

According to Regulation (EC) No. 1907/2006

Printing date: 01.08.2017

1. Identification of the substance/preparation and of the company/undertaking

Product details

1.1. Trade name

FIBRE COMPOSITE

1.2. Application of the substance / the preparation Filler/ Extender

Dental composite

1.3. Manufacturer/Supplier

DEI® ITALIA S.r.l.

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1.4. Information in case of emergency

Ospedale Niguarda di Milano-Centro antiveneni numero di emergenza +39 02 66101029

2. Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

H317 May cause an allergic skin reaction

H318 Causes serious eye damage

H319 Causes serious eye irritation

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long-lasting effects.

Classification according to Regulation 1999/45/EC

Xi Irritant

R36/37/38 Irritating to eyes, respiratory system and skin.

R41 Risk of serious damage to eyes

R43 May cause sensitisation by skin contact

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008 [CLP]

Pictogram

Signal word:

Warning

Hazard statement(s)

H315 Causes skin irritation

Precautionary statement(s)

P280 Wear protective gloves/protective clothing/eye protection/face protection. [As modified by IV ATP]

P272 Contaminated work clothing should not be allowed out of the workplace.

P261 Avoid breathing dust/fumes/gas/mist/vapours/spray. [As modified by IV ATP]

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

P302+P352 IF ON SKIN: Wash with plenty of water/... [As modified by IV ATP]

P273 Avoid release to the environment.

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P501 Dispose of contents/ container to an approved waste disposal plant.

2.3 Other hazards

- none

3. Composition/information on ingredients

3.1 Substances

Mixture of Bis-GMA, Bisphenol A ethoxylate dimethacrylate, TEGDMA, UDMA, inorganic pigments, bariumborosilicate glasses with initiators, stabilizers and UV absorber.

Hazardous ingredients according to Regulation (EC) No 1272/2008

Component	Classification	CAS #
Bis-GMA (Bisphenol A glycerolate dimethacrylate)	H318	1565-94-2
EBADMA Ethoxylated Bisphenol A dimethacrylate	H315, H317, H319, H335	41637-38-1
TEGDMA - Triethylene glycol dimethacrylate	H315, H319, H335	109-16-0
UDMA (Diurethane dimethacrylate)	H317	72869-86-4
Camphorquinone (CQ)	-----	10373-78-1
BHT	H400, H410	128-37-0

Hazardous ingredients according to Regulation 1999/45/WE

Component	Classification	CAS #
Bis-GMA (Bisphenol A glycerolate dimethacrylate)	Xi, R41	1565-94-2
EBADMA Ethoxylated Bisphenol A dimethacrylate	Xi, R36/37/38, R43	41637-38-1
TEGDMA - Triethylene glycol dimethacrylate	Xi, R36/37/38, R43	109-16-0
UDMA (Diurethane dimethacrylate)	Xi, R43	72869-86-4
Camphorquinone (CQ)	-----	10373-78-1
BHT (2,6-Di-tert-butyl-4-metylofenol)	-----	128-37-0

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For the full text of the H-Statements and R-Phrases mentioned in this Section, see Section 16.

4. First aid measures

4.1 Description of first aid measures

General advice :

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled :If breathed in, move person into fresh air. If not breathing, give artificial respiration.

Consult a physician.

In case of skin contact :Wash off with soap and plenty of water. Consult a physician.

In case of eye contact :Flush eyes with water as a precaution.

If swallowed : Never give anything by mouth to an unconscious person. Rinse mouth with water.

Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

no data available

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

no data available

5.3 Advice for firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

5.4 Further information

no data available

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas.

Ensure adequate ventilation. Avoid breathing dust.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

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7. Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin, eyes and clothing. Wash hands before and immediately after using this product.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Recommended storage temperature: 3 - 28 °C

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

8. Exposure controls and personal protection gear

8.1 Control parameters

Components with workplace control parameters

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Body Protection

impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Do not let product enter drains.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Appearance

Form: paste

Colors: (according to VITA shade guide)

b) Odour: practically odourless, slightly acrylate

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- c) Odour Threshold: no data available
- d) pH :no data available
- e) Melting point/freezing point : no data available
- f) Initial boiling point and boiling range : no data available
- g) Flash point: no data available
- h) Evaporation rate: nd
- i) Flammability (solid, gas) nd
- j) Upper/lower flammability or explosive limits: nd
- k) Vapour pressure: nd
- l) Vapour density: nd
- m) Relative density : 1.95-2.05 g/cm³ (20°C)
- n) Water solubility : insoluble
- o) Partition coefficient: octanol/water: nd
- p) Autoignition temperature: nd
- q) Decomposition temperature: nd
- r) Viscosity: nd
- s) Explosive properties: nd
- t) Oxidizing properties: nd

9.2 Other safety information
no data available

10. STABILITY AND REACTIVITY

10.1 Reactivity no data available
no data available

10.2 Chemical stability
Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions
no data available

10.4 Conditions to avoid
no data available

10.5 Incompatible materials
Strong oxidizing agents

10.6 Hazardous decomposition products
Other decomposition products – no data

11. Toxicological information

11.1. Acute toxicity
Oral LD₅₀ for rats : 5000 mg/kg rat
Skin corrosion/irritation
Uncured material: prolonged or frequently repeated skin contact may cause allergic skin reactions in some individuals
Serious eye damage/eye irritation
no data available

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Respiratory or skin sensitisation
no data available
Germ cell mutagenicity
no data available
Carcinogenicity
nd
Reproductive toxicity
no data available
Specific target organ toxicity - single exposure
Inhalation - May cause respiratory irritation.
Specific target organ toxicity - repeated exposure
no data available
Aspiration hazard
no data available

12. Ecological information

12.1 Toxicity
no data available

12.2 Persistence and degradability
no data available

12.3 Bioaccumulative potential
no data available

12.4 Mobility in soil
no data available

12.5 Results of PBT and vPvB assessment
no data available

12.6 Other adverse effects
no data available

13. Disposal considerations

13.1 Waste treatment methods
Product
Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.
Contaminated packaging
Dispose of as unused product.

14. Transport information

14.1 UN number
ADR/RID: - IMDG:

14.2 UN proper shipping name

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ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: - IMDG: -

14.4 Packaging group

ADR/RID: - IMDG: -

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

no data available

15.Regulations

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
no data available

15.2 Chemical Safety Assessment

no data available

16.Altre informazioni

Full text of R-phrases referred to under sections 2 and 3

H315 Causes skin irritation

H317 May cause an allergic skin reaction

H318 Causes serious eye damage

H319 Causes serious eye irritation

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long-lasting effects

Xi Irritant

R36/37/38 Irritating to eyes, respiratory system and skin.

R41 Risk of serious damage to eyes

R43 May cause sensitisation by skin contact

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. DEI Italia shall not be held liable for any damage resulting from handling or from contact with the above product.