



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

Printing date 14.05.2020

Version number 4

Revision: 14.05.2020

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

- **1.1 Product identifier**
 - Trade name: **Flexitime Bite Base**
- **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 impression 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
- **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**
STOT RE 1 H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
 - **2.2 Label elements**
 - **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the CLP regulation.

 - **Hazard pictograms**
- 

GHS08
- **Signal word** Danger
 - **Hazard-determining components of labelling:**
cristobalite
 - **Hazard statements**
H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
 - **Precautionary statements**
P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P264 Wash thoroughly after handling.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P314 Get medical advice/attention if you feel unwell.
- **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:** -

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· Dangerous components:

CAS: 14464-46-1	crystalalite	STOT RE 1, H372	50-75%
EINECS: 238-455-4			

· 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 rinse with water.
If skin irritation continues, consult a doctor.
 - **After eye contact**
Rinse opened eye for several minutes under running water. Then consult doctor.
 - **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**
CO₂, 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**
Avoid contact with eyes and skin.
Ensure adequate ventilation
- **6.2 Environmental precautions:** Prevent material from reaching sewage system, holes and cellars.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
- **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.
-

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Ensure good ventilation/exhaustion at the workplace.
 - **Information about protection against explosions and fires:** No special measures required.

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- **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

- **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.
Not required.

 - **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**

Keep away from foodstuffs, beverages and food.
Wash hands during breaks and at the end of the work.
 - **Breathing equipment:** Use a mask with particle filter in case of dust generation.
 - **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:** Safety glasses
 - **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:** Violet
 - **Smell:** Odourless
 - **Odour threshold:** Not determined.
 - **pH-value:** Not determined.

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· Change in condition	
· Melting point/freezing point:	Not determined
· Initial boiling point and boiling range:	2,230 °C
· Flash point:	>130 °C
· Inflammability (solid, gaseous)	Not applicable.
· Decomposition temperature:	Not determined.
· Self-inflammability:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. Not determined.
· Critical values for explosion:	
· Lower:	Not determined.
· Upper:	Not determined.
· Steam pressure:	Not determined.
· Density	Not determined
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with	
· Water:	Not miscible or difficult to mix
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
· dynamic:	Not determined.
· kinematic:	Not determined.
· 9.2 Other information	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.
 - **Primary irritant effect:**
 - **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
 - **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.

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- **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**
Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- **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.
 - **Additional ecological information:**
 - **General notes:** Not known to be hazardous to water.
- **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.
Disposal must be made according to official regulations.
- **European waste catalogue**

18 01 06*	chemicals consisting of or containing hazardous substances
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- **Uncleaned packagings:**
 - **Recommendation:**
Disposal must be made according to official regulations.
Non contaminated packagings can be used for recycling.

SECTION 14: Transport information

- | | |
|---|------|
| · 14.1 UN-Number <ul style="list-style-type: none">· ADR, IMDG, IATA | Void |
| · 14.2 UN proper shipping name <ul style="list-style-type: none">· ADR, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) <ul style="list-style-type: none">· ADR, ADN, IMDG, IATA· Class | Void |

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· 14.4 Packing group · ADR, IMDG, IATA	Void
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	-
· UN "Model Regulation":	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.
 - **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **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**
 - H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- **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)
 - PBT: Persistent, Bioaccumulative and Toxic
 - vPvB: very Persistent and very Bioaccumulative
 - STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1
- *** Data compared to the previous version altered.**