

Safety Data Sheet

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This Safety Data Sheet has been prepared in accordance with the GHS guidelines & India Hazardous substances (Classification, Labeling & Packaging) Draft Rules 2011.

SECTION 1: Identification

1.1. Product identifier

FiltekTM Supreme Flowable

Product Identification Numbers

70-2014-1907-7 70-2014-1908-5 70-2014-1909-3 70-2014-1910-1

1.2. Recommended use and restrictions on use

Recommended use

Dental Product, Composite restorative material

1.3. Supplier's details

Address: KCI Medical India Private Limited, S - 327, Greater Kailash - II, New Delhi, Delhi, 110048, India

Telephone: 1-855-423-6725

E Mail: psops_supportteam@solventum.com

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thereon.

1.4. Emergency telephone number

CHEMTREC 1-800-424-9300 OR 1-703-527-3887, Contract number# 1015211

SECTION 2: Hazard identification

Under MSIHC Rules, information is noted below on flammability, acute toxicity and explosivity relevant to this product. In line with international standards, information on other hazard classes and associated precautionary statements relevant to this product are included as well.

2.1. Classification of the substance or mixture

Acute Toxicity (oral): Category 5. Skin Sensitizer: Category 1B. Reproductive Toxicity: Category 1B.

2.2. Label elements

Signal Word

Danger

Symbols

Exclamation mark | Health Hazard |

Pictograms





HAZARD STATEMENTS:

H303 May be harmful if swallowed. H317 May cause an allergic skin reaction. H360 May damage fertility or the unborn child.

PRECAUTIONARY STATEMENTS

Prevention:

P201 Obtain special instructions before use.

P280E Wear protective gloves.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

2.3. Other hazards

None known.

SECTION 3: Composition/information on ingredients

This material is a mixture.

| Ingredient | CAS Nbr | % by Wt |
|---|-------------|---------|
| Silane Treated Ceramic | 444758-98-9 | 50 - 60 |
| Substituted Dimethacrylate | 27689-12-9 | 15 - 25 |
| Triethylene Glycol Dimethacrylate | 109-16-0 | < 10 |
| (TEGDMA) | | |
| Silane Treated Silica | 248596-91-0 | 5 - 10 |
| (1-methylethylidene)bis[4,1- | 1565-94-2 | 5 - 10 |
| phenyleneoxy(2-hydroxy-3,1-propanediyl)] | | |
| bismethacrylate | | |
| Poly[oxy(1-oxo-1,6-hexanediyl)], α , α '- | 220182-22-9 | 1 - 5 |
| (oxydi-2,1-ethanediyl)bis[ω-[[[[2-[(2- | | |
| methyl-1-oxo-2-propen-1- | | |
| yl)oxy]ethyl]amino]carbonyl]oxy]- | | |
| Ytterbium Fluoride (YbF3) | 13760-80-0 | 1 - 5 |
| Ethyl 4-dimethylaminobenzoate | 10287-53-3 | < 0.3 |
| Diphenyliodonium Hexafluorophosphate | 58109-40-3 | < 0.2 |

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.

Eve contact

No need for first aid is anticipated. If signs/symptoms persist, get medical attention.

If swallowed

Rinse mouth. If you feel unwell, get medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Allergic skin reaction (redness, swelling, blistering, and itching).

4.3. Indication of any immediate medical attention and special treatment required

Not applicable

SECTION 5: Fire-fighting measures

5.1. Suitable 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. Special protective actions 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 vapors, in accordance with good industrial hygiene practice. Use PPE - Exposure Assessment

Use personal protective equipment based on the results of an exposure assessment. Refer to Section 8 for PPE recommendations. If anticipated exposure resulting from an accidental release exceeds the protective capabilities of the PPE listed in Section 8, or are unknown, select PPE that offers an appropriate level of protection. Consider the physical and chemical hazards of the material when doing so. Examples of PPE ensembles for emergency response could include wearing bunker gear for a release of flammable material; wearing chemical protective clothing if the spilled material is a corrosive, a sensitizer, a significant dermal irritant, or can be absorbed through the skin; or donning a positive pressure supplied-air respirator for chemicals with inhalation hazards. For information regarding physical and health hazards, refer to sections 2 and 11 of the SDS.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue. Seal the container. Dispose of collected material as soon as possible in accordance with applicable local/regional/national/international regulations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

A no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate commonly-used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapours/spray. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not get in eyes. Use personal protective equipment (eg. gloves, respirators...) as required.

7.2. Conditions for safe storage including any incompatibilities

No special storage requirements.

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 |
|-----------------|------------|--------|---------------------|-------------------------|
| Fluorides, as F | 13760-80-0 | ACGIH | TWA(as F):2.5 mg/m3 | A4: Not class. as human |
| | | | | carcin |

ACGIH: American Conference of Governmental Industrial Hygienists

AIHA: American Industrial Hygiene Association

CMRG : Chemical Manufacturer's Recommended Guidelines

TWA: Time-Weighted-Average STEL: Short Term Exposure Limit

CEIL: Ceiling

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.

Skin/hand protection

See Section 7.1 for additional information on skin protection.

Respiratory protection

None required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| Physical state | Solid. | |
|---|-----------------------|--|
| Specific Physical Form: | Paste | |
| · | | |
| Color | Tooth | |
| Odor | Slight Acrylate | |
| Odour threshold | No data available. | |
| рН | Not applicable. | |
| Melting point/Freezing point: NA | No data available. | |
| Boiling point/Initial boiling point/Boiling range | Not applicable. | |
| Flash point | No flash point | |
| Evaporation rate | Not applicable. | |
| Flammability | Not applicable. | |
| | | |
| Flammable Limits(LEL) | Not applicable. | |
| Flammable Limits(UEL) | Not applicable. | |
| Vapour pressure | Not applicable. | |
| Relative Vapor Density | Not applicable. | |
| Density | 1.5 g/cm3 | |
| Relative density | 1.5 [Ref Std:WATER=1] | |
| Water solubility | Negligible | |
| Solubility- non-water | No data available. | |
| Partition coefficient: n-octanol/water | Not applicable. | |
| Autoignition temperature | No data available. | |
| Decomposition temperature | No data available. | |
| Kinematic Viscosity | No data available. | |
| Volatile organic compounds (VOC) | No data available. | |
| Percent volatile | No data available. | |
| VOC less H2O & exempt solvents | No data available. | |
| Molecular weight | No data available. | |

| Particle Characteristics | Not applicable. |
|--------------------------|-----------------|

SECTION 10: Stability and reactivity

10.1 Reactivity

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

10.2 Chemical stability

Stable.

10.3 Possibility of hazardous reactions

Hazardous polymerisation will not occur.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Substance

None known.

Condition

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labelling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

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

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.

Eve contact

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

Ingestion

May be harmful if swallowed.

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.

Toxicological Data

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

Acute Toxicity

| Name | Route | Species | Value |
|--|-----------|-----------------------------------|---|
| Overall product | Ingestion | | No data available; calculated ATE >2,000 - =5,000 mg/kg |
| Silane Treated Ceramic | Dermal | | LD50 estimated to be > 5,000 mg/kg |
| Silane Treated Ceramic | Ingestion | | LD50 estimated to be 2,000 - 5,000 mg/kg |
| Substituted Dimethacrylate | Dermal | Professio nal judgeme nt | LD50 estimated to be > 5,000 mg/kg |
| Substituted Dimethacrylate | Ingestion | Rat | LD50 > 17,600 mg/kg |
| (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate | Dermal | Professio nal judgeme nt | LD50 estimated to be > 5,000 mg/kg |
| (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate | Ingestion | Rat | LD50 > 11,700 mg/kg |
| Triethylene Glycol Dimethacrylate (TEGDMA) | Dermal | Mouse | LD50 > 2,000 |

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| Triethylene Glycol Dimethacrylate (TEGDMA) | Ingestion | Rat | LD50 10,837 mg/kg |
|--|-----------|-----------------------------------|------------------------------------|
| Silane Treated Silica | Dermal | | LD50 estimated to be > 5,000 mg/kg |
| Silane Treated Silica | Ingestion | | LD50 estimated to be > 5,000 mg/kg |
| Ytterbium Fluoride (YbF3) | Dermal | Professio nal judgeme nt | LD50 estimated to be > 5,000 mg/kg |
| Ytterbium Fluoride (YbF3) | Ingestion | Rat | LD50 > 5,000 mg/kg |
| Ethyl 4-dimethylaminobenzoate | Dermal | Rat | LD50 > 2,000 mg/kg |
| Ethyl 4-dimethylaminobenzoate | Ingestion | Rat | LD50 > 2,000 mg/kg |
| Diphenyliodonium Hexafluorophosphate | Ingestion | Rat | LD50 32 mg/kg |

ATE = acute toxicity estimate

Skin Corrosion/Irritation

| Name | Species | Value |
|--|------------|---------------------------|
| | | |
| Silane Treated Ceramic | similar | No significant irritation |
| | ds compoun | |
| Substituted Dimethacrylate | Rabbit | No significant irritation |
| (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] | Rabbit | No significant irritation |
| bismethacrylate | | |
| Triethylene Glycol Dimethacrylate (TEGDMA) | Rabbit | No significant irritation |
| Silane Treated Silica | Professio | No significant irritation |
| | nal | |
| | judgemen | |
| | t | |
| Ethyl 4-dimethylaminobenzoate | Rabbit | No significant irritation |
| Diphenyliodonium Hexafluorophosphate | Rabbit | No significant irritation |

Serious Eye Damage/Irritation

| Name | Species | Value |
|--|-----------------------------------|---------------------------|
| Silane Treated Ceramic | similar compoun ds | Mild irritant |
| Substituted Dimethacrylate | Rabbit | Mild irritant |
| (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate | In vitro data | No significant irritation |
| Triethylene Glycol Dimethacrylate (TEGDMA) | Rabbit | No significant irritation |
| Silane Treated Silica | Professio nal judgemen t | No significant irritation |
| Ytterbium Fluoride (YbF3) | Professio nal judgemen t | Mild irritant |
| Ethyl 4-dimethylaminobenzoate | Rabbit | No significant irritation |
| Diphenyliodonium Hexafluorophosphate | Rabbit | Mild irritant |

Sensitization:

Skin Sensitisation

| Name | Species | Value |
|--|--------------------------|----------------|
| Silane Treated Ceramic | similar compoun ds | Not classified |
| Substituted Dimethacrylate | Guinea pig | Not classified |
| (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate | Mouse | Not classified |

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| Triethylene Glycol Dimethacrylate (TEGDMA) | Mouse | Sensitising |
|--|-------|----------------|
| Ethyl 4-dimethylaminobenzoate | | Not classified |

Respiratory Sensitisation

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

Germ Cell Mutagenicity

| Name | Route | Value |
|--|----------|--|
| Substituted Dimethacrylate | In Vitro | Not mutagenic |
| (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate | In Vitro | Not mutagenic |
| Triethylene Glycol Dimethacrylate (TEGDMA) | In Vitro | Some positive data exist, but the data are not sufficient for classification |
| Ethyl 4-dimethylaminobenzoate | In vivo | Not mutagenic |
| Ethyl 4-dimethylaminobenzoate | In Vitro | Some positive data exist, but the data are not sufficient for classification |
| Diphenyliodonium Hexafluorophosphate | In Vitro | Some positive data exist, but the data are not sufficient for classification |

Carcinogenicity

| 3 W | | | | |
|--|------------|--------------------------|--|--|
| Name | Route | Species | Value | |
| Silane Treated Ceramic | Inhalation | similar compoun ds | Some positive data exist, but the data are not sufficient for classification | |
| Triethylene Glycol Dimethacrylate (TEGDMA) | Dermal | Mouse | Not carcinogenic | |

Reproductive Toxicity

Reproductive and/or Developmental Effects

| Name | Route | Value | Species | Test result | Exposure Duration |
|---|-----------|--|---------|-----------------------------|--------------------------|
| (1-methylethylidene)bis[4,1- phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate | Ingestion | Not classified for development | Rat | NOAEL 1,000 mg/kg/day | during gestation |
| Triethylene Glycol Dimethacrylate (TEGDMA) | Ingestion | Not classified for female reproduction | Rat | NOAEL 1,000 mg/kg/day | premating into lactation |
| Triethylene Glycol Dimethacrylate (TEGDMA) | Ingestion | Not classified for male reproduction | Rat | NOAEL 1,000 mg/kg/day | 5 weeks |
| Triethylene Glycol Dimethacrylate (TEGDMA) | Ingestion | Not classified for development | Rat | NOAEL 1,000 mg/kg/day | premating into lactation |
| Ethyl 4-dimethylaminobenzoate | Ingestion | Not classified for female reproduction | Rat | NOAEL 600 mg/kg/day | premating into lactation |
| Ethyl 4-dimethylaminobenzoate | Ingestion | Not classified for development | Rat | NOAEL 50 mg/kg/day | premating into lactation |
| Ethyl 4-dimethylaminobenzoate | 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 |
|---|------------|------------------------|----------------|------------------|-------------------------|----------------------|
| Diphenyliodonium Hexafluorophosphate | Inhalation | respiratory irritation | Not classified | Not available | Irritation Equivocal | |

Specific Target Organ Toxicity - repeated exposure

| Name | Route | Target Organ(s) | Value | Species | Test result | Exposure |
|------|-------|-----------------|-------|---------|-------------|----------|
| | | | | | | Duration |

| Silane Treated Ceramic | Inhalation | pulmonary fibrosis | Not classified | similar compoun ds | NOAEL Not available | |
|---|------------|------------------------------------|----------------|--------------------------|-----------------------------|---------|
| (1- methylethylidene)bis[4,1- phenyleneoxy(2-hydroxy- 3,1-propanediyl)] bismethacrylate | Ingestion | endocrine system | Not classified | Rat | NOAEL 1,000 mg/kg/day | 90 days |
| (1- methylethylidene)bis[4,1- phenyleneoxy(2-hydroxy- 3,1-propanediyl)] bismethacrylate | Ingestion | hematopoietic system | Not classified | Rat | NOAEL 1,000 mg/kg/day | 90 days |
| (1- methylethylidene)bis[4,1- phenyleneoxy(2-hydroxy- 3,1-propanediyl)] bismethacrylate | Ingestion | liver | Not classified | Rat | NOAEL 1,000 mg/kg/day | 90 days |
| (1- methylethylidene)bis[4,1- phenyleneoxy(2-hydroxy- 3,1-propanediyl)] bismethacrylate | Ingestion | heart | Not classified | Rat | NOAEL 1,000 mg/kg/day | 90 days |
| (1- methylethylidene)bis[4,1- phenyleneoxy(2-hydroxy- 3,1-propanediyl)] bismethacrylate | Ingestion | skin | Not classified | Rat | NOAEL 1,000 mg/kg/day | 90 days |
| (1- methylethylidene)bis[4,1- phenyleneoxy(2-hydroxy- 3,1-propanediyl)] bismethacrylate | Ingestion | gastrointestinal tract | Not classified | Rat | NOAEL 1,000 mg/kg/day | 90 days |
| (1- methylethylidene)bis[4,1- phenyleneoxy(2-hydroxy- 3,1-propanediyl)] bismethacrylate | Ingestion | bone, teeth, nails, and/or hair | Not classified | Rat | NOAEL 1,000 mg/kg/day | 90 days |
| (1- methylethylidene)bis[4,1- phenyleneoxy(2-hydroxy- 3,1-propanediyl)] bismethacrylate | Ingestion | immune system | Not classified | Rat | NOAEL 1,000 mg/kg/day | 90 days |
| (1- methylethylidene)bis[4,1- phenyleneoxy(2-hydroxy- 3,1-propanediyl)] bismethacrylate | Ingestion | muscles | Not classified | Rat | NOAEL 1,000 mg/kg/day | 90 days |
| (1- methylethylidene)bis[4,1- phenyleneoxy(2-hydroxy- 3,1-propanediyl)] bismethacrylate | Ingestion | nervous system | Not classified | Rat | NOAEL 1,000 mg/kg/day | 90 days |
| (1- methylethylidene)bis[4,1- phenyleneoxy(2-hydroxy- 3,1-propanediyl)] bismethacrylate | Ingestion | eyes | Not classified | Rat | NOAEL 1,000 mg/kg/day | 90 days |
| (1- methylethylidene)bis[4,1- phenyleneoxy(2-hydroxy- 3,1-propanediyl)] bismethacrylate | Ingestion | kidney and/or bladder | Not classified | Rat | NOAEL 1,000 mg/kg/day | 90 days |
| (1- methylethylidene)bis[4,1- phenyleneoxy(2-hydroxy- 3,1-propanediyl)] bismethacrylate | Ingestion | respiratory system | Not classified | Rat | NOAEL 1,000 mg/kg/day | 90 days |
| (1- | Ingestion | vascular system | Not classified | Rat | NOAEL | 90 days |

| methylethylidene)bis[4,1- | | | | | 1,000 | |
|--------------------------------------|-----------|-------------------------------|--|-----------|------------------------|------------|
| phenyleneoxy(2-hydroxy- | | | | | mg/kg/day | |
| 3,1-propanediyl)] bismethacrylate | | | | | | |
| Triethylene Glycol | Dermal | liver | Not classified | Mouse | NOAEL | 13 weeks |
| Dimethacrylate (TEGDMA) | Derman | | 1100011101 | 1110 4150 | 2,000 mg/kg/day | 13 Weeks |
| Triethylene Glycol | Dermal | skin | Not classified | Mouse | NOAEL 100 | 13 weeks |
| Dimethacrylate (TEGDMA) | Bernur | | Two classified | Wiouse | mg/kg/day | 15 Weeks |
| Triethylene Glycol | Dermal | gastrointestinal tract | Not classified | Mouse | NOAEL | 13 weeks |
| Dimethacrylate (TEGDMA) | | | | | 2,000 mg/kg/day | |
| Triethylene Glycol | Dermal | hematopoietic | Not classified | Mouse | NOAEL | 13 weeks |
| Dimethacrylate | | system | | | 2,000 | |
| (TEGDMA) Triethylene Glycol | Damas | | Ni-t -lici-d | M | mg/kg/day NOAEL | 13 weeks |
| Dimethacrylate | Dermal | nervous system | Not classified | Mouse | 2,000 | 13 weeks |
| (TEGDMA) | | | | | mg/kg/day | |
| Triethylene Glycol | Dermal | kidney and/or | Not classified | Mouse | NOAEL | 13 weeks |
| Dimethacrylate | | bladder | | | 2,000 | |
| (TEGDMA) | <u> </u> | | | 1 | mg/kg/day | |
| Triethylene Glycol Dimethacrylate | Dermal | respiratory system | Not classified | Mouse | NOAEL 2,000 | 13 weeks |
| (TEGDMA) | | | | | mg/kg/day | |
| Triethylene Glycol | Ingestion | hematopoietic | Not classified | Rat | NOAEL | 13 weeks |
| Dimethacrylate | | system | | | 3,849 | |
| (TEGDMA) | | | | | mg/kg/day | |
| Triethylene Glycol | Ingestion | liver | Not classified | Rat | NOAEL | 13 weeks |
| Dimethacrylate (TEGDMA) | | | | | 3,849 mg/kg/day | |
| Triethylene Glycol | Ingestion | nervous system | Not classified | Rat | NOAEL | 13 weeks |
| Dimethacrylate | ingestion | ner vous system | Trot Glassifica | 1444 | 3,849 | 15 ,, cons |
| (TEGDMA) | | | | | mg/kg/day | |
| Triethylene Glycol | Ingestion | kidney and/or | Not classified | Rat | NOAEL | 13 weeks |
| Dimethacrylate (TEGDMA) | | bladder | | | 3,849 mg/kg/day | |
| Triethylene Glycol | Ingestion | eyes | Not classified | Rat | NOAEL | 13 weeks |
| Dimethacrylate | ingestion | Cycs | Tot classifica | Tut | 3,849 | 15 Weeks |
| (TEGDMA) | | | | | mg/kg/day | |
| Ethyl 4- | Ingestion | hematopoietic | Some positive data exist, but the | Rat | NOAEL 74 | 28 days |
| dimethylaminobenzoate | | system | data are not sufficient for classification | | mg/kg/day | |
| Ethyl 4- | Ingestion | liver | Not classified | Rat | NOAEL 900 | 28 days |
| dimethylaminobenzoate | Ingestion | nver | Not classified | Kat | mg/kg/day | 20 days |
| Ethyl 4- | Ingestion | heart | Not classified | Rat | NOAEL 900 | 28 days |
| dimethylaminobenzoate | | | | | mg/kg/day | |
| Ethyl 4- | Ingestion | endocrine system | Not classified | Rat | NOAEL 900 | 28 days |
| dimethylaminobenzoate Ethyl 4- | Ingestion | gastrointestinal tract | Not classified | Rat | mg/kg/day NOAEL 900 | 28 days |
| dimethylaminobenzoate | ingestion | gastronnestmar tract | Not classified | Kat | mg/kg/day | 20 days |
| Ethyl 4- | Ingestion | bone, teeth, nails, | Not classified | Rat | NOAEL 900 | 28 days |
| dimethylaminobenzoate | ٥ | and/or hair | | | mg/kg/day | , |
| Ethyl 4- | Ingestion | immune system | Not classified | Rat | NOAEL 900 | 28 days |
| dimethylaminobenzoate | * | , | N . 1 | D i | mg/kg/day | 20.1 |
| Ethyl 4- dimethylaminobenzoate | Ingestion | muscles | Not classified | Rat | NOAEL 900 mg/kg/day | 28 days |
| Ethyl 4- | Ingestion | nervous system | Not classified | Rat | NOAEL 900 | 28 days |
| dimethylaminobenzoate | 5001011 | | | 1 | mg/kg/day | |
| Ethyl 4- | Ingestion | eyes | Not classified | Rat | NOAEL 900 | 28 days |
| dimethylaminobenzoate | 1. | | | <u> </u> | mg/kg/day | |
| Ethyl 4- | Ingestion | kidney and/or | Not classified | Rat | NOAEL 900 | 28 days |
| dimethylaminobenzoate Ethyl 4- | Ingestion | bladder respiratory system | Not classified | Rat | mg/kg/day NOAEL 900 | 28 days |
| dimethylaminobenzoate | mgestion | respiratory system | 140t Classified | Nat | mg/kg/day | 20 days |
| Ethyl 4- | Ingestion | vascular system | Not classified | Rat | NOAEL 900 | 28 days |
| dimethylaminobenzoate | | I | | | mg/kg/day | |

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Aspiration Hazard

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

Please contact the address or phone number listed on the first page of the SDS for additional toxicological information on this material and/or its components.

SECTION 12: Ecological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. Additional information leading to material classification in Section 2 is available upon request. In addition, environmental fate and effects data on ingredients may not be reflected in this section because an ingredient is present below the threshold for labelling, an ingredient is not expected to be available for exposure, or the data is considered not relevant to the material as a whole.

12.1. Toxicity

Acute aquatic hazard:

Not acutely toxic to aquatic life by GHS criteria.

Chronic aquatic hazard:

Not chronically toxic to aquatic life by GHS criteria.

No product test data available.

| Material | CAS Nbr | Organism | Type | Exposure | Test endpoint | Test result |
|---|-------------|-------------|---|----------|-----------------------------------|-------------|
| Silane Treated Ceramic | 444758-98-9 | N/A | Data not available or insufficient for classification | N/A | N/A | N/A |
| Substituted Dimethacrylate | 27689-12-9 | Green algae | Experimental | 72 hours | EC50 | >100 mg/l |
| Substituted Dimethacrylate | 27689-12-9 | Water flea | Experimental | 48 hours | EC50 | >100 mg/l |
| Substituted Dimethacrylate | 27689-12-9 | Green algae | Experimental | 72 hours | NOEC | >100 mg/l |
| (1- methylethylidene)b is[4,1- phenyleneoxy(2- hydroxy-3,1- propanediyl)] bismethacrylate | 1565-94-2 | Common Carp | Analogous Compound | 96 hours | No tox obs at lmt of water sol | >100 mg/l |
| (1- methylethylidene)b is[4,1- phenyleneoxy(2- hydroxy-3,1- propanediyl)] bismethacrylate | 1565-94-2 | Green algae | Endpoint not reached | 96 hours | EC50 | >100 mg/l |
| (1- methylethylidene)b is[4,1- phenyleneoxy(2- hydroxy-3,1- propanediyl)] bismethacrylate | 1565-94-2 | Green algae | Experimental | 96 hours | EC10 | 1.1 mg/l |
| Silane Treated Silica | 248596-91-0 | N/A | Data not available or insufficient for classification | N/A | N/A | N/A |
| Triethylene Glycol Dimethacrylate (TEGDMA) | 109-16-0 | Green algae | Experimental | 72 hours | ErC50 | >100 mg/l |

| Triethylene Glycol Dimethacrylate (TEGDMA) | 109-16-0 | Zebra Fish | Experimental | 96 hours | LC50 | 16.4 mg/l |
|--|-------------|------------------|---|----------|--------------------------------|--------------|
| Triethylene Glycol Dimethacrylate (TEGDMA) | 109-16-0 | Green algae | Experimental | 72 hours | NOEC | 18.6 mg/l |
| Triethylene Glycol Dimethacrylate (TEGDMA) | 109-16-0 | Water flea | Experimental | 21 days | NOEC | 32 mg/l |
| Poly[oxy(1-oxo- 1,6-hexanediyl)], α,α'-(oxydi-2,1- ethanediyl)bis[ω- [[[[2-[(2-methyl-1- oxo-2-propen-1- yl)oxy]ethyl]amino]carbonyl]oxy]- | 220182-22-9 | N/A | Data not available or insufficient for classification | N/A | N/A | N/A % weight |
| | 13760-80-0 | Water flea | Experimental | 48 hours | No tox obs at lmt of water sol | >100 mg/l |
| Ethyl 4- dimethylaminobenz oate | 10287-53-3 | Activated sludge | Experimental | 3 hours | EC50 | >1,000 mg/l |
| Ethyl 4- dimethylaminobenz oate | 10287-53-3 | Green algae | Experimental | 72 hours | EL50 | 2.8 mg/l |
| Ethyl 4- dimethylaminobenz oate | 10287-53-3 | Rainbow trout | Experimental | 96 hours | LC50 | 1.9 mg/l |
| Ethyl 4- dimethylaminobenz oate | 10287-53-3 | Water flea | Experimental | 48 hours | EC50 | 4.5 mg/l |
| Ethyl 4- dimethylaminobenz oate | 10287-53-3 | Green algae | Experimental | 72 hours | ErC10 | 0.71 mg/l |
| Diphenyliodonium Hexafluorophospha te | 58109-40-3 | Water flea | Experimental | 48 hours | EC50 | 9.5 mg/l |

12.2. Persistence and degradability

| Material | CAS Nbr | Test type | Duration | Study Type | Test result | Protocol |
|---|-------------|--|----------|--------------------------------|---|-----------------------------------|
| Silane Treated Ceramic | 444758-98-9 | Data not available- insufficient | N/A | N/A | N/A | N/A |
| Substituted Dimethacrylate | 27689-12-9 | Experimental Biodegradation | 28 days | CO2 evolution | 7-12 %CO2 evolution/THCO2 evolution | OECD 301B - Modified sturm or CO2 |
| (1- methylethylidene)b is[4,1- phenyleneoxy(2- hydroxy-3,1- propanediyl)] bismethacrylate | 1565-94-2 | Experimental Biodegradation | 28 days | BOD | 21 %BOD/ThOD | similar to OECD 301F |
| (1- methylethylidene)b is[4,1- phenyleneoxy(2- hydroxy-3,1- propanediyl)] bismethacrylate | 1565-94-2 | Experimental Hydrolysis | | Hydrolytic half-life (pH 7) | 29 days (t 1/2) | |
| Silane Treated Silica | 248596-91-0 | Data not available-insufficient | N/A | N/A | N/A | N/A |

| Triethylene Glycol Dimethacrylate (TEGDMA) | 109-16-0 | Experimental Biodegradation | 28 days | | 85 %CO2 evolution/THCO2 evolution | OECD 301B - Modified sturm or CO2 |
|--|-------------|--|---------|-----------------------------|---|--------------------------------------|
| Poly[oxy(1-oxo- 1,6-hexanediyl)], α,α' -(oxydi-2,1- ethanediyl)bis[ω - [[[[2-[(2-methyl-1- oxo-2-propen-1- yl)oxy]ethyl]amino]carbonyl]oxy]- | 220182-22-9 | Data not available- insufficient | N/A | N/A | N/A | N/A |
| Ytterbium Fluoride (YbF3) | 13760-80-0 | Data not available- insufficient | N/A | N/A | N/A | N/A |
| Ethyl 4- dimethylaminobenz oate | 10287-53-3 | Experimental Biodegradation | 28 days | CO2 evolution | 40 %CO2 evolution/THCO2 evolution | OECD 301B - Modified sturm or CO2 |
| Ethyl 4- dimethylaminobenz oate | 10287-53-3 | Experimental Hydrolysis | | Hydrolytic half-life (pH 7) | >1 years (t 1/2) | OECD 111 Hydrolysis func of pH |
| Diphenyliodonium Hexafluorophospha te | 58109-40-3 | Data not available- insufficient | N/A | N/A | N/A | N/A |

12.3 : Bioaccumulative potential

| Material | CAS Nbr | Test type | Duration | Study Type | Test result | Protocol |
|--|-------------|---|----------|------------|-------------|---------------------------------|
| Silane Treated Ceramic | 444758-98-9 | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| Substituted Dimethacrylate | 27689-12-9 | Modeled Bioconcentration | | Log Kow | 7.61 | Episuite TM |
| (1- methylethylidene)b is[4,1- phenyleneoxy(2- hydroxy-3,1- propanediyl)] bismethacrylate | 1565-94-2 | Experimental Bioconcentration | | Log Kow | 4.63 | |
| Silane Treated Silica | 248596-91-0 | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| Triethylene Glycol Dimethacrylate (TEGDMA) | 109-16-0 | Experimental Bioconcentration | | Log Kow | 2.3 | EC A.8 Partition Coefficient |
| Poly[oxy(1-oxo- 1,6-hexanediyl)], α,α' -(oxydi-2,1- ethanediyl)bis[ω - [[[[2-[(2-methyl-1- oxo-2-propen-1- yl)oxy]ethyl]amino]carbonyl]oxy]- | 220182-22-9 | Data not available or insufficient for classification | | N/A | N/A | N/A |
| Ytterbium Fluoride (YbF3) | 13760-80-0 | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| Ethyl 4- dimethylaminobenz oate | 10287-53-3 | Experimental Bioconcentration | | Log Kow | 3.2 | OECD 117 log Kow HPLC method |
| Diphenyliodonium Hexafluorophospha te | 58109-40-3 | 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 Other Adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Disposal methods

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

Dispose of completely cured (or polymerised) material in a permitted industrial waste facility. As a disposal alternative, incinerate uncured product in a permitted waste incineration facility. If no other disposal options are available, waste product that has been completely cured or polymerised may be placed in a landfill properly designed for industrial waste.

SECTION 14: Transport Information

Not hazardous for transportation.

Air Transport (IATA)Regulations

UN No Not applicable

Proper Shipping Name Not applicable Hazard Classs/Division Not applicable Subsidiary Risk Not applicable Packing Group: Not applicable

Marine Transport (IMDG)

UN No Not applicable

Proper Shipping Name
Hazard Classs/Division
Subsidiary Risk
Packing Group:
Not applicable
Not applicable
Not applicable

Environmental Hazards: Not applicable

SECTION 15: Regulatory information

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

Global inventory status

Contact manufacturer for more information

Applicable Environmental, Health and Safety Regulations

The Manufacture, Storage and Import of Hazardous Chemical Rules, 1989

The Bio Medical Waste (Management & Handling) Rules, 1998

Hazardous Chemicals (Classification, Packaging and Labelling Draft Rules), 2011

The following ingredients are listed as hazardous on Part II of Schedule I of the India Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) rules

None.

The following ingredients are classified as hazardous based on the criteria listed under Part I of Schedule I of the India Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) rules:

The product is classified as Non-Hazardous as per MSIHC Rules, 1989.

SECTION 16: Other information

NFPA Hazard Classification

Health: 2 Flammability: 1 Instability: 0 Special Hazards: None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

Revision information:

Section 2: Ingredient table information was modified.

Section 8: Occupational exposure limit table information was modified.

Section 11: Target Organs - Repeated Table information was modified.

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