

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITA VIONIC BASE

Revision date: 30.03.2023

Product code: 315

Page 1 of 7

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

1.1. Product identifier

VITA VIONIC BASE

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, Plastic articles

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

1.4. Emergency telephone

+49-(0)761-19240

number:

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

Plastic articles, Polymer preparations and compounds

Hazardous components

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

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

No special measures are necessary.

After inhalation

Provide fresh air.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITA VIONIC BASE

Revision date: 30.03.2023

Product code: 315

Page 2 of 7

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, drink, smoke, sniff.

7.2. Conditions for safe storage, including any incompatibilities

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITA VIONIC BASE

Revision date: 30.03.2023

Product code: 315

Page 3 of 7

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. No special measures are necessary.

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. No special measures are necessary.

Skin protection

Use of protective clothing.

Respiratory protection

Provide adequate ventilation as well as local exhaustion at critical locations. Do not breathe dust.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: solid
 Colour:
 Odour: odourless

Changes in the physical state

Melting point/freezing point: not determined
 Boiling point or initial boiling point and boiling range: nicht anwendbar
 Flash point: ?

Flammability

Solid/liquid: not determined
 Gas: not applicable

Explosive properties

The product is not: Explosive.

Lower explosion limits: not determined
 Upper explosion limits: not determined

Self-ignition temperature

Solid: not determined
 Gas: not applicable

Decomposition temperature: not determined

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITA VIONIC BASE

Revision date: 30.03.2023

Product code: 315

Page 4 of 7

| | |
|-------------------------------------------------------|----------------|
| pH-Value: | not determined |
| Water solubility: | No |
| Solubility in other solvents not determined | |
| Partition coefficient n-octanol/water: | not determined |
| Vapour pressure: (at 50 °C) | not determined |
| Density: | nicht bestimmt |
| 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: | 100,0 % |
| 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.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITA VIONIC BASE

Revision date: 30.03.2023

Product code: 315

Page 5 of 7

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.

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

Dispose of waste according to applicable legislation. Waste codes/waste designations according to EWC/AVV

Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled. Waste codes/waste designations according to EWC/AVV

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)

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITA VIONIC BASE

Revision date: 30.03.2023

Product code: 315

Page 6 of 7

- | | |
|------------------------------------------|----------------------------------------------------------|
| 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

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%

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITA VIONIC BASE

Revision date: 30.03.2023

Product code: 315

Page 7 of 7

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.)