



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

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:**

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 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 06/03/2017

Reviewed on 06/03/2017

Trade name: Flexitime Bite (base + cat)

· **HMIS-Ratings (Scale 0-4)**

(Contd. of page 1)

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%
----------	------------------------------	-----------------------------------	------

- **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.

(Contd. on page 3)



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Flexitime Bite (base + cat)

· **Additional information -**

(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.
-

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**

(Contd. on page 4)

USA



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Flexitime Bite (base + cat)

(Contd. of page 3)

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

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:**

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

(Contd. on page 5)



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Flexitime Bite (base + cat)

(Contd. of page 4)

- **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.

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)
------	------	--------------------

- **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.

USA

(Contd. on page 6)



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Flexitime Bite (base + cat)

(Contd. of page 5)

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.

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

USA
(Contd. on page 7)



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Flexitime Bite (base + cat)

(Contd. of page 6)

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).

· **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.

· **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** 06/03/2017 / 2

· **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

(Contd. on page 8)



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Flexitime Bite (base + cat)

(Contd. of page 7)

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 – Category 3
Repr. 2: Reproductive toxicity – Category 2

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

USA