

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### VITA VIONIC WAX

Revision date: 15.08.2023

Product code: 316

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

##### 1.1. Product identifier

VITA VIONIC WAX

##### 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,wax

##### 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                    |                             |

##### 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

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

###### Precautionary statements

|      |  |
|------|--|
| P210 | Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. |
|------|--|

##### 2.3. Other hazards

No information available.

#### SECTION 3: Composition/information on ingredients

##### 3.2. Mixtures

###### Chemical characterization

wax  
Paraffin

###### Hazardous components

none (according to Regulation (EC) No 1907/2006 (REACH))

#### SECTION 4: First aid measures

##### 4.1. Description of first aid measures

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#### General information

No special measures are necessary.

#### 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.

#### 5.3. 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

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

#### 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 or drink.

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#### 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)

Auxilliary for manufacture of dental prothesis Plastic articles

### 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

Wear suitable gloves.

##### Skin protection

Wear suitable protective clothing.

##### Respiratory protection

No special measures are necessary.

### SECTION 9: Physical and chemical properties

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

|   |       |                                  |
|---|-------|----------------------------------|
| Physical state:   | solid |                                  |
| Colour:   | pink  |                                  |
| Melting point/freezing point:                             |       | 70 - 110 °C                      |
| Boiling point or initial boiling point and boiling range: |       | nicht anwendbar                  |
| Flammability:   |       | not determined<br>not applicable |
| Lower explosion limits:                                   |       | not determined                   |
| Upper explosion limits:                                   |       | not determined                   |
| Flash point:  |       | >140 °C                          |
| 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:  |       | not determined                   |
| (at 50 °C)  |       |                                  |
| Density:  |       | 0,9 g/cm <sup>3</sup>            |
| Relative vapour density:                                  |       | not determined                   |

#### 9.2. Other information

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

Self-ignition temperature

Solid:

not determined

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Gas: not applicable  
Oxidizing properties  
Not oxidising.

#### Other safety characteristics

Evaporation rate: not determined  
Solid content: 100,0 %

## 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

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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.

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. Waste codes/waste designations according to EWC/AVV

##### **Contaminated packaging**

Completely emptied packages can be recycled. Waste codes/waste designations according to EWC/AVV

### SECTION 14: Transport information

#### **Land transport (ADR/RID)**

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

#### **Inland waterways transport (ADN)**

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

#### **Marine transport (IMDG)**

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

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

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

#### **14.5. Environmental hazards**

ENVIRONMENTALLY HAZARDOUS: No

#### **14.6. Special precautions for user**

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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): 1 - slightly 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%

#### **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.)*