



**Safety data sheet  
according to 1907/2006/EC, Article 31**

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

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

- **1.1 Product identifier**
  - Trade name: **Flexitime Bite (base + cat)**
- **1.2 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
- **1.3 Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:**  
Kulzer GmbH  
Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522
  - **Informing department:** E-Mail: [msds@kulzer-dental.com](mailto:msds@kulzer-dental.com)
- **1.4 Emergency telephone number:** Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
  - **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified according to the CLP regulation.
- **2.2 Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008** Void
    - **Hazard pictograms** Void
    - **Signal word** Void
    - **Hazard statements** Void
  - **Additional information:**  
Safety data sheet available on request.
- **2.3 Other hazards -**
  - **Results of PBT and vPvB assessment**
    - **PBT:** Not applicable.
    - **vPvB:** Not applicable.

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

- **3.2 Chemical characterisation: Mixtures**
  - **Description:**  
2-component bite registration material comprising base paste and matching catalyst paste for addition curing
  - **Dangerous components:**

CAS: 556-67-2	octamethylcyclotetrasiloxane	0-5%
EINECS: 209-136-7	Flam. Liq. 3, H226; Repr. 2, H361f; Aquatic Chronic 4, H413	
  - **Additional information** For the wording of the listed hazard phrases refer to section 16.

**SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
  - **After inhalation** Supply fresh air; consult doctor in case of symptoms.
  - **After skin contact** Instantly wash with water and soap and rinse thoroughly.
  - **After eye contact** Rinse opened eye for several minutes under running water.

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- **After swallowing**  
Rinse out mouth and then drink plenty of water.  
In case of persistent symptoms consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### **SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
  - **Suitable extinguishing agents**  
CO<sub>2</sub>, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.  
Use fire fighting measures that suit the environment.
- **5.2 Special hazards arising from the substance or mixture**  
Formation of toxic gases is possible during heating or in case of fire.
- **5.3 Advice for firefighters**
  - **Protective equipment:** No special measures required.
  - **Additional information -**

### **SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:** Collect mechanically.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling  
See Section 8 for information on personal protection equipment.  
See Section 13 for information on disposal.  
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### **SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling**  
No special measures required.  
Ensure good ventilation/exhaustion at the workplace.
  - **Information about protection against explosions and fires:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
  - **Storage**
    - **Requirements to be met by storerooms and containers:** No special requirements.
    - **Information about storage in one common storage facility:** Not required.
    - **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

### **SECTION 8: Exposure controls/personal protection**

- **Additional information about design of technical systems:** No further data; see item 7.

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- **8.1 Control parameters**
  - **Components with critical 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 compilation were used as basis.
- **8.2 Exposure controls**
  - **Personal protective equipment**
    - **General protective and hygienic measures**  
Wash hands during breaks and at the end of the work.
    - **Breathing equipment:** Not required.
    - **Protection of hands:**  
Check protective gloves prior to each use for their proper condition.  
recommended
      - **Material of gloves**  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
      - **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 of a maximum of 15 minutes gloves made of the following materials are suitable:**  
Butyl rubber, BR  
Nitrile rubber, NBR
  - **Eye protection:** Protective goggles are recommended.
  - **Body protection:** Light weight protective clothing

**SECTION 9: Physical and chemical properties**

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - **Form:** Pasty
      - **Colour:** Different according to colour
    - **Smell:** Odourless
    - **Odour threshold:** Not determined.
  - **pH-value:** Not determined.
  - **Change in condition**
    - **Melting point/Melting range:** Not determined
    - **Boiling point/Boiling range:** 315 °C
  - **Flash point:** 131 °C
  - **Inflammability (solid, gaseous)** Not applicable.
  - **Ignition temperature:** > 460 °C

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· <b>Decomposition temperature:</b>	Not determined.
· <b>Self-inflammability:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product is not explosive.
· <b>Critical values for explosion:</b>	
· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.
· <b>Steam pressure:</b>	Not determined.
· <b>Density</b>	Not determined
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with</b>	
· <b>Water:</b>	Not miscible or difficult to mix
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
· <b>dynamic:</b>	Not determined.
· <b>kinematic:</b>	Not determined.
· <b>9.2 Other information</b>	No further relevant information available.

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
  - **Conditions to be avoided:** No decomposition if used and stored according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None
  - **Additional information:** -

**SECTION 11: Toxicological information**

- **11.1 Information on toxicological effects**
  - **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values that are relevant for classification:**

**Polydimethylsiloxan mit Vinylgruppen**

Oral	LD50	> 5000 mg/kg (rat)
Dermal	LD50	>10000 mg/kg (rabbit)

**Polydimethylsiloxan**

Oral	LD50	> 5000 mg/kg (rat)
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- **Primary irritant effect:**
  - **Skin corrosion/irritation** Based on available data, the classification criteria are not met.

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- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
  - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
  - **Carcinogenicity** Based on available data, the classification criteria are not met.
  - **Reproductive toxicity** 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.

**SECTION 12: Ecological information**

- **12.1 Toxicity**
  - **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

**SECTION 13: Disposal considerations**

- **13.1 Waste treatment methods**
  - **Recommendation**  
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
  - **Uncleaned packagings:**
    - **Recommendation:** Disposal must be made according to official regulations.

**SECTION 14: Transport information**

- |   |      |
|---|------|
| · <b>14.1 UN-Number</b><br>· ADR, ADN, IMDG, IATA                             | Void |
| · <b>14.2 UN proper shipping name</b><br>· ADR, ADN, IMDG, IATA               | Void |
| · <b>14.3 Transport hazard class(es)</b><br>· ADR, ADN, IMDG, IATA<br>· Class | Void |
| · <b>14.4 Packing group</b><br>· ADR, IMDG, IATA                              | Void |

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- |  |                 |
|--|-----------------|
| · <b>14.5 Environmental hazards:</b>   |                 |
| · <b>Marine pollutant:</b>   | No              |
| · <b>14.6 Special precautions for user</b>                                       | Not applicable. |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |
| · <b>Transport/Additional information:</b>                                       | -               |
| · <b>UN "Model Regulation":</b>  | Void            |

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - **Directive 2012/18/EU**
    - **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**SECTION 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.

- **Relevant phrases**
  - H226 Flammable liquid and vapour.
  - H361f Suspected of damaging fertility.
  - H413 May cause long lasting harmful effects to aquatic life.
- **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 Harmonised 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 (division of the American Chemical Society)
  - LC50: Lethal concentration, 50 percent
  - LD50: Lethal dose, 50 percent
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
  - Flam. Liq. 3: Flammable liquids – Category 3
  - Repr. 2: Reproductive toxicity – Category 2
  - Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4
- **\* Data compared to the previous version altered.**