

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

Printing date 16.01.2018

Version: 5

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
- **Article number:** CHR., COSVITUD., COSVITUE., CR., COSVITI.
- **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.

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· 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:**

1,4-Butandioldimethacrylate
 Urethandimethacrylate
 Bis-GMA

· 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.

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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:**
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.
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves** Butyl rubber, BR
- **Penetration time of glove material**
0,1 - 0,2 mm
Penetration time: 5 min.

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· **Eye protection:** *Goggles recommended during refilling.*

SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

· Form:	<i>Pasty</i>
· Colour:	<i>Different according to colouring</i>
· Odour:	<i>Weak, characteristic</i>
· Odour threshold:	<i>Not determined.</i>

· **pH-value:** *Not determined.*

· **Change in condition**

· Melting point/freezing point:	<i>undetermined</i>
· Initial boiling point and boiling range:	<i>251 °C</i>

· **Flash point:** *101 °C*· **Flammability (solid, gaseous)** *Not applicable.*· **Ignition temperature:** *>370 °C*· **Decomposition temperature:** *Not determined.*· **Auto-ignition temperature:** *Product is not selfigniting.*· **Explosive properties:** *Product does not present an explosion hazard.*

· **Explosion limits:**

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

· **Vapour pressure:** *Not determined.*

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

· **Solubility in / Miscibility with**

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

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

· **Viscosity:**

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

· **Solvent content:**

· **Solids content:** *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**

Photoreactive

Danger of 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**
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.

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· Recommended cleansing agents: Alcohol

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 | 2.5-10 |
- 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.
- **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

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*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**** Data compared to the previous version altered.**

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