



Safety Information Sheet for Medical Devices

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

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

1.1. Product identifier

3M™ Scotchbond™ Universal Plus Vial (41294, 41295, 41296, 41307)

Product Identification Numbers

| | | | | |
|----------------|----------------|----------------|----------------|----------------|
| UU-0109-0661-6 | UU-0109-0662-4 | UU-0109-0663-2 | UU-0109-6372-4 | UU-0109-6373-2 |
| 7100227711 | 7100227712 | 7100227710 | 4100046862 | 4100046865 |

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

Dental Adhesive

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

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

1.4. Emergency telephone number

+44 (0)1344 858 000

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

CLP REGULATION (EC) No 1272/2008

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

This material has been tested for skin corrosion/irritation and the test results are reflected in the assigned classification.

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

Skin Corrosion/Irritation, Category 2 - Skin Irrit. 2; H315

Serious Eye Damage/Eye Irritation, Category 1 - Eye Dam. 1; H318

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

Reproductive Toxicity, Category 1B - Repr. 1B; H360F

Hazardous to the Aquatic Environment (Chronic), Category 3 - Aquatic Chronic 3; H412

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) | GHS08 (Health Hazard) |

Pictograms



Ingredients:

| Ingredient | CAS Nbr | EC No. | % by Wt |
|-----------------------------|--------------|-----------|---------|
| Methacrylate (HEMA) | 868-77-9 | 212-782-2 | 15 - 25 |
| Phosphorylated methacrylate | 1207736-18-2 | 944-391-4 | < 20 |
| Aromatic amine | 10287-53-3 | 233-634-3 | < 2 |

HAZARD STATEMENTS:

| | |
|-------|--|
| H225 | Highly flammable liquid and vapour. |
| H315 | Causes skin irritation. |
| H318 | Causes serious eye damage. |
| H317 | May cause an allergic skin reaction. |
| H360F | May damage fertility. |
| H412 | Harmful to aquatic life with long lasting effects. |

PRECAUTIONARY STATEMENTS

Prevention:

| | |
|-------|--|
| P201 | Obtain special instructions before use. |
| P210 | 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.

For containers not exceeding 125 ml the following Hazard and Precautionary statements may be used:

<=125 ml Hazard statements

H318 Causes serious eye damage.
 H317 May cause an allergic skin reaction.
 H360F May damage fertility.

 H412 Harmful to aquatic life with long lasting effects.

<=125 ml Precautionary statements

Prevention:

P201 Obtain special instructions before use.
 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.

SUPPLEMENTAL INFORMATION:

Supplemental Precautionary Statements:

Restricted to professional users.

2.3. Other hazards

For information on hazards and safe use, please consider the corresponding sections of this document. This material does not contain any substances that are assessed to be a PBT or vPvB

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

| Ingredient | Identifier(s) | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|-----------------------------|--|------------|---|
| Bromited dimethacrylate | (CAS-No.) 2305048-54-6 (EC-No.) 944-271-1 | 25 - 35 | Skin Irrit. 2, H315 Skin Sens. 1B, H317 |
| Methacrylate (HEMA) | (CAS-No.) 868-77-9 (EC-No.) 212-782-2 | 15 - 25 | Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 Nota D |
| Phosphorylated methacrylate | (CAS-No.) 1207736-18-2 (EC-No.) 944-391-4 | < 20 | Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Acute 1, H400,M=1 Aquatic Chronic 2, H411 |

| | | | |
|-----------------------|--|--------|---|
| Water | (CAS-No.) 7732-18-5 (EC-No.) 231-791-2 | 5 - 15 | Substance not classified as hazardous |
| Ethyl alcohol | (CAS-No.) 64-17-5 (EC-No.) 200-578-6 | 5 - 15 | Flam. Liq. 2, H225 Eye Irrit. 2, H319 |
| Silane treated silica | (CAS-No.) 2680625-03-8 | 5 - 15 | Substance not classified as hazardous |
| Silica | (CAS-No.) 112945-52-5 | 1 - 10 | Substance with a national occupational exposure limit |
| Methacrylated silane | (CAS-No.) 21142-29-0 (EC-No.) 244-239-0 | < 5 | Substance not classified as hazardous |
| Dimethacrylate | (CAS-No.) 2358-84-1 (EC-No.) 219-099-9 | < 0.5 | Skin Sens. 1B, H317 |
| Aminopropylsilane | (CAS-No.) 919-30-2 (EC-No.) 213-048-4 | < 0.5 | Acute Tox. 4, H302 Skin Corr. 1B, H314 Skin Sens. 1B, H317 |
| Camphorquinone | (CAS-No.) 10373-78-1 (EC-No.) 233-814-1 | < 2 | Substance not classified as hazardous |
| Aromatic amine | (CAS-No.) 10287-53-3 (EC-No.) 233-634-3 | < 2 | Aquatic Chronic 2, H411 Repr. 1B, H360F |
| Polymeric acid | (CAS-No.) 25948-33-8 | < 2 | Substance not classified as hazardous |
| Copper salt | (CAS-No.) 6046-93-1 | < 0.1 | Acute Tox. 4, H302 Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Acute 1, H400,M=10 Aquatic Chronic 1, H410,M=10 |

Any entry in the Identifier(s) column that begins with the numbers 6, 7, 8, or 9 are a Provisional List Number provided by ECHA pending publication of the official EC Inventory Number for the substance.

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

Specific Concentration Limits

| Ingredient | Identifier(s) | Specific Concentration Limits |
|---------------|---|-------------------------------|
| Ethyl alcohol | (CAS-No.) 64-17-5 (EC-No.) 200-578-6 | (C >= 50%) Eye Irrit. 2, H319 |

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 that is resistant to polar solvents. 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 |
|-----------------|-------------|--------|---|---------------------|
| Silicon dioxide | 112945-52-5 | UK HSC | TWA(as respirable dust):2.4 mg/m ³ ;TWA(as inhalable dust):6 mg/m ³ | |
| Ethyl alcohol | 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

| | |
|------------------------------|--|
| Physical state | Liquid. |
| Specific Physical Form: | Viscous Liquid |
| Colour | Yellow |
| Odor | Alcohol |
| Melting point/freezing point | <i>No data available.</i> |
| Boiling point/boiling range | > 78 °C |
| Flammability (solid, gas) | Not applicable. |
| Flammable Limits(LEL) | <i>No data available.</i> |
| Flammable Limits(UEL) | <i>No data available.</i> |
| Flash point | approximately 21 °C [Test Method:Closed Cup] |
| Autoignition temperature | <i>No data available.</i> |
| Relative density | approximately 1.1 |
| pH | |
| Kinematic Viscosity | <i>Not applicable.</i> |
| Water solubility | Appreciable |

Density approximately 1.1 g/cm³

9.2. Other information

9.2.2 Other safety characteristics

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

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 internal hazard assessments.

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

Signs and Symptoms of Exposure

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

Inhalation

Respiratory tract irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.

Skin contact

Skin Irritation: Signs/symptoms may include localised redness, swelling, itching, dryness, cracking, blistering, and pain.
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. May cause additional health effects (see below).

Additional Health Effects:

Reproductive/Developmental Toxicity:

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

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 |
| Bromited dimethacrylate | Dermal | Professional judgement | LD50 estimated to be > 5,000 mg/kg |
| Bromited dimethacrylate | Ingestion | Rat | LD50 > 2,000 mg/kg |
| Methacrylate (HEMA) | Dermal | Rabbit | LD50 > 5,000 mg/kg |
| Methacrylate (HEMA) | Ingestion | Rat | LD50 5,564 mg/kg |
| Ethyl alcohol | Dermal | Rabbit | LD50 > 15,800 mg/kg |
| Ethyl alcohol | Inhalation-Vapour (4 hours) | Rat | LC50 124.7 mg/l |
| Ethyl alcohol | Ingestion | Rat | LD50 17,800 mg/kg |
| Phosphorylated methacrylate | Dermal | Professional judgement | LD50 estimated to be > 5,000 mg/kg |
| Phosphorylated methacrylate | Ingestion | Rat | LD50 > 2,000 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 |
| Camphorquinone | Dermal | Professional judgement | LD50 estimated to be 2,000 - 5,000 mg/kg |
| Camphorquinone | Ingestion | Rat | LD50 > 2,000 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 |
| Aromatic amine | Dermal | Rat | LD50 > 2,000 mg/kg |
| Aromatic amine | Ingestion | Rat | LD50 > 2,000 mg/kg |
| Dimethacrylate | Dermal | similar compounds | LD50 > 2,000 mg/kg |
| Dimethacrylate | Ingestion | similar compounds | LD50 Not available. |
| Aminopropylsilane | Dermal | Rabbit | LD50 4,290 mg/kg |
| Aminopropylsilane | Ingestion | Rat | LD50 1,570 mg/kg |
| Copper salt | Dermal | Rat | LD50 > 2,000 mg/kg |
| Copper salt | Ingestion | Rat | LD50 > 300, < 2000 mg/kg |

ATE = acute toxicity estimate

Skin Corrosion/Irritation

| Name | Species | Value |
|-----------------------------|-------------------|---------------------------|
| Overall product | In vitro data | Irritant |
| Bromited dimethacrylate | In vitro data | Irritant |
| Methacrylate (HEMA) | Rabbit | Minimal irritation |
| Ethyl alcohol | Rabbit | No significant irritation |
| Phosphorylated methacrylate | In vitro data | Corrosive |
| Silica | Rabbit | No significant irritation |
| Aromatic amine | Rabbit | No significant irritation |
| Dimethacrylate | similar compounds | No significant irritation |
| Aminopropylsilane | Rabbit | Corrosive |
| Copper salt | In vitro data | Corrosive |

Serious Eye Damage/Irritation

| Name | Species | Value |
|-----------------------------|-------------------|---------------------------|
| Bromited dimethacrylate | In vitro data | No significant irritation |
| Methacrylate (HEMA) | Rabbit | Moderate irritant |
| Ethyl alcohol | Rabbit | Severe irritant |
| Phosphorylated methacrylate | In vitro data | Corrosive |
| Silica | Rabbit | No significant irritation |
| Aromatic amine | Rabbit | No significant irritation |
| Dimethacrylate | similar compounds | No significant irritation |
| Aminopropylsilane | Rabbit | Corrosive |
| Copper salt | Rabbit | Corrosive |

Skin Sensitisation

| Name | Species | Value |
|-----------------------------|------------------------|----------------|
| Bromited dimethacrylate | Professional judgement | Sensitising |
| Methacrylate (HEMA) | Human and animal | Sensitising |
| Ethyl alcohol | Human | Not classified |
| Phosphorylated methacrylate | Mouse | Sensitising |
| Silica | Human and animal | Not classified |
| Aromatic amine | | Not classified |
| Dimethacrylate | similar compounds | Sensitising |
| Aminopropylsilane | Guinea pig | Sensitising |
| Copper salt | 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 |
|-----------------------------|----------|--|
| Bromited dimethacrylate | In vivo | Not mutagenic |
| Bromited dimethacrylate | In Vitro | Some positive data exist, but the data are not sufficient for classification |
| Methacrylate (HEMA) | In vivo | Not mutagenic |
| Methacrylate (HEMA) | In Vitro | Some positive data exist, but the data are not sufficient for classification |
| Ethyl alcohol | In Vitro | Some positive data exist, but the data are not sufficient for classification |
| Ethyl alcohol | In vivo | Some positive data exist, but the data are not sufficient for classification |
| Phosphorylated methacrylate | In Vitro | Not mutagenic |
| Silica | In Vitro | Not mutagenic |
| Aromatic amine | In vivo | Not mutagenic |
| Aromatic amine | In Vitro | Some positive data exist, but the data are not sufficient for classification |
| Dimethacrylate | In Vitro | Not mutagenic |
| Copper salt | In Vitro | Not mutagenic |

Carcinogenicity

| Name | Route | Species | Value |
|---------------|----------------|-------------------------|--|
| Ethyl alcohol | Ingestion | Multiple animal species | Some positive data exist, but the data are not sufficient for classification |
| Silica | Not specified. | Mouse | 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 |
|-------------------------|------------|--|---------|-----------------------|--------------------------------|
| Bromited dimethacrylate | Ingestion | Not classified for female reproduction | Rat | NOAEL 1,000 mg/kg/day | prematuring into lactation |
| Bromited dimethacrylate | Ingestion | Not classified for male reproduction | Rat | NOAEL 1,000 mg/kg/day | 29 days |
| Bromited dimethacrylate | Ingestion | Not classified for development | Rat | NOAEL 1,000 mg/kg/day | prematuring into lactation |
| Methacrylate (HEMA) | Ingestion | Not classified for female reproduction | Rat | NOAEL 1,000 mg/kg/day | prematuring & during gestation |
| Methacrylate (HEMA) | Ingestion | Not classified for male reproduction | Rat | NOAEL 1,000 mg/kg/day | 49 days |
| Methacrylate (HEMA) | Ingestion | Not classified for development | Rat | NOAEL 1,000 mg/kg/day | prematuring & during gestation |
| Ethyl alcohol | Inhalation | Not classified for development | Rat | NOAEL 38 mg/l | during gestation |
| Ethyl alcohol | Ingestion | Not classified for development | Rat | NOAEL 5,200 mg/kg/day | prematuring & during gestation |
| 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 |
| Aromatic amine | Ingestion | Not classified for female reproduction | Rat | NOAEL 600 mg/kg/day | prematuring into lactation |
| Aromatic amine | Ingestion | Not classified for development | Rat | NOAEL 50 mg/kg/day | prematuring into lactation |
| Aromatic amine | Ingestion | Toxic to male reproduction | Rat | NOAEL 50 mg/kg/day | 53 days |

Target Organ(s)

Specific Target Organ Toxicity - single exposure

| Name | Route | Target Organ(s) | Value | Species | Test result | Exposure Duration |
|-----------------------------|------------|-----------------------------------|--|-------------------------|---------------------|-------------------|
| Bromited dimethacrylate | Inhalation | respiratory irritation | Some positive data exist, but the data are not sufficient for classification | similar health hazards | NOAEL Not available | |
| Ethyl alcohol | Inhalation | respiratory irritation | Some positive data exist, but the data are not sufficient for classification | Human | LOAEL 9.4 mg/l | not available |
| Ethyl alcohol | Inhalation | central nervous system depression | Not classified | Human and animal | NOAEL not available | |
| Ethyl alcohol | Ingestion | central nervous system depression | Not classified | Multiple animal species | NOAEL not available | |
| Ethyl alcohol | Ingestion | kidney and/or bladder | Not classified | Dog | NOAEL 3,000 mg/kg | |
| Phosphorylated methacrylate | Inhalation | respiratory irritation | Some positive data exist, but the data are not sufficient for classification | similar health hazards | NOAEL Not available | |
| Polymeric acid | Ingestion | nervous system | Not classified | Rat | NOAEL 5,000 mg/kg | |
| Copper salt | Inhalation | respiratory irritation | Some positive data exist, but the data are not sufficient for classification | similar health hazards | NOAEL Not available | |

Specific Target Organ Toxicity - repeated exposure

| Name | Route | Target Organ(s) | Value | Species | Test result | Exposure Duration |
|-------------------------|------------|---|--|---------|-----------------------|-----------------------|
| Bromited dimethacrylate | Ingestion | heart endocrine system gastrointestinal tract bone, teeth, nails, and/or hair hematopoietic system liver immune system muscles nervous system eyes kidney and/or bladder respiratory system | Not classified | Rat | NOAEL 1,000 mg/kg/day | 29 days |
| Ethyl alcohol | Inhalation | liver | Some positive data exist, but the data are not sufficient for classification | Rabbit | LOAEL 124 mg/l | 365 days |
| Ethyl alcohol | Inhalation | hematopoietic system immune system | Not classified | Rat | NOAEL 25 mg/l | 14 days |
| Ethyl alcohol | Ingestion | liver | Some positive data exist, but the data are not sufficient for classification | Rat | LOAEL 8,000 mg/kg/day | 4 months |
| Ethyl alcohol | Ingestion | kidney and/or bladder | Not classified | Dog | NOAEL 3,000 mg/kg/day | 7 days |
| 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 |
| Aromatic amine | Ingestion | hematopoietic system | Some positive data exist, but the data are not sufficient for classification | Rat | NOAEL 74 mg/kg/day | 28 days |
| Aromatic amine | Ingestion | liver heart endocrine system gastrointestinal tract bone, teeth, nails, and/or hair immune system muscles nervous system eyes kidney and/or bladder respiratory system vascular system | Not classified | Rat | NOAEL 900 mg/kg/day | 28 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.

11.2. Information on other hazards

This material does not contain any substances that are assessed to be an endocrine disruptor for human health.

SECTION 12: Ecological information

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

3M assessments.

12.1. Toxicity

No product test data available.

| Material | CAS # | Organism | Type | Exposure | Test endpoint | Test result |
|-----------------------------|--------------|-------------------|--------------------|-----------------|----------------------|-----------------------------|
| Bromited dimethacrylate | 2305048-54-6 | Green algae | Experimental | 72 hours | EC50 | >100 mg/l |
| Bromited dimethacrylate | 2305048-54-6 | Water flea | Experimental | 48 hours | EC50 | >100 mg/l |
| Bromited dimethacrylate | 2305048-54-6 | Green algae | Experimental | 72 hours | EC10 | >100 mg/l |
| Methacrylate (HEMA) | 868-77-9 | Turbot | Analogous Compound | 96 hours | LC50 | 833 mg/l |
| Methacrylate (HEMA) | 868-77-9 | Fathead minnow | Experimental | 96 hours | LC50 | 227 mg/l |
| Methacrylate (HEMA) | 868-77-9 | Green algae | Experimental | 72 hours | EC50 | 710 mg/l |
| Methacrylate (HEMA) | 868-77-9 | Water flea | Experimental | 48 hours | EC50 | 380 mg/l |
| Methacrylate (HEMA) | 868-77-9 | Green algae | Experimental | 72 hours | NOEC | 160 mg/l |
| Methacrylate (HEMA) | 868-77-9 | Water flea | Experimental | 21 days | NOEC | 24.1 mg/l |
| Methacrylate (HEMA) | 868-77-9 | N/A | Experimental | 16 hours | EC0 | >3,000 mg/l |
| Methacrylate (HEMA) | 868-77-9 | N/A | Experimental | 18 hours | LD50 | <98 mg per kg of bodyweight |
| Phosphorylated methacrylate | 1207736-18-2 | Green algae | Experimental | 72 hours | EC50 | 0.718 mg/l |
| Phosphorylated methacrylate | 1207736-18-2 | Water flea | Experimental | 48 hours | EL50 | >104 mg/l |
| Phosphorylated methacrylate | 1207736-18-2 | Green algae | Experimental | 72 hours | NOEC | 0.1 mg/l |
| Ethyl alcohol | 64-17-5 | Fathead minnow | Experimental | 96 hours | LC50 | 14,200 mg/l |
| Ethyl alcohol | 64-17-5 | Fish | Experimental | 96 hours | LC50 | 11,000 mg/l |
| Ethyl alcohol | 64-17-5 | Green algae | Experimental | 72 hours | EC50 | 275 mg/l |
| Ethyl alcohol | 64-17-5 | Water flea | Experimental | 48 hours | LC50 | 5,012 mg/l |
| Ethyl alcohol | 64-17-5 | Green algae | Experimental | 72 hours | ErC10 | 11.5 mg/l |
| Ethyl alcohol | 64-17-5 | Water flea | Experimental | 10 days | NOEC | 9.6 mg/l |
| Silica | 112945-52-5 | Green algae | Analogous Compound | 72 hours | ErC50 | >173.1 mg/l |
| Silica | 112945-52-5 | Sediment organism | Analogous Compound | 96 hours | EC50 | 8,500 mg/kg (Dry Weight) |
| Silica | 112945-52-5 | Water flea | Analogous Compound | 24 hours | EL50 | >10,000 mg/l |
| Silica | 112945-52-5 | Zebra Fish | Analogous Compound | 96 hours | LL50 | >10,000 mg/l |
| Silica | 112945-52-5 | Green algae | Analogous Compound | 72 hours | NOEC | 173.1 mg/l |
| Silica | 112945-52-5 | Water flea | Analogous Compound | 21 days | NOEC | 68 mg/l |
| Silica | 112945-52-5 | Activated sludge | Experimental | 3 hours | EC50 | >1,000 mg/l |
| Aminopropylsilane | 919-30-2 | Bacteria | Experimental | 5.75 hours | EC50 | 43 mg/l |
| Aminopropylsilane | 919-30-2 | Green algae | Experimental | 72 hours | EC50 | 603 mg/l |

| | | | | | | |
|----------------------|------------|------------------|---|----------|-------|-------------------------------|
| Aminopropylsilane | 919-30-2 | Invertebrate | Experimental | 48 hours | LC50 | 580 mg/l |
| Aminopropylsilane | 919-30-2 | Water flea | Experimental | 48 hours | EC50 | 331 mg/l |
| Aminopropylsilane | 919-30-2 | Zebra Fish | Experimental | 96 hours | LC50 | >934 mg/l |
| Aminopropylsilane | 919-30-2 | Green algae | Experimental | 72 hours | NOEC | 1.3 mg/l |
| Dimethacrylate | 2358-84-1 | Green algae | Analogous Compound | 72 hours | ErC50 | 17.3 mg/l |
| Dimethacrylate | 2358-84-1 | Water flea | Analogous Compound | 48 hours | EC50 | 44.9 mg/l |
| Dimethacrylate | 2358-84-1 | Zebra Fish | Analogous Compound | 96 hours | LC50 | 15.95 mg/l |
| Dimethacrylate | 2358-84-1 | Water flea | Analogous Compound | 21 days | NOEC | 5.05 mg/l |
| Dimethacrylate | 2358-84-1 | Activated sludge | Analogous Compound | 3 hours | EC50 | 570 mg/l |
| Methacrylated silane | 21142-29-0 | N/A | Data not available or insufficient for classification | N/A | N/A | N/A |
| Aromatic amine | 10287-53-3 | Activated sludge | Experimental | 3 hours | EC50 | >1,000 mg/l |
| Aromatic amine | 10287-53-3 | Green algae | Experimental | 72 hours | EL50 | 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 | ErC10 | 0.71 mg/l |
| Camphorquinone | 10373-78-1 | N/A | Data not available or insufficient for classification | N/A | N/A | N/A |
| Polymeric acid | 25948-33-8 | N/A | Data not available or insufficient for classification | N/A | N/A | N/A |
| Copper salt | 6046-93-1 | Green algae | Estimated | 72 hours | EC50 | 0.33 mg/l |
| Copper salt | 6046-93-1 | Water flea | Estimated | 48 hours | EC50 | 0.04 mg/l |
| Copper salt | 6046-93-1 | Zebra Fish | Estimated | 96 hours | LC50 | 0.037 mg/l |
| Copper salt | 6046-93-1 | Fathead minnow | Estimated | 32 days | EC10 | 0.019 mg/l |
| Copper salt | 6046-93-1 | Green algae | Estimated | N/A | NOEC | 0.069 mg/l |
| Copper salt | 6046-93-1 | Water flea | Estimated | 7 days | NOEC | 0.01 mg/l |
| Copper salt | 6046-93-1 | Activated sludge | Estimated | N/A | EC50 | 22 mg/l |
| Copper salt | 6046-93-1 | Barley | Estimated | 4 days | NOEC | 50 mg/kg (Dry Weight) |
| Copper salt | 6046-93-1 | Bobwhite quail | Estimated | 14 days | LD50 | 4,402 mg per kg of bodyweight |
| Copper salt | 6046-93-1 | Redworm | Estimated | 56 days | NOEC | 31 mg/kg (Dry Weight) |
| Copper salt | 6046-93-1 | Sediment Worm | Estimated | 28 days | NOEC | 57.5 mg/kg (Dry Weight) |
| Copper salt | 6046-93-1 | Soil microbes | Estimated | 4 days | NOEC | 38 mg/kg (Dry Weight) |
| Copper salt | 6046-93-1 | Springtail | Estimated | 28 days | NOEC | 87.7 mg/kg (Dry Weight) |

12.2. Persistence and degradability

| Material | CAS Nbr | Test type | Duration | Study Type | Test result | Protocol |
|-----------------------------|--------------|-----------------------------------|----------|-------------------------------|-------------------------------------|-------------------------------------|
| Bromited dimethacrylate | 2305048-54-6 | Experimental Biodegradation | 28 days | CO2 evolution | 3.69 %CO2 evolution/THCO2 evolution | OECD 301B - Modified sturm or CO2 |
| Methacrylate (HEMA) | 868-77-9 | Experimental Biodegradation | 28 days | BOD | 84 %BOD/COD | OECD 301D - Closed bottle test |
| Methacrylate (HEMA) | 868-77-9 | Experimental Hydrolysis | | Hydrolytic half-life basic pH | 10.9 days (t 1/2) | OECD 111 Hydrolysis func of pH |
| Phosphorylated methacrylate | 1207736-18-2 | Experimental Biodegradation | 28 days | BOD | 77-80 %BOD/ThOD | OECD 301F - Manometric respirometry |
| Ethyl alcohol | 64-17-5 | Experimental Biodegradation | 14 days | BOD | 89 %BOD/ThOD | OECD 301C - MITI test (I) |
| Silane treated silica | 2680625-03-8 | Data not availbl-insufficient | N/A | N/A | N/A | N/A |
| Silica | 112945-52-5 | Data not availbl-insufficient | N/A | N/A | N/A | N/A |
| Aminopropylsilane | 919-30-2 | Experimental Biodegradation | 28 days | BOD | 54 %BOD/ThOD | OECD 301C - MITI test (I) |
| Aminopropylsilane | 919-30-2 | Estimated Photolysis | | Photolytic half-life (in air) | 7.28 hours (t 1/2) | |
| Aminopropylsilane | 919-30-2 | Experimental Hydrolysis | | Hydrolytic half-life | 8.5 hours (t 1/2) | |
| Dimethacrylate | 2358-84-1 | Experimental Biodegradation | 28 days | BOD | 91 %BOD/ThOD | OECD 301C - MITI test (I) |
| Methacrylated silane | 21142-29-0 | Data not availbl-insufficient | N/A | N/A | N/A | N/A |
| Aromatic amine | 10287-53-3 | Experimental Biodegradation | 28 days | CO2 evolution | 40 %CO2 evolution/THCO2 evolution | OECD 301B - Modified sturm or CO2 |
| Aromatic amine | 10287-53-3 | Experimental Hydrolysis | | Hydrolytic half-life (pH 7) | >1 years (t 1/2) | OECD 111 Hydrolysis func of pH |
| Camphorquinone | 10373-78-1 | Modeled Biodegradation | 28 days | BOD | 20.6 %BOD/ThoD | Catalogic™ |
| Polymeric acid | 25948-33-8 | Data not availbl-insufficient | N/A | N/A | N/A | N/A |
| Copper salt | 6046-93-1 | Analogous Compound Biodegradation | 14 days | BOD | 74 %BOD/ThOD | OECD 301C - MITI test (I) |

12.3 : Bioaccumulative potential

| Material | Cas No. | Test type | Duration | Study Type | Test result | Protocol |
|-----------------------------|--------------|---|----------|------------------------|-------------|---------------------------------|
| Bromited dimethacrylate | 2305048-54-6 | Modeled Bioconcentration | | Bioaccumulation factor | 5.5-6.0 | Catalogic™ |
| Bromited dimethacrylate | 2305048-54-6 | Experimental Bioconcentration | | Log Kow | 4.77 | OECD 107 log Kow shke flask mtd |
| Bromited dimethacrylate | 2305048-54-6 | Experimental Bioconcentration | | Log Kow | 5.22 | OECD 107 log Kow shke flask mtd |
| Bromited dimethacrylate | 2305048-54-6 | Experimental Bioconcentration | | Log Kow | 5.36 | OECD 107 log Kow shke flask mtd |
| Methacrylate (HEMA) | 868-77-9 | Experimental Bioconcentration | | Log Kow | 0.42 | OECD 107 log Kow shke flask mtd |
| Phosphorylated methacrylate | 1207736-18-2 | Modeled Bioconcentration | | Log Kow | -2.02 | ACD/Labs ChemSketch™ |
| Ethyl alcohol | 64-17-5 | Experimental Bioconcentration | | Log Kow | -0.35 | |
| Silane treated silica | 2680625-03-8 | 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 |
| Aminopropylsilane | 919-30-2 | Experimental BCF - Fish | 56 days | Bioaccumulation factor | <3.4 | OECD305-Bioconcentration |
| Dimethacrylate | 2358-84-1 | Experimental Bioconcentration | | Log Kow | 0.81 | |

| | | | | | | |
|----------------------|------------|---|-----|------------------------|-------|------------------------------|
| Methacrylated silane | 21142-29-0 | 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 | OECD 117 log Kow HPLC method |
| Camphorquinone | 10373-78-1 | Modeled Bioconcentration | | Bioaccumulation factor | 7.1 | Catalogic™ |
| Camphorquinone | 10373-78-1 | Experimental Bioconcentration | | Log Kow | 1.52 | |
| Polymeric acid | 25948-33-8 | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| Copper salt | 6046-93-1 | Analogous Compound Bioconcentration | | Log Kow | -0.17 | |

12.4. Mobility in soil

| Material | Cas No. | Test type | Study Type | Test result | Protocol |
|---------------------|------------|-------------------------------------|------------|-------------|--------------------------------|
| Methacrylate (HEMA) | 868-77-9 | Experimental Mobility in Soil | Koc | 42.7 l/kg | |
| Dimethacrylate | 2358-84-1 | Modeled Mobility in Soil | Koc | 14 l/kg | Episuite™ |
| Aromatic amine | 10287-53-3 | Experimental Mobility in Soil | Koc | 560 l/kg | OECD 121 Estim. of Koc by HPLC |
| Camphorquinone | 10373-78-1 | Modeled Mobility in Soil | Koc | 20 l/kg | Episuite™ |
| Copper salt | 6046-93-1 | Analogous Compound Mobility in Soil | Koc | 228 l/kg | |

12.5. Results of the PBT and vPvB assessment

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

12.6. Endocrine disrupting properties

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

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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

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

EU waste code (product as sold)

070104* Other organic solvents, washing liquids and mother liquors

SECTION 14: Transportation information

| | Ground Transport (ADR) | Air Transport (IATA) | Marine Transport (IMDG) |
|------------------------------------|------------------------|----------------------|-------------------------|
| 14.1 UN number or ID number | UN2924 | UN2924 | UN2924 |

| | | | |
|---|---|---|---|
| 14.2 UN proper shipping name | FLAMMABLE LIQUID, CORROSIVE, N.O.S.(ETHANOL; 2-PROPENOIC ACID, 2-METHYL-,REACTION PRODUCTS WITH 1,10-DECANEDIOL AND PHOSPHORUS OXIDE) | FLAMMABLE LIQUID, CORROSIVE, N.O.S.(ETHANOL; 2-PROPENOIC ACID, 2-METHYL-,REACTION PRODUCTS WITH 1,10-DECANEDIOL AND PHOSPHORUS OXIDE) | FLAMMABLE LIQUID, CORROSIVE, N.O.S.(ETHANOL; 2-PROPENOIC ACID, 2-METHYL-,REACTION PRODUCTS WITH 1,10-DECANEDIOL AND PHOSPHORUS OXIDE; ACETIC ACID, COPPER (2+) SALT, MONOHYDRATE) |
| 14.3 Transport hazard class(es) | 3(8) | 3(8) | 3(8) |
| 14.4 Packing group | II | II | II |
| 14.5 Environmental hazards | Environmentally Hazardous | Not applicable | Marine Pollutant |
| 14.6 Special precautions for user | Please refer to the other sections of the SDS for further information. | Please refer to the other sections of the SDS for further information. | Please refer to the other sections of the SDS for further information. |
| 14.7 Marine Transport in bulk according to IMO instruments | No data available. | No data available. | No data available. |
| Control Temperature | No data available. | No data available. | No data available. |
| Emergency Temperature | No data available. | No data available. | No data available. |
| ADR Classification Code | FC | Not applicable. | Not applicable. |
| IMDG Segregation Code | Not applicable. | Not applicable. | NONE |

Please contact the address or phone number listed on the first page of the SDS for additional information on the transport/shipment of the material by rail (RID) or inland waterways (ADN).

SECTION 15: Regulatory information

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

Global inventory status

Contact the manufacturer for more information

SECTION 16: Other information

List of relevant H statements

| | |
|-------|---|
| H225 | Highly flammable liquid and vapour. |
| H302 | Harmful if swallowed. |
| 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. |
| H360F | May damage fertility. |
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |
| H411 | Toxic to aquatic life with long lasting effects. |
| H412 | Harmful to aquatic life with long lasting effects. |

Revision information:

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