

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.05.2024

Version: 4

Revision: 22.05.2024

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

- **1.1 Product identifier**
- **Trade name:** Bio Composite
- **Article number:** 435361-435371, 435331-435338
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Dental filling material
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
MANI MEDICAL GERMANY GmbH
Hertha-Sponer-Straße 2
D-61191 Rosbach v.d.H.
Germany
Tel: +49 6003/8286-0
www.mani-germany.com
- **Further information obtainable from:** R&D, MANI MEDICAL GERMANY GmbH, Tel: +049 6003/8286-0
- **1.4 Emergency telephone number:**
+49 (0) 6003 82 86-0, MANI MEDICAL GERMANY GmbH (8:00 - 17:00) or
+49 (0) 6131 19240 Poison Information Center, University Mainz (24 h)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Skin Sens. 1 H317 May cause an allergic skin reaction.
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**
di-urethane dimethacrylate
Tricyclodecan dimethanol dimethacrylate
tetramethylene dimethacrylate
- **Hazard statements**
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P273 Avoid release to the environment.
P280 Wear protective gloves.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P321 Specific treatment (see on this label).
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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- Labelling of packages where the contents do not exceed 125 ml
- Hazard pictograms



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**
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Tricyclodecan dimethanol dimethacrylate
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P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** Preparation of methacryl acid ester.

· **Dangerous components:**

CAS: 60676-86-0 EINECS: 262-373-8	Silica, vitreous substance with a Community workplace exposure limit	50-75%
CAS: 41137-60-4	di-urethane dimethacrylate ⚠ Aquatic Chronic 2, H411; ⚠ Skin Sens. 1B, H317	10-25%
CAS: 43048-08-4	Tricyclodecan dimethanol dimethacrylate ⚠ Aquatic Chronic 2, H411; ⚠ Skin Sens. 1, H317	2.5-10%
CAS: 2082-81-7 EINECS: 218-218-1	tetramethylene dimethacrylate ⚠ Skin Sens. 1B, H317	<2.5%

- **Additional information** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information** Immediately remove any clothing soiled by the product.
- **After inhalation** Supply fresh air; consult doctor in case of complaints.
- **After skin contact**
If skin irritation continues, consult a doctor.
Immediately wash with water and soap and rinse thoroughly.
- **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing** Do not induce vomiting; call for medical help immediately.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

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- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents**
Foam
Fire-extinguishing powder
Water haze
Carbon dioxide
Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.
- **6.4 Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Keep receptacles tightly sealed.
Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:**
Storage between 10 °C and 25 °C.
Close container immediately after use and protect product from light incidence.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

60676-86-0 Silica, vitreous

OEL (Ireland)	Long-term value: 0.08 mg/m ³ fused respirable dust
WEL (Great Britain)	Long-term value: 0.08 mg/m ³ fused respirable dust

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PEL (USA)	20mppcf or 80mg/m ³ /%SiO ₂
TLV (USA)	TLV withdrawn

· **Additional information:** The lists valid during the making were used as basis.

· **8.2 Exposure controls**

· **Appropriate engineering controls** No further data; see section 7.

· **Individual protection measures, such as personal protective equipment**

· **General protective and hygienic measures**

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

· **Respiratory protection:** Not necessary if room is well-ventilated.

· **Hand protection** Protective gloves.

· **Material of gloves**

Butyl rubber, BR

Nitrile rubber, NBR

· **Penetration time of glove material**

0,3 mm

Penetration time 60 min.

0,11 mm

Penetration time 10 min.

· **Eye/face protection** Safety glasses

· **Body protection:** Protective work clothing.

SECTION 9: Physical and chemical properties

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

· **General Information**

· **Physical state**

Solid.

· **Colour:**

According to product specification

· **Odour:**

Weak, characteristic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

undetermined

· **Boiling point or initial boiling point and boiling range**

>136 °C (43048-08-4 Tricyclodecan dimethanol dimethacrylate)

Not determined.

· **Flammability**

· **Lower and upper explosion limit**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

200 °C (43048-08-4 Tricyclodecan dimethanol dimethacrylate)

Not determined.

· **Decomposition temperature:**

· **pH**

Mixture is non-soluble (in water).

Not applicable.

· **Viscosity:**

· **Kinematic viscosity**

Not applicable.

· **dynamic:**

Not applicable.

· **Solubility**

· **Water:**

Insoluble

· **Partition coefficient n-octanol/water (log value)**

Not determined.

· **Vapour pressure:**

Not applicable.

· **Density and/or relative density**

· **Density at 20 °C:**

1.95 g/cm³

· **Relative density**

Not determined.

· **Vapour density**

Not applicable.

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- **Particle characteristics**

See section 3.

- **9.2 Other information**

- **Appearance:**

- **Form:**

Pasty

- **Important information on protection of health and environment, and on safety.**

- **Ignition temperature:**

Product is not selfigniting.

- **Explosive properties:**

Product does not present an explosion hazard.

- **Change in condition**

- **Evaporation rate**

Not applicable.

- **Information with regard to physical hazard classes**

- **Explosives**

Void

- **Flammable gases**

Void

- **Aerosols**

Void

- **Oxidising gases**

Void

- **Gases under pressure**

Void

- **Flammable liquids**

Void

- **Flammable solids**

Void

- **Self-reactive substances and mixtures**

Void

- **Pyrophoric liquids**

Void

- **Pyrophoric solids**

Void

- **Self-heating substances and mixtures**

Void

- **Substances and mixtures, which emit flammable gases in contact with water**

Void

- **Oxidising liquids**

Void

- **Oxidising solids**

Void

- **Organic peroxides**

Void

- **Corrosive to metals**

Void

- **Desensitised explosives**

Void

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.

- **10.2 Chemical stability**

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

- **10.3 Possibility of hazardous reactions**

Photoreactive

Danger of polymerization

- **10.4 Conditions to avoid** No further relevant information available.

- **10.5 Incompatible materials:**

In presence of radical formers (e. g. peroxides), deoxidizing substances, and/or heavy metal ions, polymerization with heat release is possible.

- **10.6 Hazardous decomposition products:** No dangerous decomposition products known

SECTION 11: Toxicological information

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

- **Acute toxicity** Based on available data, the classification criteria are not met.

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.

- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.

- **Respiratory or skin sensitisation** May cause an allergic skin reaction.

- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

- **Carcinogenicity** Based on available data, the classification criteria are not met.

- **Reproductive toxicity** Based on available data, the classification criteria are not met.

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- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**

· Endocrine disrupting properties	
128-37-0	Butylated hydroxytoluene
List II	

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**
 Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water.
 Do not allow product to reach ground water, water course or sewage system.
 Danger to drinking water if even small quantities leak into the ground.
 Harmful to aquatic organisms

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
 Must be specially treated adhering to official regulations.
 Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:**
 Packagings that may not be cleansed are to be disposed of in the same manner as the product.
- **Recommended cleansing agents:** Alcohol

SECTION 14: Transport information

- | | |
|--|------|
| · 14.1 UN number or ID number | |
| · ADR, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | |
| · ADR, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · 14.4 Packing group | |
| · ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | |
| · Marine pollutant: | No |

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· 14.6 Special precautions for user	Not applicable.
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· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
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· UN "Model Regulation":	Void
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SECTION 15: Regulatory information

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

- **Directive 2012/18/EU**

- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

- **REGULATION (EU) 2019/1148**

· Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS
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None of the ingredients is listed.

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

- **National regulations**

- **Technical instructions (air):**

Class	Share in %
III	<2.5

- **Waterhazard class:** Water hazard class 2 (Self-assessment): hazardous for water.

- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**

H317 May cause an allergic skin reaction.

H411 Toxic to aquatic life with long lasting effects.

- **Department issuing SDS:** R&D, MANI MEDICAL GERMANY GmbH

- **Contact:** Fr. R.Naveenakumar

- **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

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*vPvB: very Persistent and very Bioaccumulative**Skin Sens. 1: Skin sensitisation – Category 1**Skin Sens. 1B: Skin sensitisation – Category 1B**Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2**Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3*

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