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

1.1. Product identifier

VITA ENAMIC Blocs, Disc

Further trade names

VITA ENAMIC, VITA ENAMIC multiColor

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 prothesis

1.3. Details of the supplier of the safety data sheet

Company name: VITA Zahnfabrik H. Rauter GmbH & Co. KG
Post-office box: 1338
79704 Bad Säckingen
Telephone: +49(0)7761-562-0
Fax: +49(0)7761-562-299
E-mail: info@vita-zahnfabrik.com
Internet: www.vita-zahnfabrik.com

1.4. Emergency telephone number:

+49-(0)7761-562-0

Further Information

medical device

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

This mixture is not classified as hazardous in accordance with Regulation (EC) No. 1272/2008.

2.2. Label elements

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Stone, plaster, cement, glass and ceramic articles

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.

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
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

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

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.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels
Keep container tightly closed.

Hints on joint storage
No special measures are necessary.

7.3. Specific end use(s)

Stone, plaster, cement, glass and ceramic articles Auxilliary for manufacture of dental prothesis

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Protective and hygiene measures
Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat, drink, smoke, sniff.

Eye/face protection
Wear eye protection/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 exhaustion at critical locations.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: solid
Colour: odourless
pH-Value: not determined

Changes in the physical state
Melting point: not determined
Initial boiling point and boiling range: ?
Flash point: ?

Flammability
Solid: not determined
Gas: not applicable

Explosive properties
The product is not: Explosive.

Auto-ignition temperature
Solid: not determined
Gas: not applicable

Decomposition temperature: not determined

Oxidizing properties
Not oxidising.

Vapour pressure: <=1100 hPa
(at 50 °C)
Density: 2,00000 g/cm³
Water solubility: No

Solubility in other solvents
not determined
Partition coefficient: not determined
Vapour density: not determined
Evaporation rate: not determined

9.2. Other information
Solid content: 0,0 %
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 toxicological effects

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.

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 product has not been tested.

12.6. Other adverse effects
No information available.
### 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: | 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: | 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: | 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. |

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

| 14.1. UN 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. Transport in bulk according to Annex II of Marpol and the IBC Code

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

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
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.)