

**Safety Data Sheet  
acc. to OSHA HCS**

Printing date 05/12/2015

Reviewed on 05/12/2015

**1 Identification**· **Product identifier**· **Trade name:** Flexitime Bite (base + cat)· **Relevant identified uses of the substance or mixture and uses advised against**

No further relevant information available.

· **Application of the substance / the mixture** dental bite registration material· **Details of the supplier of the safety data sheet**· **Manufacturer/Supplier:**

Heraeus Kulzer GmbH

Grüner Weg 11, D-63450 Hanau

Tel.: 0800 4372522

· **Information department:**

Marc Henn

Tel. +1 (574) 2995444 / Fax: +1 (574) 2912542

e-mail: marc.henn@kulzer-dental.com

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-Number)

GBK/Infotrac ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

**2 Hazard(s) identification**· **Classification of the substance or mixture**

Carc. 2 H351 Suspected of causing cancer.

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.

· **Label elements**· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**

GHS08

· **Signal word** Warning· **Hazard-determining components of labeling:**

Silanisiertes Quarzmehl

· **Hazard statements**

Suspected of causing cancer.

May cause damage to organs through prolonged or repeated exposure.

· **Precautionary statements**

Do not breathe dust/fume/gas/mist/vapours/spray.

Use personal protective equipment as required.

IF exposed or concerned: Get medical advice/attention.

Get medical advice/attention if you feel unwell.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system**· **NFPA ratings for USA (scale 0-4)**

Health = 0

Fire = 1

Reactivity = 0

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**Trade name: Flexitime Bite (base + cat)**
**· HMIS-Ratings (Scale 0-4)**

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HEALTH	0
FIRE	1
REACTIVITY	0

Health = \*0

Fire = 1

Reactivity = 0

**· Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### 3 Composition/information on ingredients

**· Chemical characterization: Mixtures**
**· Description:**

2-component bite registration material comprising base paste and matching catalyst paste for addition curing

**· Dangerous components:** Void

### 4 First-aid measures

**· Description of first aid measures**
**· General information** No special measures required.

**· After skin contact**

Immediately wash with water and soap and rinse thoroughly.  
Generally the product does not irritate the skin.

**· After eye contact**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

**· After swallowing**

Rinse out mouth and then drink plenty of water.  
Seek immediate medical advice.

**· Most important symptoms and effects, both acute and delayed**

No further relevant information available.

**· Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

### 5 Fire-fighting measures

**· Extinguishing media**
**· Suitable extinguishing agents**

CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Use fire fighting measures that suit the environment.

**· Special hazards arising from the substance or mixture** No further relevant information available.

**· Advice for firefighters**
**· Protective equipment:** No special measures required.

**· Additional information -**

### 6 Accidental release measures

**· Personal precautions, protective equipment and emergency procedures** Not required.

**· Environmental precautions:** No special measures required.

**· Methods and material for containment and cleaning up:** Pick up mechanically.

**· Reference to other sections**

See Section 13 for disposal information.

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See Section 8 for information on personal protection equipment.

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## 7 Handling and storage

- **Precautions for safe handling** No special measures required.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
  - **Storage**
    - **Requirements to be met by storerooms and receptacles:** No special requirements.
    - **Information about storage in one common storage facility:** Not required.
    - **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

## 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
  - **Components with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
  - **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
  - **Personal protective equipment**
    - **General protective and hygienic measures**  
The usual precautionary measures for handling chemicals should be followed.
    - **Breathing equipment:** Not required.
    - **Protection of hands:** Not absolutely necessary.
      - **Penetration time of glove material**  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
      - **For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:**  
PVC or PE gloves
    - **Eye protection:** Protective goggles are recommended.
    - **Body protection:** Light weight protective clothing

## 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - **Form:** Pasty
      - **Color:** Different according to coloring
      - **Odor:** Odorless
  - **Change in condition**
    - **Melting point/Melting range:** undetermined
    - **Boiling point/Boiling range:** undetermined
  - **Flash point:** > 130 °C (> 266 °F)
  - **Auto igniting:** Product is not selfigniting.

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- |   |  |
|---|--|
| <b>· Danger of explosion:</b>             | Product does not present an explosion hazard.    |
| <b>· Density at 20 °C (68 °F):</b>        | 1.4-1.6 g/cm <sup>3</sup> (11.683-13.35 lbs/gal) |
| <b>· Solubility in / Miscibility with</b> |  |
| <b>· Water:</b>                           | Not miscible or difficult to mix                 |
| <b>· Other information</b>                | No further relevant information available.       |

### 10 Stability and reactivity

- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** none
- **Additional information:** -

### 11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

- **Primary irritant effect:**

- **on the skin:** No irritant effect.

- **on the eye:** No irritating effect.

- **Sensitization:** No sensitizing effects known.

- **Additional toxicological information:**

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

13463-67-7 Titanium dioxide	3
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- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

### 12 Ecological information

- **Toxicity**

- **Aquatic toxicity:** No further relevant information available.

- **Persistence and degradability** No further relevant information available.

- **Bioaccumulative potential** No further relevant information available.

- **Mobility in soil** No further relevant information available.

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **Other adverse effects** No further relevant information available.

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## 13 Disposal considerations

- **Waste treatment methods**
  - **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packagings:**
  - **Recommendation:** Disposal must be made according to official regulations.

## 14 Transport information

- |  |                 |
|--|-----------------|
| · <b>UN-Number</b>   |                 |
| · DOT, ADR, ADN, IMDG, IATA  | Void            |
| · <b>UN proper shipping name</b>   |                 |
| · DOT, ADR, ADN, IMDG, IATA  | Void            |
| · <b>Transport hazard class(es)</b>  |                 |
| · DOT, ADR, ADN, IMDG, IATA  |                 |
| · Class  | Void            |
| · <b>Packing group</b>   |                 |
| · DOT, ADR, IMDG, IATA   | Void            |
| · <b>Environmental hazards:</b>  |                 |
| · Marine pollutant:  | No              |
| · <b>Special precautions for user</b>  | Not applicable. |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable. |
| · <b>Transport/Additional information:</b>                                       | -               |
| · <b>UN "Model Regulation":</b>  | -               |

## 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**

- **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

- **TSCA (Toxic Substances Control Act)** Medical devices are exempted from TSCA.

- **Carcinogenicity categories**

- **TLV (Threshold Limit Value established by ACGIH)**

13463-67-7 Titanium dioxide

A4

- **GHS label elements**

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- **Hazard pictograms**



GHS08

- **Signal word** Warning

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- **Hazard-determining components of labeling:**  
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- **Hazard statements**  
Suspected of causing cancer.  
May cause damage to organs through prolonged or repeated exposure.
- **Precautionary statements**  
Do not breathe dust/fume/gas/mist/vapours/spray.  
Use personal protective equipment as required.  
If exposed or concerned: Get medical advice/attention.  
Get medical advice/attention if you feel unwell.  
Store locked up.  
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**16 Other information**

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Date of preparation / last revision** 05/12/2015 / -

- **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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

Carc. 2: Carcinogenicity, Hazard Category 2

STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2

- **\* Data compared to the previous version altered.**

USA