

Safety Data Sheet

according to 1907/2006/EC, Article 31

Enamel Plus HRi

Revision date: 08.04.2024

Product code: sd184

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Enamel Plus HRi

Further trade names

Art.-No.: CHR., COSVITUD., COSVITUE., CR., COSVITI.....COSSTAIN...

1.2. Relevant identified uses of the substance or mixture and uses advised against**Use of the substance/mixture**

Dental filling material

1.3. Details of the supplier of the safety data sheet

Company name:	Micerium S.p.A.
Street:	Via G. Marconi, 83
Place:	I-16036 Avegno (GE), Italy
Telephone:	+39-0185-7887870
E-mail:	quality@micerium.it
Contact person:	Dr. Eugenio Miceli
Internet:	www.micerium.com
Responsible Department:	Dr. Eugenio Miceli
1.4. Emergency telephone number:	Ospedale San Martino Centro Antiveleni (Genoa, Italy) Tel.: +39-010-35-2808 (disp. h. 24/24)

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****CLP Regulation**

Skin Sens. 1; H317
 Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

2.2. Label elements**CLP Regulation****Hazard components for labelling**

di-urethane dimethacrylate
 tetramethylene dimethacrylate

Signal word: Warning**Pictograms:****Hazard statements**

H317 May cause an allergic skin reaction.
 H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P501 Dispose of contents/container to Dispose of waste according to applicable legislation..
 P280 Wear protective gloves.
 P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P273 Avoid release to the environment.
 P321 Specific treatment (see ... on this label).
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P362+P364 Take off contaminated clothing and wash it before reuse.

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Labelling of packages where the contents do not exceed 125 ml**Signal word:** Warning**Pictograms:****Hazard statements**

H317-H412

Precautionary statements

P501-P280-P261-P321-P333+P313-P362+P364

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients**3.2. Mixtures****Relevant ingredients**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (CLP Regulation)			
41137-60-4	di-urethane dimethacrylate			10 - < 25 %
	Skin Sens. 1B, Aquatic Chronic 2; H317 H411			
2082-81-7	tetramethylene dimethacrylate			2.5 - < 10 %
	218-218-1	607-134-00-4		
	Skin Sens. 1B; H317			

Full text of H and EUH statements: see section 16.

SECTION 4: First aid measures**4.1. Description of first aid measures****After inhalation**

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap. In case of skin irritation, consult a physician.

After contact with eyes

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

After ingestion

Do NOT induce vomiting. Call a physician immediately.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures**5.1. Extinguishing media**

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Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.
Foam
Extinguishing powder
Water mist
Carbon dioxide (CO₂)

Unsuitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately.
Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For cleaning up

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Keep container tightly closed.

Advice on protection against fire and explosion

Keep away from sources of ignition - No smoking. Take precautionary measures against static discharges.

Advice on general occupational hygiene

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.
Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink, smoke, sniff.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. After use replace the closing cap immediately. Protect against: Light

Hints on joint storage

No special measures are necessary.

Further information on storage conditions

Recommended storage temperature 10-25 °C

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7.3. Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
60676-86-0	Silica, fused respirable dust	-	0.08		TWA (8 h)	WEL

8.2. Exposure controls



Individual protection measures, such as personal protective equipment

Eye/face protection

Wear eye/face protection.

Hand protection

Tested protective gloves must be worn

Butyl caoutchouc (butyl rubber)

NBR (Nitrile rubber)

Permeation time (maximum wear duration): 0,3 mm: 60 min

Permeation time (maximum wear duration): 0,11 mm: 10 min

Skin protection

Use of protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:

Colour:

Melting point/freezing point:

not determined

Boiling point or initial boiling point and

251 °C

boiling range:

Flammability:

not determined

Lower explosion limits:

not determined

Upper explosion limits:

not determined

Flash point:

101 °C

Auto-ignition temperature:

not determined

Decomposition temperature:

not determined

pH-Value:

not determined

Viscosity / kinematic:

not determined

Water solubility:

No

Solubility in other solvents

not determined

Partition coefficient n-octanol/water:

not determined

Vapour pressure:

not determined

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Density: not determined
Relative vapour density: not determined
Particle characteristics: not applicable

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

The product is not: Explosive.

Oxidizing properties

The product is not: oxidising.

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

10.4. Conditions to avoid

none

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in CLP Regulation

Acute toxicity

Based on available data, the classification criteria are not met.

ATE_{mix} calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

May cause an allergic skin reaction. (di-urethane dimethacrylate; tetramethylene dimethacrylate)

Carcinogenic/mutagenic/toxic effects for reproduction

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.

11.2. Information on other hazards

Other information

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

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SECTION 12: Ecological information**12.1. Toxicity**

Harmful to aquatic life with long lasting effects.

Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH.

The product has not been tested.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations**

Send to a hazardous waste incinerator facility under observation of official regulations.

List of Wastes Code - residues/unused products

080410 WASTES FROM THE MANUFACTURE, FORMULATION, SUPPLY AND USE (MFSU) OF COATINGS (PAINTS, VARNISHES AND VITREOUS ENAMELS), ADHESIVES, SEALANTS AND PRINTING INKS; wastes from MFSU of adhesives and sealants (including waterproofing products); waste adhesives and sealants other than those mentioned in 08 04 09

Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information**Land transport (ADR/RID)****14.1. UN number or ID number:** No dangerous good in sense of this transport regulation.**14.2. UN proper shipping name:** No dangerous good in sense of this transport regulation.**14.3. Transport hazard class(es):** No dangerous good in sense of this transport regulation.**14.4. Packing group:** No dangerous good in sense of this transport regulation.**14.5. Environmental hazards**

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No information available.

14.7. Maritime transport in bulk according to IMO instruments

not applicable

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SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****EU regulatory information**

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 75

Information according to Directive
2012/18/EU (SEVESO III):

Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Employment restrictions:

Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

Water hazard class (D):

2 - obviously hazardous to water

Skin resorption/Sensitization:

Causes allergic hypersensitivity reactions.

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information**Changes**

This data sheet contains changes from the previous version in section(s): 1.

Abbreviations and acronyms

Skin Sens: Skin sensitisation

Aquatic Chronic: Chronic aquatic hazard

CLP: Classification, labelling and Packaging

REACH: Registration, Evaluation and Authorization of Chemicals

GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals

UN: United Nations

EC/EEC: European Community/European Economic Community

EU: European Union

CAS: Chemical Abstracts Service

DNEL: Derived No Effect Level

DMEL: Derived Minimal Effect Level

PNEC: Predicted No Effect Concentration

ATE: Acute toxicity estimate

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

LL50: Lethal loading, 50%

EL50: Effect loading, 50%

EC50: Effective Concentration 50%

ErC50: Effective Concentration 50%, growth rate

NOEC: No Observed Effect Concentration

BCF: Bio-concentration factor

PBT: persistent, bioaccumulative, toxic

vPvB: very persistent, very bioaccumulative

M-factor: Multiplying factor

ADR: Accord européen sur le transport des marchandises dangereuses par Route

(European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Regulations concerning the international carriage of dangerous goods by rail

MARPOL: International Convention for the Prevention of Marine Pollution from Ships

IBC: Intermediate Bulk Container

SVHC: Substance of Very High Concern

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

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Classification for mixtures and used evaluation method according to CLP Regulation

Classification	Classification procedure
Skin Sens. 1; H317	Calculation method
Aquatic Chronic 3; H412	Calculation method

Relevant H and EUH statements (number and full text)

H317	May cause an allergic skin reaction.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the relevant ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)