

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

Printing date 03.02.2020

Version: 2M

Revision: 06.07.2018

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

- **1.1 Product identifier**
- **Trade name:** Enamel Plus HRi Biofunction
- **Article number:**
CRBF1, CRBF2, CRBF3, CHRBF1, CHRBF2, CHRBF3, CRBD0 - CRBD6, CHRBD0 - CHRBD6
- **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.
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- **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:**
Tricyclodecan dimethanol dimethacrylate
- **Hazard statements**
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P273 Avoid release to the environment.
P280 Wear protective gloves.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P321 Specific treatment (see on this label).
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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- Labelling of packages where the contents do not exceed 125 ml
- Hazard pictograms



GHS07

- Signal word **Warning**
- Hazard-determining components of labelling:
Tricyclodecan dimethanol dimethacrylate
- Hazard statements
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.
- Precautionary statements
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves.
P362+P364 Take off contaminated clothing and wash it before reuse.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P321 Specific treatment (see on this label).
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: Light curing resin

· Dangerous components:

43048-08-4	Tricyclodecan dimethanol dimethacrylate	10-25%
	⚠ Aquatic Chronic 2, H411; ⚠ Skin Sens. 1, H317	
100402-78-6	2-Propensäure, 2-methyl-, 3-(trimethoxysilyl)propylester, Reaktionsprodukte mit Siliciumdioxid	2.5-10%
	⚠ Self-heat. 2, H252	

- 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
- After inhalation Supply fresh air and to be sure call for a doctor.
- After skin contact
If skin irritation continues, consult a doctor.
Immediately wash with water and soap and rinse thoroughly.
- 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.

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SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents**
 - Foam*
 - Fire-extinguishing powder*
 - Water haze*
 - Carbon dioxide*
- **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.*
- **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).*
 - Dispose contaminated material as waste according to item 13.*
 - Ensure adequate ventilation.*
- **6.4 Reference to other sections**
 - 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:**
 - Storage between 10 °C and 25 °C.*
 - 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:** *Keep receptacle tightly sealed.*
- **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** *Avoid contact with the eyes and skin.*
- **Respiratory protection:** *Not required.*
- **Protection of hands:** *Protective gloves.*
- **Material of gloves** *Butyl rubber, BR*

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- **Penetration time of glove material**
0,1 - 0,2 mm
Penetration time: 5 min.
- **Eye protection:** Safety glasses

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

- | | |
|---------------------------|------------------------------------|
| · Form: | Pasty |
| · Colour: | According to product specification |
| · Odour: | Weak, characteristic |
| · Odour threshold: | Not determined. |

- | | |
|--------------------|-----------------|
| · pH-value: | Not determined. |
|--------------------|-----------------|

· Change in condition

- | | |
|---|--------------|
| · Melting point/freezing point: | undetermined |
| · Initial boiling point and boiling range: | 251 °C |

- | | |
|-----------------------|--------|
| · Flash point: | 151 °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: | Not determined. |
| · Upper: | Not determined. |

- | | |
|---------------------------|-----------------|
| · Vapour pressure: | Not determined. |
|---------------------------|-----------------|

- | | |
|----------------------------|------------------------|
| · Density at 20 °C: | 1.86 g/cm ³ |
| · Relative density | Not determined. |
| · Vapour density | Not determined. |
| · Evaporation rate | Not determined. |

· Solubility in / Miscibility with

- | | |
|-----------------|----------------------------------|
| · Water: | Not miscible or difficult to mix |
|-----------------|----------------------------------|

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

· Viscosity:

- | | |
|---------------------|-----------------|
| · dynamic: | Not determined. |
| · kinematic: | 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. |
|--|---|

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- **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.
- **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.
- **Ecotoxicological effects:**
- **Remark:** Harmful to fish
- **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.
Harmful to aquatic organisms
- **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

- | | |
|---|--|
| · 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. |
| · Transport/Additional information: | Not dangerous according to the above specifications. |
| · 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**
- **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**
H252 Self-heating in large quantities; may catch fire.
H317 May cause an allergic skin reaction.
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)
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO: International Civil Aviation Organisation

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*ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)**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)**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**Self-heat. 2: Self-heating substances and mixtures – Category 2**Skin Sens. 1: Skin sensitisation – Category 1**Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2**Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3**** Data compared to the previous version altered.**

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