

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

Printing date 01/20/2016

Reviewed on 12/30/2015

1 Identification

· **Product identifier**

· **Trade name:** **Flexitime Bite (base + cat)**

· **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:**

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545

e-mail: customer.servicehkna@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**

Repr. 2 H361 Suspected of damaging fertility or the unborn child.

· **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:**

octamethylcyclotetrasiloxane

· **Hazard statements**

Suspected of damaging fertility or the unborn child.

· **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

IF exposed or concerned: Get medical advice/attention.

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

(Contd. on page 2)

USA

Safety Data Sheet acc. to OSHA HCS

Printing date 01/20/2016

Reviewed on 12/30/2015

Trade name: Flexitime Bite (base + cat)

(Contd. of page 1)

· **HMIS-Ratings (Scale 0-4)**

HEALTH	0	Health = *0
FIRE	1	Fire = 1
REACTIVITY	0	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:**

556-67-2	octamethylcyclotetrasiloxane	Flam. Liq. 3, H226; Repr. 2, H361	0-5%
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- **Additional information** For the wording of the listed hazard phrases refer to section 16.

4 First-aid measures

· **Description of first aid measures**

- **After inhalation** Supply fresh air; consult doctor in case of complaints.
- **After skin contact** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact** Rinse opened eye for several minutes under running water.
- **After swallowing**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.

· **Information for doctor**

- **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**

CO₂, 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**

Formation of toxic gases is possible during heating or in case of fire.

· **Advice for firefighters**

- **Protective equipment:** No special measures required.

· **Additional information -**

USA

(Contd. on page 3)

**Safety Data Sheet
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(Contd. of page 2)

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 7 for information on safe handling
 - See Section 8 for information on personal protection equipment.
 - See Section 13 for disposal information.

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7 Handling and storage

- **Handling**
 - **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.
- **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** Wash hands before breaks and at the end of 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.

(Contd. on page 4)

USA

**Safety Data Sheet
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Trade name: Flexitime Bite (base + cat)

(Contd. of page 3)

- **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

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

- **Form:** Pasty
- **Color:** Different according to coloring

- **Odor:** Odorless
- **Odor threshold:** Not determined.

- **pH-value:** Not determined.

· **Change in condition**

- **Melting point/Melting range:** undetermined
- **Boiling point/Boiling range:** 315 °C (599 °F)

- **Flash point:** 131 °C (268 °F)

- **Flammability (solid, gaseous)** Not applicable.

- **Ignition temperature:** > 460 °C (> 860 °F)

- **Decomposition temperature:** Not determined.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

- **Lower:** Not determined.
- **Upper:** Not determined.

- **Vapor pressure:** Not determined.

- **Density:** Not determined

- **Relative density** Not determined.
- **Vapor 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.

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

USA

(Contd. on page 5)

**Safety Data Sheet
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(Contd. of page 4)

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **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:**

- **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:**
 - **on the skin:** Based on available data, the classification criteria are not met.
 - **on the eye:** Based on available data, the classification criteria are not met.
- **Sensitization:** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**

- **Carcinogenic categories**

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

None of the ingredients is listed.

- **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.
- **Behavior in environmental systems:**
 - **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.

USA

(Contd. on page 6)

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(Contd. of page 5)

13 Disposal considerations

- **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.

14 Transport information

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

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)**
None of the ingredients is listed.
Medical devices are exempted from TSCA.
 - **Carcinogenicity categories**
 - **TLV (Threshold Limit Value established by ACGIH)**
None of the ingredients is listed.
 - **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).

(Contd. on page 7)

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Trade name: Flexitime Bite (base + cat)

(Contd. of page 6)

· **Hazard pictograms**



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· **Signal word** Warning

· **Hazard-determining components of labeling:**

octamethylcyclotetrasiloxane

· **Hazard statements**

Suspected of damaging fertility or the unborn child.

· **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.

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Do not handle until all safety precautions have been read and understood.

IF exposed or concerned: Get medical advice/attention.

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.

· **Relevant phrases**

H226 Flammable liquid and vapor.

H361 Suspected of damaging fertility or the unborn child.

· **Date of preparation / last revision** 01/20/2016 / 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

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Flam. Liq. 3: Flammable liquids, Hazard Category 3

Repr. 2: Reproductive toxicity, Hazard Category 2

· *** Data compared to the previous version altered.**