

according to Regulation (EC) No 1907/2006

## **VITA ENAMIC Blocs, Disc**

Revision date: 13.08.2019

Product code: 270

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# 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 Auxilary 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	
Post-office box:	1338	
	79704 Bad Säckingen	
Telephone:	+49(0)7761-562-0	Telefax:+49(0)7761-562-299
e-mail:	info@vita-zahnfabrik.com	
Internet:	www.vita-zahnfabrik.com	
1.4. Emergency telephone	+49-(0)7761-562-0	
<u>number:</u>		

# 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

## 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



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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

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 Auxilary for manufacture of dental products

## **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.



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## 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	
pH-Value:	ododnobo	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.		
Lower explosion limits:		not determined
Upper explosion limits:		not determined
Auto-ignition temperature		
Solid:		not determined
Gas:		not applicable not determined
Decomposition temperature:		not determined
Oxidizing properties Not oxidising.		
Vapour pressure: (at 50 °C)		<=1100 hPa
Density:		2,00000 g/cm <sup>3</sup>
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 %



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## **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.



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## **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) No dangerous good in sense of this transport regulation. 14.1. UN number: 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) No dangerous good in sense of this transport regulation. 14.1. UN number: 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. No dangerous good in sense of this transport regulation. 14.4. Packing group: Marine transport (IMDG) 14.1. UN number: No dangerous good in sense of this transport regulation. 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: 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 Not subject to 2012/18/EU (SEVESO III) (SEVESO III): National regulatory information Water hazard class (D): - - non-hazardous to water



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## 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.)