

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 16.01.2018

Version: 1

Revision: 09/05/2021

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

- **1.1 Product identifier**
- **Trade name:** Ena Cem HV Bio
- **Article number:** CPCBD...
- **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:**  
Micerium spa., Via G. Marconi, 83 - 16036 Avegno (GE), Italy, Tel.: +39-0185-7887870, Fax:  
+39-0185-7887970
- **Further information obtainable from:** Dr. Eugenio Miceli
- **1.4 Emergency telephone number:**  
Poison Control Center San Martino Hospital (Genoa, Italy) Tel.: +39-010-352808 (available 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.

- **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:**  
tetramethylene dimethacrylate
- **Hazard statements**  
H317 May cause an allergic skin reaction.
- **Precautionary statements**  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P280 Wear protective gloves.  
P302+P352 IF ON SKIN: Wash with plenty of water.  
P321 Specific treatment (see on this label).  
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Labelling of packages where the contents do not exceed 125 ml**
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**  
tetramethylene dimethacrylate
- **Hazard statements**  
H317 May cause an allergic skin reaction.

(Contd. on page 2)

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(Contd. of page 1)

**· Precautionary statements**


- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
  - P280 Wear protective gloves.
  - P302+P352 IF ON SKIN: Wash with plenty of water.
  - P321 Specific treatment (see on this label).
  - P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
  - 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 Chemical characterisation: Mixtures****· Description:**

Resin mixture with colouring agents.  
Light curing resin

**· Dangerous components:**

|                   |                               |  |         |
|-------------------|-------------------------------|--|---------|
| CAS: 2082-81-7    | tetramethylene dimethacrylate |  Skin Sens. 1B, H317 | 2.5-10% |
| EINECS: 218-218-1 |                               |  |         |

**· 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** No special measures required.
- **After inhalation** Supply fresh air; consult doctor in case of complaints.
- **After skin contact**  
Immediately wash with water and soap and rinse thoroughly.  
If skin irritation continues, consult a doctor.
- **After eye contact** Rinse opened eye for several minutes under running water. Then 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.
- **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

· **For safety reasons unsuitable extinguishing agents** Water with full jet.

· **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.

(Contd. on page 3)

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(Contd. of page 2)

- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.
- **Information about fire - and explosion protection:**  
Keep ignition sources away - Do not smoke.  
Protect against electrostatic charges.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:**  
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:** Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **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 required.
- **Protection of hands:** Protective gloves.
- **Material of gloves** Butyl rubber, BR
- **Penetration time of glove material**  
0,1 - 0,2 mm  
Penetration time: 5 min.
- **Eye protection:** Goggles recommended during refilling.

### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

|                         |                                  |
|-------------------------|----------------------------------|
| <b>Form:</b>            | Viscous                          |
| <b>Colour:</b>          | Different according to colouring |
| <b>Odour:</b>           | Weak, characteristic             |
| <b>Odour threshold:</b> | Not determined.                  |

(Contd. on page 4)

**Safety data sheet**  
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(Contd. of page 3)

|  |  |
|--|--|
| · <i>pH-value:</i>   | <i>Not determined.</i>                               |
| · <i>Change in condition</i><br><i>Melting point/freezing point:</i> | <i>undetermined</i>                                  |
| <i>Initial boiling point and boiling range:</i>                      | <i>251 °C</i>  |
| · <i>Flash point:</i>  | <i>113 °C</i>  |
| · <i>Flammability (solid, gaseous)</i>                               | <i>Not applicable.</i>                               |
| · <i>Ignition temperature:</i>                                       | <i>&gt;370 °C</i>                                    |
| · <i>Decomposition temperature:</i>                                  | <i>Not determined.</i>                               |
| · <i>Auto-ignition temperature:</i>                                  | <i>Product is not selfigniting.</i>                  |
| · <i>Explosive properties:</i>                                       | <i>Product does not present an explosion hazard.</i> |
| · <i>Explosion limits:</i><br><i>Lower:</i>                          | <i>Not determined.</i>                               |
| <i>Upper:</i>  | <i>Not determined.</i>                               |
| · <i>Vapour pressure:</i>  | <i>Not determined.</i>                               |
| · <i>Density at 20 °C:</i>   | <i>2 g/cm<sup>3</sup></i>                            |
| · <i>Relative density</i>  | <i>Not determined.</i>                               |
| · <i>Vapour density</i>  | <i>Not determined.</i>                               |
| · <i>Evaporation rate</i>  | <i>Not determined.</i>                               |
| · <i>Solubility in / Miscibility with</i><br><i>Water:</i>           | <i>Not miscible or difficult to mix</i>              |
| · <i>Partition coefficient: n-octanol/water:</i>                     | <i>Not determined.</i>                               |
| · <i>Viscosity:</i><br><i>dynamic at 20 °C:</i>                      | <i>145.000 mPas</i>                                  |
| <i>kinematic:</i>  | <i>Not determined.</i>                               |
| · <i>9.2 Other information</i>                                       | <i>No further relevant information available.</i>    |

### **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 toxicological effects**
- **Acute toxicity** *Based on available data, the classification criteria are not met.*
- **LD/LC50 values relevant for classification:**  
*tetramethylene dimethacrylate LD-50 oral > 5000 mg/kg (rat)*
- **Primary irritant effect:**
- **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.*

(Contd. on page 5)

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Version: 1

Revision: 09/05/2021

**Trade name: Ena Cem HV Bio**

(Contd. of page 4)

- **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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.
- **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.

### 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.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### 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.

- **European waste catalogue**

|          |   |
|----------|---|
| 08 04 10 | waste adhesives and sealants other than those mentioned in 08 04 09 |
|----------|---|

- **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

- |   |      |
|---|------|
| <ul style="list-style-type: none"> <li>· <b>14.1 UN-Number</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>  | Void |
| <ul style="list-style-type: none"> <li>· <b>14.2 UN proper shipping name</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>                            | Void |
| <ul style="list-style-type: none"> <li>· <b>14.3 Transport hazard class(es)</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | Void |
| <ul style="list-style-type: none"> <li>· <b>14.4 Packing group</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>   | Void |

(Contd. on page 6)

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(Contd. of page 5)

- |  |                 |
|--|-----------------|
| · <b>14.5 Environmental hazards:</b>   |                 |
| · <b>Marine pollutant:</b>   | No              |
| · <b>14.6 Special precautions for user</b>                                       | Not applicable. |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>  | Void            |

### 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.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **National regulations**
- **Technical instructions (air):**

| Class | Share in % |
|-------|------------|
| III   | 2.5-10     |

- **Waterhazard class:** Water hazard class 1 (Self-assessment): slightly 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.
- **Department issuing SDS:** Micerium S.p.a.
- **Contact:** Dr. Eugenio Miceli
- **Abbreviations and acronyms:**  
 RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)  
 ICAO: International Civil Aviation Organisation  
 ADR: Accord européen sur le transport 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)  
 LC50: Lethal concentration, 50 percent  
 LD50: Lethal dose, 50 percent  
 PBT: Persistent, Bioaccumulative and Toxic  
 vPvB: very Persistent and very Bioaccumulative  
 Skin Sens. 1: Skin sensitisation – Category 1  
 Skin Sens. 1B: Skin sensitisation – Category 1B