/physician.

Notes on labelling

P260 not applied since the product is a gel, 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 |
|---|-------------|-----------|---------|--|
| Water | 7732-18-5 | 231-791-2 | 50 - 65 | Substance not classified as hazardous |
| Phosphoric acid (REACH Reg. No.:01-2119485924-24) | 7664-38-2 | 231-633-2 | 30 - 40 | Skin Corr. 1B, H314 - Nota B Met. Corr. 1, H290 Acute Tox. 4, H302 |
| Silica (REACH Reg. No.:01-2119379499-16) | 112945-52-5 | | 5 - 10 | Substance with a Community level exposure limit in the workplace |
| Polyglycol | 25322-68-3 | | 1 - 5 | Substance not classified as hazardous |
| Aluminum oxide (REACH Reg. No.:01-2119529248-35) | 1344-28-1 | 215-691-6 | < 2 | Substance with a Community level exposure limit in the workplace |

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 flush with large amounts of water for at least 15 minutes. Remove contaminated clothing. Get immediate medical attention. Wash clothing before reuse.

Eye contact

Immediately flush with large amounts of water for at least 15 minutes. Remove contact lenses if easy to do. Continue rinsing. Immediately 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 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.

Condition

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

Contain spill. For large spills, if necessary, get assistance from professional spill clean up team. For small spills, carefully cover the spill with soda ash (sodium carbonate) or sodium bicarbonate. Work from around the perimeter inward. Avoid splashing. Add enough water to ease mixing and stir. Continue stirring and adding water and neutralizing agent until the reaction stops. Let cool before collecting. Or use a commercially available 'Acid spill' clean-up kit. Follow the kit directions exactly, as specified. 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. Place in a metal container approved for use in transportation by appropriate authorities. The container must be lined with polyethylene plastic or contain a plastic drum liner made of polyethylene. Clean up residue with water. Cover, but do not seal for 48 hours. 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 | 112945-52-5 | UK HSC | TWA(as inhalable dust):6 mg/m ³ ;TWA(as respirable dust):2.4 mg/m ³ | |
| Aluminum oxide | 1344-28-1 | UK HSC | TWA(as inhalable dust):10 mg/m ³ ;TWA(as respirable dust):4 mg/m ³ | |
| Phosphoric acid | 7664-38-2 | UK HSC | TWA:1 mg/m ³ ;STEL:2 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

Liquid.

Colour

Blue

Specific Physical Form:

Gel

Odor

Slight Odor, Characteristic Odour

pH

< 1

Boiling point/boiling range

No data available.

Melting point

Not applicable.

Flammability (solid, gas)

Not applicable.

Explosive properties

Not classified

Oxidising properties

Not classified

Flash point

> 100 °C [Test Method: Closed Cup]

Autoignition temperature

No data available.

Flammable Limits(LEL)

No data available.

Flammable Limits(UEL)

No data available.

Relative density

1.1 - 1.2 [Ref.Std: WATER=1]

Water solubility

Complete

Viscosity

No data available.

Density

1.1 g/ml - 1.2 g/ml

9.2. Other information

EU Volatile Organic Compounds

No data available.

Molecular weight

No data available.

Percent volatile

No data available.

SECTION 10: Stability and reactivity

10.1 Reactivity

This material may be reactive with certain agents under certain conditions - see the remaining headings in this

section

10.2 Chemical stability

Stable.

10.3 Possibility of hazardous reactions

Hazardous polymerisation will not occur.

10.4 Conditions to avoid

Heat.

10.5 Incompatible materials

Strong bases.

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

Corrosive (skin burns): Signs/symptoms may include localised redness, swelling, itching, intense pain, blistering, ulceration, and tissue destruction.

Eye contact

Corrosive (eye burns): Signs/symptoms may include cloudy appearance of the cornea, chemical burns, severe pain, tearing, ulcerations, significantly impaired vision or complete loss of vision.

Ingestion

Gastrointestinal corrosion: Signs/symptoms may include severe mouth, throat and abdominal pain, nausea, vomiting, and diarrhea; blood in the faeces and/or vomitus may also be seen.

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 |
| Phosphoric acid | Dermal | Rabbit | LD50 2,740 mg/kg |
| Phosphoric acid | Ingestion | Rat | LD50 1,530 mg/kg |
| Silica | Dermal | Rabbit | LD50 > 5,000 mg/kg |
| Silica | Inhalation-Dust/Mist (4 hours) | Rat | LC50 > 0.691 mg/l |
| Silica | Ingestion | Rat | LD50 > 5,110 mg/kg |
| Polyglycol | Dermal | Rabbit | LD50 > 20,000 mg/kg |
| Polyglycol | Ingestion | Rat | LD50 32,770 mg/kg |
| Aluminum oxide | Dermal | | LD50 estimated to be > 5,000 mg/kg |
| Aluminum oxide | Inhalation-Dust/Mist (4 hours) | Rat | LC50 > 2.3 mg/l |
| Aluminum oxide | Ingestion | Rat | LD50 > 5,000 mg/kg |

ATE = acute toxicity estimate

Skin Corrosion/Irritation

| Name | Species | Value |
|-----------------|---------|---------------------------|
| Phosphoric acid | Rabbit | Corrosive |
| Silica | Rabbit | No significant irritation |
| Polyglycol | Rabbit | Minimal irritation |
| Aluminum oxide | Rabbit | No significant irritation |

Serious Eye Damage/Irritation

| Name | Species | Value |
|-----------------|-------------------------|---------------------------|
| Phosphoric acid | official classification | Corrosive |
| Silica | Rabbit | No significant irritation |
| Polyglycol | Rabbit | Mild irritant |
| Aluminum oxide | Rabbit | No significant irritation |

Skin Sensitisation

| Name | Species | Value |
|-----------------|------------------|----------------|
| Phosphoric acid | Human | Not classified |
| Silica | Human and animal | Not classified |
| Polyglycol | 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 |
|-----------------|----------|---------------|
| Phosphoric acid | In Vitro | Not mutagenic |
| Silica | In Vitro | Not mutagenic |
| Polyglycol | In Vitro | Not mutagenic |
| Polyglycol | In vivo | Not mutagenic |
| Aluminum oxide | In Vitro | Not mutagenic |

Carcinogenicity

| Name | Route | Species | Value |
|----------------|----------------|---------|--|
| Silica | Not specified. | Mouse | Some positive data exist, but the data are not sufficient for classification |
| Polyglycol | Ingestion | Rat | Not carcinogenic |
| Aluminum oxide | Inhalation | Rat | Not carcinogenic |

Reproductive Toxicity

Reproductive and/or Developmental Effects

| Name | Route | Value | Species | Test result | Exposure Duration |
|-----------------|----------------|--|---------|-------------------------------|----------------------|
| Phosphoric acid | Ingestion | Not classified for female reproduction | Rat | NOAEL 750 mg/kg/day | 2 generation |
| Phosphoric acid | Ingestion | Not classified for male reproduction | Rat | NOAEL 750 mg/kg/day | 2 generation |
| Phosphoric acid | Ingestion | Not classified for development | Rat | NOAEL 750 mg/kg/day | 2 generation |
| Silica | Ingestion | Not classified for female reproduction | Rat | NOAEL 509 mg/kg/day | 1 generation |
| Silica | Ingestion | Not classified for male reproduction | Rat | NOAEL 497 mg/kg/day | 1 generation |
| Silica | Ingestion | Not classified for development | Rat | NOAEL 1,350 mg/kg/day | during organogenesis |
| Polyglycol | Ingestion | Not classified for female reproduction | Rat | NOAEL 1,125 mg/kg/day | during gestation |
| Polyglycol | Ingestion | Not classified for male reproduction | Rat | NOAEL 5699 +/- 1341 mg/kg/day | 5 days |
| Polyglycol | Not specified. | Not classified for reproduction and/or development | | NOEL N/A | |
| Polyglycol | Ingestion | Not classified for development | Mouse | NOAEL 562 mg/animal/day | during gestation |

Target Organ(s)**Specific Target Organ Toxicity - single exposure**

| Name | Route | Target Organ(s) | Value | Species | Test result | Exposure Duration |
|-----------------|------------|------------------------|--|---------|---------------------|-----------------------|
| Phosphoric acid | Inhalation | respiratory irritation | Some positive data exist, but the data are not sufficient for classification | Human | NOAEL Not available | occupational exposure |
| Polyglycol | Inhalation | respiratory irritation | Not classified | Rat | NOAEL 1.008 mg/l | 2 weeks |

Specific Target Organ Toxicity - repeated exposure

| Name | Route | Target Organ(s) | Value | Species | Test result | Exposure Duration |
|----------------|------------|--|--|---------|-----------------------|-----------------------|
| Silica | Inhalation | respiratory system silicosis | Not classified | Human | NOAEL Not available | occupational exposure |
| Polyglycol | Inhalation | respiratory system | Not classified | Rat | NOAEL 1.008 mg/l | 2 weeks |
| Polyglycol | Ingestion | kidney and/or bladder heart endocrine system hematopoietic system liver nervous system | Not classified | Rat | NOAEL 5,640 mg/kg/day | 13 weeks |
| Aluminum oxide | Inhalation | pneumoconiosis | Some positive data exist, but the data are not sufficient for classification | Human | NOAEL Not available | occupational exposure |
| Aluminum oxide | Inhalation | pulmonary fibrosis | Not classified | Human | NOAEL Not available | occupational exposure |

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 |
|-----------------|-------------|-----------------|--------------|----------|---------------|-------------|
| Phosphoric acid | 7664-38-2 | Green algae | Experimental | 72 hours | EC50 | >100 mg/l |
| Phosphoric acid | 7664-38-2 | Water flea | Experimental | 48 hours | EC50 | >100 mg/l |
| Phosphoric acid | 7664-38-2 | Green algae | Experimental | 72 hours | NOEC | 100 mg/l |
| Silica | 112945-52-5 | Green Algae | Experimental | 72 hours | EC50 | >100 mg/l |
| Silica | 112945-52-5 | Water flea | Experimental | 24 hours | EC50 | >100 mg/l |
| Silica | 112945-52-5 | Zebra Fish | Experimental | 96 hours | LC50 | >100 mg/l |
| Silica | 112945-52-5 | Green Algae | Experimental | 72 hours | NOEC | 60 mg/l |
| Polyglycol | 25322-68-3 | Atlantic Salmon | Experimental | 96 hours | LC50 | >1,000 mg/l |
| Aluminum oxide | 1344-28-1 | Fish | Experimental | 96 hours | LC50 | >100 mg/l |
| Aluminum oxide | 1344-28-1 | Green Algae | Experimental | 72 hours | EC50 | >100 mg/l |
| Aluminum oxide | 1344-28-1 | Water flea | Experimental | 48 hours | LC50 | >100 mg/l |
| Aluminum oxide | 1344-28-1 | Green Algae | Experimental | 72 hours | NOEC | >100 mg/l |

12.2. Persistence and degradability

| Material | CAS Nbr | Test type | Duration | Study Type | Test result | Protocol |
|-----------------|-------------|------------------------------------|----------|------------|----------------|---------------------------|
| Phosphoric acid | 7664-38-2 | Data not available or insufficient | | | N/A | |
| Silica | 112945-52-5 | Data not available or insufficient | | | N/A | |
| Polyglycol | 25322-68-3 | Experimental Biodegradation | 28 days | BOD | 53 % BOD/ThBOD | OECD 301C - MITI test (I) |
| Aluminum oxide | 1344-28-1 | Data not available or insufficient | | | N/A | |

12.3 : Bioaccumulative potential

| Material | Cas No. | Test type | Duration | Study Type | Test result | Protocol |
|-----------------|-------------|---|----------|------------------------|-------------|------------------------------------|
| Phosphoric acid | 7664-38-2 | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| Silica | 112945-52-5 | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| Polyglycol | 25322-68-3 | Estimated Bioconcentration | | Bioaccumulation factor | 2.3 | Estimated: Bioconcentration factor |
| Aluminum oxide | 1344-28-1 | 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: UN1805; Phosphoric Acid Solution; 8; III; (E); C1.

IATA: UN1805; Phosphoric Acid Solution; 8; III.

IMDG: UN1805; Phosphoric Acid Solution; 8; III; FA, SB.

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**

| | |
|------|--|
| H290 | May be corrosive to metals. |
| H302 | Harmful if swallowed. |
| H314 | Causes severe skin burns and eye damage. |

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

Copyright, 2019, 3M Company All rights reserved. Copying and/or downloading of this information for the purpose of properly utilising 3M products is allowed provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from 3M, and (2) neither the copy nor the original is resold or otherwise distributed with the intention of earning a profit thereon.

Document group: 29-8287-4 **Version number:** 1.00
Revision date: 23/10/2019 **Supersedes date:** Initial issue.
Transportation version number: 1.00 (23/10/2019)

A safety data sheet is not required for this Product. This Safety Information Sheet has been created on a voluntary basis.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

3M™ ESPE™ Scotchbond™ Universal

Product Identification Numbers

LE-F100-1014-6 LE-F100-1014-7 LE-F100-1014-9 70-2011-3903-0

7000055178

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

Identified uses

Medical device; refer to Instructions for Use

Restrictions on Use

For use only by dental professionals.

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

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

1.4. Emergency telephone number

+44 (0)1344 858 000

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

CLP REGULATION (EC) No 1272/2008

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

classification and label information, as applicable, is provided below.

CLASSIFICATION:

Flammable Liquid, Category 3 - Flam. Liq. 3; H226
 Serious Eye Damage/Eye Irritation, Category 1 - Eye Dam. 1; H318
 Skin Sensitization, Category 1 - Skin Sens. 1; H317

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) | GHS05 (Corrosion) | GHS07 (Exclamation mark) |

Pictograms



Ingredients:

| Ingredient | CAS Nbr | EC No. | % by Wt |
|----------------------------------|--------------|-----------|---------|
| Bis-GMA | 1565-94-2 | 216-367-7 | 15 - 25 |
| Hydroxyethyl Methacrylate (HEMA) | 868-77-9 | 212-782-2 | 15 - 25 |
| Methacrylic phosphoric acid | 1207736-18-2 | | 10 - 20 |
| Methacrylated amine | 2867-47-2 | 220-688-8 | < 1 |

HAZARD STATEMENTS:

| | |
|------|--------------------------------------|
| H226 | Flammable liquid and vapour. |
| H318 | Causes serious eye damage. |
| H317 | May cause an allergic skin reaction. |

PRECAUTIONARY STATEMENTS

Prevention:

| | |
|-------|--|
| P210A | Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. |
| P280B | Wear protective gloves and eye/face protection. |

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. |
| P310 | Immediately call a POISON CENTRE or doctor/physician. |
| P333 + P313 | If skin irritation or rash occurs: Get medical advice/attention. |
| P370 + P378G | In case of fire: Use a fire fighting agent suitable for flammable liquids such as dry chemical or carbon dioxide to extinguish. |

Notes on labelling

Per test data, this product is not classified as H314.

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 |
|--|--------------|-----------|------------|--|
| Bis-GMA | 1565-94-2 | 216-367-7 | 15 - 25 | Skin Sens. 1B, H317 |
| Hydroxyethyl Methacrylate (HEMA) (REACH Reg. No.:01-2119490169-29) | 868-77-9 | 212-782-2 | 15 - 25 | Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 - Nota D |
| Methacrylic phosphoric acid | 1207736-18-2 | | 10 - 20 | Skin Corr. 1B, H314; Eye Dam. 1, H318; Skin Sens. 1, H317; STOT SE 3, H335 |
| Water | 7732-18-5 | 231-791-2 | 10 - 15 | Substance not classified as hazardous |
| Ethanol (REACH Reg. No.:01-2119457610-43) | 64-17-5 | 200-578-6 | 10 - 15 | Flam. Liq. 2, H225 Eye Irrit. 2, H319 |
| Silane treated silica | 122334-95-6 | 310-178-4 | 7 - 13 | Substance not classified as hazardous |
| Polymeric acid | 25948-33-8 | | 1 - 5 | Substance not classified as hazardous |
| Camphorquinone | 10373-78-1 | 233-814-1 | < 2 | Substance not classified as hazardous |
| Aromatic amine | 10287-53-3 | 233-634-3 | < 2 | Aquatic Chronic 2, H411 |
| Methacrylated amine | 2867-47-2 | 220-688-8 | < 1 | Acute Tox. 4, H312; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 - Nota D |
| BHT (REACH Reg. No.:01-2119565113-46) | 128-37-0 | 204-881-4 | 0.01 - 0.5 | Aquatic Acute 1, H400,M=1; Aquatic Chronic 1, H410,M=1 |

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

Immediately flush with large amounts of water for at least 15 minutes. Remove contact lenses if easy to do. Continue rinsing. Immediately 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.

Hazardous Decomposition or By-Products

| <u>Substance</u> | <u>Condition</u> |
|----------------------------|--------------------|
| Formaldehyde | During combustion. |
| Carbon monoxide. | During combustion. |
| Carbon dioxide. | During combustion. |
| Irritant vapours or gases. | During combustion. |
| Oxides of nitrogen. | During combustion. |

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 designed for use on solvents, such as alcohols and acetone, that can dissolve in water. An AR-AFFF type foam is recommended. 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 detergent and water. 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 |
|------------|----------|--------|---------------------------------------|---------------------|
| BHT | 128-37-0 | UK HSC | TWA:10 mg/m ³ | |
| Ethanol | 64-17-5 | UK HSC | TWA:1920 mg/m ³ (1000 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

Yellow

Specific Physical Form:

Viscous Liquid

Odor

Characteristic Odour

pH

Not applicable.

Boiling point/boiling range

≥ 78 °C

Melting point

No data available.

Flammability (solid, gas)

Not applicable.

Explosive properties

Not classified

Oxidising properties

Not classified

Flash point

30.5 °C [*Test Method:*Closed Cup]

Autoignition temperature

No data available.

Flammable Limits(LEL)

No data available.

| | |
|------------------------------|-------------------------------------|
| Flammable Limits(UEL) | <i>No data available.</i> |
| Relative density | 1 - 1.2 [<i>Ref Std: WATER=1</i>] |
| Water solubility | Appreciable |
| Viscosity | <i>Not applicable.</i> |
| Density | 1 - 1.2 g/cm ³ |

9.2. Other information

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

Heat.

10.5 Incompatible materials

None known.

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

No health effects are expected.

Skin contact

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

Corrosive (eye burns): Signs/symptoms may include cloudy appearance of the cornea, chemical burns, severe pain, tearing, ulcerations, significantly impaired vision or complete loss of vision.

Ingestion

Gastrointestinal corrosion: Signs/symptoms may include severe mouth, throat and abdominal pain, nausea, vomiting, and diarrhea; blood in the faeces and/or vomitus may also be seen.

Additional information:

This product contains ethanol. Alcoholic beverages and ethanol in alcoholic beverages have been classified by the International Agency for Research on Cancer as carcinogenic to humans. There are also data associating human consumption of alcoholic beverages with developmental toxicity and liver toxicity. Exposure to ethanol during the foreseeable use of this product is not expected to cause cancer, developmental toxicity, or liver toxicity.

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 |
| Hydroxyethyl Methacrylate (HEMA) | Dermal | Rabbit | LD50 > 5,000 mg/kg |
| Hydroxyethyl Methacrylate (HEMA) | Ingestion | Rat | LD50 5,564 mg/kg |
| Bis-GMA | Ingestion | | LD50 estimated to be 2,000 - 5,000 mg/kg |
| Bis-GMA | Dermal | Professional judgement | LD50 estimated to be 2,000 - 5,000 mg/kg |
| Ethanol | Dermal | Rabbit | LD50 > 15,800 mg/kg |
| Ethanol | Inhalation-Vapour (4 hours) | Rat | LC50 124.7 mg/l |
| Ethanol | Ingestion | Rat | LD50 17,800 mg/kg |
| Methacrylic phosphoric acid | Dermal | Professional judgement | LD50 estimated to be > 5,000 mg/kg |
| Methacrylic phosphoric acid | Ingestion | Rat | LD50 > 2,000 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 |
| Polymeric acid | Ingestion | Rat | LD50 > 5,000 mg/kg |
| Polymeric acid | Dermal | similar health hazards | LD50 estimated to be > 5,000 mg/kg |
| Camphorquinone | Dermal | Professional judgement | LD50 estimated to be 2,000 - 5,000 mg/kg |
| Camphorquinone | Ingestion | Rat | LD50 > 2,000 mg/kg |
| Aromatic amine | Dermal | Rat | LD50 > 2,000 mg/kg |
| Aromatic amine | Ingestion | Rat | LD50 > 2,000 mg/kg |
| Methacrylated amine | Dermal | Rat | LD50 > 2,000 mg/kg |
| Methacrylated amine | Inhalation-Dust/Mist (4 hours) | Rat | LC50 > 0.436 mg/l |
| Methacrylated amine | Ingestion | Rat | LD50 > 2,000 mg/kg |
| BHT | Dermal | Rat | LD50 > 2,000 mg/kg |
| BHT | Ingestion | Rat | LD50 > 2,930 mg/kg |

ATE = acute toxicity estimate

Skin Corrosion/Irritation

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

| | | |
|----------------------------------|------------------|---------------------------|
| Overall product | Rabbit | No significant irritation |
| Hydroxyethyl Methacrylate (HEMA) | Rabbit | Minimal irritation |
| Bis-GMA | Not available | Minimal irritation |
| Ethanol | Rabbit | No significant irritation |
| Methacrylic phosphoric acid | In vitro data | Corrosive |
| Silane treated silica | Rabbit | No significant irritation |
| Aromatic amine | Rabbit | No significant irritation |
| BHT | Human and animal | Minimal irritation |

Serious Eye Damage/Irritation

| Name | Species | Value |
|----------------------------------|---------------|---------------------------|
| Overall product | In vitro data | Corrosive |
| Hydroxyethyl Methacrylate (HEMA) | Rabbit | Moderate irritant |
| Bis-GMA | Not available | Moderate irritant |
| Ethanol | Rabbit | Severe irritant |
| Methacrylic phosphoric acid | In vitro data | Corrosive |
| Silane treated silica | Rabbit | No significant irritation |
| Aromatic amine | Rabbit | Mild irritant |
| BHT | Rabbit | Mild irritant |

Skin Sensitisation

| Name | Species | Value |
|----------------------------------|------------------------|----------------|
| Hydroxyethyl Methacrylate (HEMA) | Human and animal | Sensitising |
| Bis-GMA | Guinea pig | Sensitising |
| Ethanol | Human | Not classified |
| Methacrylic phosphoric acid | Professional judgement | Sensitising |
| Silane treated silica | Human and animal | Not classified |
| BHT | Human | 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 |
|----------------------------------|----------|--|
| Hydroxyethyl Methacrylate (HEMA) | In vivo | Not mutagenic |
| Hydroxyethyl Methacrylate (HEMA) | In Vitro | Some positive data exist, but the data are not sufficient for classification |
| Bis-GMA | In Vitro | Some positive data exist, but the data are not sufficient for classification |
| Ethanol | In Vitro | Some positive data exist, but the data are not sufficient for classification |
| Ethanol | In vivo | Some positive data exist, but the data are not sufficient for classification |
| Methacrylic phosphoric acid | In Vitro | Not mutagenic |
| Silane treated silica | In Vitro | Not mutagenic |
| BHT | In Vitro | Not mutagenic |
| BHT | In vivo | Not mutagenic |

Carcinogenicity

| Name | Route | Species | Value |
|-----------------------|----------------|-------------------------|--|
| Ethanol | Ingestion | Multiple animal species | Some positive data exist, but the data are not sufficient for classification |
| Silane treated silica | Not specified. | Mouse | Some positive data exist, but the data are not sufficient for classification |
| BHT | Ingestion | Multiple animal species | 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 |
|----------------------------------|------------|--|---------|-----------------------|--------------------------------|
| Hydroxyethyl Methacrylate (HEMA) | Ingestion | Not classified for female reproduction | Rat | NOAEL 1,000 mg/kg/day | prematuring & during gestation |
| Hydroxyethyl Methacrylate (HEMA) | Ingestion | Not classified for male reproduction | Rat | NOAEL 1,000 mg/kg/day | 49 days |
| Hydroxyethyl Methacrylate (HEMA) | Ingestion | Not classified for development | Rat | NOAEL 1,000 mg/kg/day | prematuring & during gestation |
| Bis-GMA | Ingestion | Not classified for female reproduction | Mouse | NOAEL 0.8 mg/kg/day | prematuring & during gestation |
| Bis-GMA | Ingestion | Not classified for male reproduction | Mouse | NOAEL 0.8 mg/kg/day | prematuring & during gestation |
| Bis-GMA | Ingestion | Not classified for development | Mouse | NOAEL 0.8 mg/kg/day | prematuring & during gestation |
| Ethanol | Inhalation | Not classified for development | Rat | NOAEL 38 mg/l | during gestation |
| Ethanol | Ingestion | Not classified for development | Rat | NOAEL 5,200 mg/kg/day | prematuring & during gestation |
| 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 |
| BHT | Ingestion | Not classified for female reproduction | Rat | NOAEL 500 mg/kg/day | 2 generation |
| BHT | Ingestion | Not classified for male reproduction | Rat | NOAEL 500 mg/kg/day | 2 generation |
| BHT | Ingestion | Not classified for development | Rat | NOAEL 100 mg/kg/day | 2 generation |

Target Organ(s)**Specific Target Organ Toxicity - single exposure**

| Name | Route | Target Organ(s) | Value | Species | Test result | Exposure Duration |
|-----------------------------|------------|-----------------------------------|--|-------------------------|---------------------|-------------------|
| Ethanol | Inhalation | central nervous system depression | May cause drowsiness or dizziness | Human | LOAEL 2.6 mg/l | 30 minutes |
| Ethanol | Inhalation | respiratory irritation | Some positive data exist, but the data are not sufficient for classification | Human | LOAEL 9.4 mg/l | not available |
| Ethanol | Ingestion | central nervous system depression | May cause drowsiness or dizziness | Multiple animal species | NOAEL not available | |
| Ethanol | Ingestion | kidney and/or bladder | Not classified | Dog | NOAEL 3,000 mg/kg | |
| Methacrylic phosphoric acid | Inhalation | respiratory irritation | May cause respiratory irritation | similar health hazards | NOAEL Not available | |
| Polymeric acid | Ingestion | nervous system | Not classified | Rat | NOAEL 5,000 mg/kg | |

Specific Target Organ Toxicity - repeated exposure

| Name | Route | Target Organ(s) | Value | Species | Test result | Exposure Duration |
|---------|------------|---|--|---------|---------------------|--------------------------------|
| Bis-GMA | Ingestion | endocrine system liver nervous system kidney and/or bladder | Not classified | Mouse | NOAEL 0.8 mg/kg/day | prematuring & during gestation |
| Ethanol | Inhalation | liver | Some positive data exist, but the data are not sufficient for classification | Rabbit | LOAEL 124 mg/l | 365 days |
| Ethanol | Inhalation | hematopoietic system immune system | Not classified | Rat | NOAEL 25 mg/l | 14 days |
| Ethanol | Ingestion | liver | Some positive data exist, but the data are not sufficient for | Rat | LOAEL 8,000 | 4 months |

| | | | classification | | mg/kg/day | |
|-----------------------|------------|--|--|-------|-----------------------|-----------------------|
| Ethanol | Ingestion | kidney and/or bladder | Not classified | Dog | NOAEL 3,000 mg/kg/day | 7 days |
| Silane treated silica | Inhalation | respiratory system silicosis | Not classified | Human | NOAEL Not available | occupational exposure |
| Polymeric acid | Ingestion | endocrine system hematopoietic system liver | Not classified | Rat | NOAEL 200 mg/kg/day | 28 days |
| Polymeric acid | Ingestion | heart bone, teeth, nails, and/or hair immune system muscles nervous system eyes kidney and/or bladder respiratory system vascular system | Not classified | Rat | NOAEL 2,000 mg/kg/day | 28 days |
| BHT | Ingestion | liver | Some positive data exist, but the data are not sufficient for classification | Rat | NOAEL 250 mg/kg/day | 28 days |
| BHT | Ingestion | kidney and/or bladder | Not classified | Rat | NOAEL 500 mg/kg/day | 2 generation |
| BHT | Ingestion | blood | Not classified | Rat | LOAEL 420 mg/kg/day | 40 days |
| BHT | Ingestion | endocrine system | Not classified | Rat | NOAEL 25 mg/kg/day | 2 generation |
| BHT | Ingestion | heart | Not classified | Mouse | NOAEL 3,480 mg/kg/day | 10 weeks |

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 |
|----------------------------------|-----------|----------------|---|----------|---------------|-------------|
| Bis-GMA | 1565-94-2 | | Data not available or insufficient for classification | | | |
| Hydroxyethyl Methacrylate (HEMA) | 868-77-9 | Fathead minnow | Experimental | 96 hours | LC50 | 227 mg/l |
| Hydroxyethyl Methacrylate (HEMA) | 868-77-9 | Green algae | Experimental | 72 hours | EC50 | 710 mg/l |
| Hydroxyethyl Methacrylate (HEMA) | 868-77-9 | Water flea | Experimental | 48 hours | EC50 | 380 mg/l |
| Hydroxyethyl Methacrylate (HEMA) | 868-77-9 | Green Algae | Experimental | 72 hours | NOEC | 160 mg/l |

| | | | | | | |
|----------------------------------|--------------|---------------|---|----------|--------------------------------|------------|
| Hydroxyethyl Methacrylate (HEMA) | 868-77-9 | Water flea | Experimental | 21 days | NOEC | 24.1 mg/l |
| Methacrylic phosphoric acid | 1207736-18-2 | | Data not available or insufficient for classification | | | |
| Ethanol | 64-17-5 | Rainbow trout | Experimental | 96 hours | LC50 | 42 mg/l |
| Ethanol | 64-17-5 | Water flea | Experimental | 48 hours | LC50 | 5,012 mg/l |
| Ethanol | 64-17-5 | Algae other | Experimental | 96 hours | NOEC | 1,580 mg/l |
| Ethanol | 64-17-5 | Water flea | Experimental | 10 days | NOEC | 9.6 mg/l |
| Silane treated silica | 122334-95-6 | | Data not available or insufficient for classification | | | |
| Polymeric acid | 25948-33-8 | | Data not available or insufficient for classification | | | |
| Aromatic amine | 10287-53-3 | Green Algae | Experimental | 72 hours | EC50 | 2.8 mg/l |
| Aromatic amine | 10287-53-3 | Rainbow trout | Experimental | 96 hours | LC50 | 1.9 mg/l |
| Aromatic amine | 10287-53-3 | Water flea | Experimental | 48 hours | EC50 | 4.5 mg/l |
| Aromatic amine | 10287-53-3 | Green Algae | Experimental | 72 hours | Effect Conc. 10% - Growth Rate | 0.71 mg/l |
| Camphorquinone | 10373-78-1 | | Data not available or insufficient for classification | | | |
| Methacrylated amine | 2867-47-2 | Green Algae | Experimental | 72 hours | EC50 | 69.7 mg/l |
| Methacrylated amine | 2867-47-2 | Ricefish | Experimental | 96 hours | LC50 | 19 mg/l |
| Methacrylated amine | 2867-47-2 | Water flea | Experimental | 48 hours | EC50 | 33 mg/l |
| Methacrylated amine | 2867-47-2 | Green Algae | Experimental | 72 hours | NOEC | 32 mg/l |
| Methacrylated amine | 2867-47-2 | Water flea | Experimental | 21 days | NOEC | 4.35 mg/l |
| BHT | 128-37-0 | Green algae | Experimental | 72 hours | EC50 | >0.4 mg/l |
| BHT | 128-37-0 | Water flea | Experimental | 48 hours | EC50 | 0.48 mg/l |
| BHT | 128-37-0 | Zebra Fish | Experimental | 96 hours | LC50 | >100 mg/l |
| BHT | 128-37-0 | Green algae | Experimental | 72 hours | Effect Concentration 10% | 0.4 mg/l |
| BHT | 128-37-0 | Ricefish | Experimental | 42 days | NOEC | 0.053 mg/l |
| BHT | 128-37-0 | Water flea | Experimental | 21 days | NOEC | 0.023 mg/l |

12.2. Persistence and degradability

| Material | CAS Nbr | Test type | Duration | Study Type | Test result | Protocol |
|----------------------------------|--------------|-----------------------------------|----------|------------|----------------|---------------------------|
| Bis-GMA | 1565-94-2 | Estimated Biodegradation | 28 days | BOD | 32 % weight | OECD 301C - MITI test (I) |
| Hydroxyethyl Methacrylate (HEMA) | 868-77-9 | Experimental Biodegradation | 14 days | BOD | 95 % BOD/ThBOD | OECD 301C - MITI test (I) |
| Methacrylic phosphoric acid | 1207736-18-2 | Estimated Biodegradation | 28 days | BOD | 91 % weight | OECD 301C - MITI test (I) |
| Ethanol | 64-17-5 | Experimental Biodegradation | 14 days | BOD | 89 % BOD/ThBOD | OECD 301C - MITI test (I) |
| Silane treated silica | 122334-95-6 | Data not available - insufficient | | | N/A | |

| | | | | | | |
|---------------------|------------|---------------------------------|---------|--------------------------------|------------------------------------|-----------------------------------|
| Polymeric acid | 25948-33-8 | Data not available/insufficient | | | N/A | |
| Aromatic amine | 10287-53-3 | Experimental Biodegradation | 28 days | CO2 evolution | 40 %CO2 evolution/THC O2 evolution | OECD 301B - Modified sturm or CO2 |
| Camphorquinone | 10373-78-1 | Estimated Biodegradation | 28 days | BOD | 20.6 % BOD/ThBOD | OECD 301C - MITI test (I) |
| Methacrylated amine | 2867-47-2 | Estimated Photolysis | | Photolytic half-life (in air) | 3.88 hours (t 1/2) | Other methods |
| Methacrylated amine | 2867-47-2 | Experimental Hydrolysis | | Hydrolytic half-life | 4.5 days (t 1/2) | Other methods |
| Methacrylated amine | 2867-47-2 | Experimental Biodegradation | 28 days | Dissolv. Organic Carbon Deplet | 95.3 % weight | OECD 301E - Modified OECD Scre |
| BHT | 128-37-0 | Data not available/insufficient | | | N/A | |

12.3 : Bioaccumulative potential

| Material | Cas No. | Test type | Duration | Study Type | Test result | Protocol |
|----------------------------------|--------------|---|----------|------------------------|-------------|--|
| Bis-GMA | 1565-94-2 | Estimated Bioconcentration | | Bioaccumulation factor | 5.8 | Estimated: Bioconcentration factor |
| Hydroxyethyl Methacrylate (HEMA) | 868-77-9 | Experimental Bioconcentration | | Log Kow | 0.42 | Other methods |
| Methacrylic phosphoric acid | 1207736-18-2 | Estimated Bioconcentration | | Bioaccumulation factor | 4.5 | Other methods |
| Ethanol | 64-17-5 | Experimental Bioconcentration | | Log Kow | -0.35 | Other methods |
| Silane treated silica | 122334-95-6 | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| Polymeric acid | 25948-33-8 | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| Aromatic amine | 10287-53-3 | Experimental Bioconcentration | | Log Kow | 3.2 | Other methods |
| Camphorquinone | 10373-78-1 | Estimated Bioconcentration | | Bioaccumulation factor | 7.1 | Estimated: Bioconcentration factor |
| Methacrylated amine | 2867-47-2 | Experimental Bioconcentration | | Log Kow | 1.13 | Other methods |
| BHT | 128-37-0 | Experimental BCF-Carp | 56 days | Bioaccumulation factor | 1277 | OECD 305E - Bioaccumulation flow-through fish test |

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: UN1133; ADHESIVES; 3; III; (D/E); F1.

IATA: UN1133; ADHESIVES; 3; III.

IMDG: UN1133; ADHESIVES; 3; III; FE, SD.

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

| | |
|------|---|
| H225 | Highly flammable liquid and vapour. |
| H226 | Flammable liquid and vapour. |
| H302 | Harmful if swallowed. |
| H312 | Harmful in contact with skin. |
| H314 | Causes severe skin burns and eye damage. |
| H315 | Causes skin irritation. |
| H317 | May cause an allergic skin reaction. |
| H318 | Causes serious eye damage. |
| H319 | Causes serious eye irritation. |
| H335 | May cause respiratory irritation. |
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |
| H411 | Toxic to aquatic life with long lasting effects. |

Revision information:

Revision information not available

The product to which this Safety Information Sheet applies is classified as a medical device according to the EU Medical Device Regulation EU 2017/745. _x000D_

Medical devices which are invasive or used in direct physical contact with the human body are exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). _x000D_

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

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