

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 28.07.2016

Version: 2

Revision: 28.07.2016

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

- **1.1 Product identifier**
- **Trade name:** Ena Flow Pit & Fissure Sealant
- **Article number:** EHFS
- **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 sealing 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  
diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide
- **Hazard statements**  
H317 May cause an allergic skin reaction.
- **Precautionary statements**  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.  
P321 Specific treatment (see on this label).  
P363 Wash contaminated clothing before reuse.  
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  
diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide

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- **Precautionary statements**  
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P321 Specific treatment (see on this label).  
P363 Wash contaminated clothing before reuse.  
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:** Liquid based on methacryl acid ester, containing an activator.

- **Dangerous components:**

CAS: 2082-81-7	tetramethylene dimethacrylate	10-25%
EINECS: 218-218-1	⚠ Skin Sens. 1B, H317	
CAS: 75980-60-8	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide	< 2.5%
EINECS: 278-355-8	⚠ Repr. 2, H361f; ⚠ Aquatic Chronic 2, H411; ⚠ Skin Sens. 1B, H317	

- **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**  
Take affected persons into fresh air and keep quiet.  
Seek medical treatment in case of complaints.
- **After skin contact** If skin irritation continues, consult a doctor.
- **After eye contact** Rinse opened eye for several minutes under running water.
- **After swallowing**  
Rinse out mouth and then drink plenty of water.  
Call a doctor 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**  
Water spray  
Fire-extinguishing powder  
Carbon dioxide  
Foam
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

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- **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** *Ensure adequate ventilation*
- **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.*  
*Keep away from heat and direct sunlight.*
- **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:**  
*Close container immediately after use and protect product from light incidence.*  
*Storage between 10 °C and 25 °C.*
- **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

- **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**  
*The usual precautionary measures are to be adhered to when handling chemicals.*
- **Respiratory protection:** *Not necessary if room is well-ventilated.*
- **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.*
- **Body protection:**  
*Protective work clothing.*

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### 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>	Opaque
· <b>Odour:</b>	Weak, characteristic
· <b>Odour threshold:</b>	Not determined.

· **pH-value:** Not determined.

##### · Change in condition

· <b>Melting point/Melting range:</b>	undetermined
· <b>Boiling point/Boiling range:</b>	251 °C

· **Flash point:** 101 °C

· **Flammability (solid, gaseous)** Not applicable.

##### · Ignition temperature:

· **Decomposition temperature:** Not determined.

· **Self-igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

##### · Explosion limits:

· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.

· **Vapour pressure:** Not determined.

· <b>Density:</b>	Not determined
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.

##### · Solubility in / Miscibility with

· **Water:** Not miscible or difficult to mix

· **Partition coefficient (n-octanol/water):** Not determined.

##### · Viscosity:

· <b>dynamic:</b>	Not determined.
· <b>kinematic:</b>	Not determined.

##### · Solvent content:

· **Organic solvents:** 0.0 %

· **9.2 Other information** No further relevant information available.

### 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** Exothermic polymerization

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

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- **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.*
- **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 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.*
- **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**  
*After prior treatment product has to be disposed of in an incinerator for hazardous waste adhering to the regulations pertaining to the disposal of particularly hazardous waste.*
- **European waste catalogue**

07 01 04*	<i>other organic solvents, washing liquids and mother liquors</i>
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- **Uncleaned packaging:**
- **Recommendation:** *Disposal must be made according to official regulations.*

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### SECTION 14: Transport information

· 14.1 UN-Number · ADR, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name · ADR, ADN, 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
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	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   | 10-25      |
- 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.  
H361f Suspected of damaging fertility.  
H411 Toxic to aquatic life with long lasting effects.
- **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

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*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**Repr. 2: Reproductive toxicity – Category 2**Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2***\* Data compared to the previous version altered.**

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