

# Safety data sheet

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

Printing date 16.01.2018

Version: 1

Revision: 16.01.2018

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

- **1.1 Product identifier**
- **Trade name:** Enamel Plus HRi Flow
- **Article number:** CFF...
- **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)

# Safety data sheet

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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)

## Safety data sheet

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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)

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(Contd. of page 3)

· <b>pH-value:</b>	Not determined.
· <b>Change in condition</b> Melting point/freezing point:	undetermined
Initial boiling point and boiling range:	251 °C
· <b>Flash point:</b>	113 °C
· <b>Flammability (solid, gaseous)</b>	Not applicable.
· <b>Ignition temperature:</b>	>370 °C
· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b> Lower:	Not determined.
Upper:	Not determined.
· <b>Vapour pressure:</b>	Not determined.
· <b>Density at 20 °C:</b>	2 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with</b> Water:	Not miscible or difficult to mix
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b> dynamic at 20 °C:	145.000 mPas
kinematic:	Not determined.
· <b>9.2 Other information</b>	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**  
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)

# Safety data sheet

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(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
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- **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)

**Safety data sheet**  
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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

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