

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### VITA AMBRIA

Revision date: 30.03.2023

Product code: 321

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

### 1.1. Product identifier

VITA AMBRIA

CAS No: 65997-17-3

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

#### Use of the substance/mixture

Auxilliary for manufacture of dental prothesis

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

Company name: VITA Zahnfabrik H.Rauter GmbH &amp; 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

#### Regulation (EC) No 1272/2008

This substance 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

### 3.1. Substances

#### 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.

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**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.

## 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**

No special environmental measures are necessary. Clean contaminated articles and floor according to the environmental legislation.

**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 or drink.

**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 Auxilliary for manufacture of dental prothesis

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

#### 8.2. Exposure controls

##### Appropriate engineering controls

This product is not to be used under conditions of poor ventilation.

##### 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

Wear suitable protective clothing.

##### Respiratory protection

Provide adequate ventilation as well as local exhaustion at critical locations. This product is not to be used under conditions of poor ventilation.

### SECTION 9: Physical and chemical properties

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

Physical state:	solid
Colour:	translucent
Odour:	odourless

##### Changes in the physical state

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

##### Flammability

Solid/liquid:	not determined
Gas:	not applicable
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: 2,6000 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: 100 %

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 Regulation (EC) No 1272/2008

##### 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 substance 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

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

The product has not been tested.

#### 12.6. Endocrine disrupting properties

This substance does not have endocrine disrupting properties with respect to non-target organisms.

#### 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

Dispose of waste according to applicable legislation.

##### Contaminated packaging

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)

- 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

##### National regulatory information

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

#### 15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been 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%

#### 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.