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 prosthesis

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: D-79704 Bad Säckingen

Telephone: +49(0)7761-562-0
E-mail: info@vita-zahnfabrik.com

Telefax: +49(0)7761-562-299
E-mail: info@vita-zahnfabrik.com
Internet: www.vita-zahnfabrik.com

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

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 Regulation (EC) No 1907/2006 (REACH))

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
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.
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

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 exhaustion at critical locations.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: solid
Colour: 
Odour: odourless
Melting point/freezing point: not determined
Boiling point or initial boiling point and boiling range: ?
flammability: not determined
Lower explosion limits: not determined
Upper explosion limits: not determined
Flash point: ?
Decomposition temperature: not determined
pH-Value: not determined
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/cm³
Relative vapour density: not determined

9.2. Other information

Information with regard to physical hazard classes
Explosive properties
The product is not: Explosive.

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

Oxidizing properties
Not oxidising.

Other safety characteristics
Evaporation rate: not determined
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 hazard classes as defined in Regulation (EC) No 1272/2008

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

ATEmix 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
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 substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

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.

Air transport (ICAO-TI/IATA-DGR)
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

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%
ER50: 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.)