

## Safety Data Sheet

according to UK REACH Regulation

### VITA ENAMIC IS

Revision date: 30.03.2023

Product code: 3043

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

### 1.1. Product identifier

VITA ENAMIC IS

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

#### Use of the substance/mixture

Stone, plaster, cement, glass and ceramic articles Auxiliary for manufacture of dental products

### 1.3. Details of the supplier of the safety data sheet

Company name:	VITA Zahnfabrik H.Rauter GmbH & Co.KG	
Street:	Spitalgasse 3	
Place:	D-79713 Bad Säckingen	
Post-office box:	1338	
	D-79704 Bad Säckingen	
Telephone:	+49(0)7761-562-0	Telefax: +49(0)7761-562-299
e-mail:	info@vita-zahnfabrik.com	
Contact person:	regulatory affairs	
e-mail:	info@vita-zahnfabrik.com	
Internet:	www.vita-zahnfabrik.com	
Responsible Department:	Regulatory Affairs	

### 1.4. Emergency telephone number:

+49-(0)761-19240

### Further Information

medical device

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### GB CLP Regulation

This mixture is not classified as hazardous in accordance with GB CLP Regulation.

### 2.2. Label elements

### 2.3. Other hazards

No information available.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

#### Chemical characterization

Stone, plaster, cement, glass and ceramic articles

#### Hazardous components

none (according to UK REACH Regulation)

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

#### After inhalation

Provide fresh air.

#### After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

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#### **After contact with eyes**

Rinse immediately carefully and thoroughly with eye-bath or water.

#### **After ingestion**

Rinse mouth immediately and drink plenty of water.

#### **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**

##### **Suitable extinguishing media**

Co-ordinate fire-fighting measures to the fire surroundings.

#### **5.2. Special hazards arising from the substance or mixture**

Non-flammable.

#### **5.3. Advice for firefighters**

In case of fire: Wear self-contained breathing apparatus.

#### **Additional information**

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**

Avoid dust formation. Do not breathe dust.

#### **6.2. Environmental precautions**

Do not allow to enter into surface water or drains.

#### **6.3. Methods and material for containment and cleaning up**

##### **Other information**

Take up mechanically. 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**

No special measures are necessary.

##### **Advice on protection against fire and explosion**

No special fire protection measures are necessary.

##### **Advice on general occupational hygiene**

Take off contaminated clothing. Wash hands before breaks and after work. 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.

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#### Hints on joint storage

No special measures are necessary.

#### 7.3. Specific end use(s)

Stone, plaster, cement, glass and ceramic articles Auxiliary for manufacture of dental products

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

#### 8.2. Exposure controls

##### Individual protection measures, such as personal protective equipment

##### Eye/face protection

Wear eye/face protection.

##### Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

##### Skin protection

Use of protective clothing.

##### Respiratory protection

In case of inadequate ventilation wear respiratory protection. Do not breathe dust. Provide adequate ventilation as well as local exhaust at critical locations.

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state: solid  
 Colour:  
 Odour: odourless

##### Changes in the physical state

Melting point/freezing point: not determined  
 Boiling point or initial boiling point and boiling range: ?  
 Flash point: ?

##### Flammability

Solid/liquid: not determined  
 Gas: not applicable

##### Explosive properties

The product is not: Explosive.

Lower explosion limits: not determined  
 Upper explosion limits: not determined

##### Self-ignition temperature

Solid: not determined  
 Gas: not applicable  
 Decomposition temperature: not determined  
 pH-Value: not determined

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Water solubility: No

#### Solubility in other solvents

not determined

Partition coefficient n-octanol/water: not determined

Vapour pressure: <=1100 hPa  
(at 50 °C)

Density: 2,00000 g/cm<sup>3</sup>

Relative vapour density: not determined

#### 9.2. Other information

##### Information with regard to physical hazard classes

Oxidizing properties

Not oxidising.

##### Other safety characteristics

Solid content: 0,0 %

Evaporation rate: not determined

##### Further Information

### 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

No known hazardous reactions.

#### 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 GB CLP Regulation

##### Acute toxicity

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

##### Irritation and corrosivity

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

##### Sensitising effects

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

##### 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.

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#### Aspiration hazard

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

#### Additional information on tests

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

### SECTION 12: Ecological information

#### 12.1. Toxicity

The product is not: Ecotoxic.

#### 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 UK 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

Avoid release to the environment.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

##### Disposal recommendations

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

##### Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

### 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.

#### Inland waterways transport (ADN)

##### 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.

#### Marine transport (IMDG)

##### 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.

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#### Air transport (ICAO-TI/IATA-DGR)

<b>14.1. UN number or ID number:</b>	No dangerous good in sense of this transport regulation.
<b>14.2. UN proper shipping name:</b>	No dangerous good in sense of this transport regulation.
<b>14.3. Transport hazard class(es):</b>	No dangerous good in sense of this transport regulation.
<b>14.4. Packing group:</b>	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

### SECTION 15: Regulatory information

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

##### EU regulatory information

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

##### National regulatory information

Water hazard class (D): -- non-hazardous to water

#### 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

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 Harmonized 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  
LC50: Lethal concentration, 50%  
LD50: Lethal dose, 50%  
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  
DNEL: Derived No Effect Level  
DMEL: Derived Minimal Effect Level  
PNEC: Predicted No Effect Concentration  
ATE: Acute toxicity estimate  
LL50: Lethal loading, 50%  
EL50: Effect loading, 50%  
EC50: Effective Concentration 50%  
ErC50: Effective Concentration 50%, growth rate

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NOEC: No Observed Effect Concentration

BCF: Bio-concentration factor

PBT: persistent, bioaccumulative, toxic

vPvB: very persistent, very bioaccumulative

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

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways  
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)

EmS: Emergency Schedules

MFAG: Medical First Aid Guide

ICAO: International Civil Aviation Organization

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 table at <http://abbrev.esdscom.eu>

#### 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 hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*