

SAFETY DATA SHEETS

This SDS packet was issued with item:

074575239

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

074575247

**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

(Contd. on page 2)

USA

Safety Data Sheet
acc. to ISO/DIS 11014

Printing date 11/08/2012

Version number 4

Reviewed on 11/08/2012

Trade name: **IPS e.max CAD**

(Contd. of page 4)

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.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **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:**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **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 MARPOL 73/78 and the IBC Code** Not applicable.
- **UN "Model Regulation":** -

1.5A
(Contd. on page 6)

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/12/2015

Reviewed on 05/12/2015

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:** 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**
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** 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.

(Contd. on page 3)

USA

Safety Data Sheet
acc. to ISO/DIS 11014

Printing date 11/08/2012

Version number 4

Reviewed on 11/08/2012

Trade name: **IPS e.max CAD**

(Contd. of page 5)

15 Regulatory information

- *Safety, health and environmental regulations/legislation specific for the substance or mixture*
- *Sara*
- *Section 355 (extremely hazardous substances):*
Substance is not listed.
- *Section 313 (Specific toxic chemical listings):*
Substance is not listed.
- *TSCA (Toxic Substances Control Act):*
Substance is not listed.
- *Proposition 65*
- *Chemicals known to cause cancer:*
Substance is not listed.
- *Chemicals known to cause reproductive toxicity for females:*
Substance is not listed.
- *Chemicals known to cause reproductive toxicity for males:*
Substance is not listed.
- *Chemicals known to cause developmental toxicity:*
Substance is not listed.
- *Carcinogenic categories*
- *EPA (Environmental Protection Agency)*
Substance is not listed.
- *TLV (Threshold Limit Value established by ACGIH)*
Substance is not listed.
- *NIOSH-Ca (National Institute for Occupational Safety and Health)*
Substance is not listed.
- *OSHA-Ca (Occupational Safety & Health Administration)*
Substance is not listed.
- *Product related hazard informations:*
The substance is not subject to classification according to the sources of literature known to us.
- *National regulations:*
- *Other regulations, limitations and prohibitive regulations*
The product is a medical device according to the EC-directive 93/42/EEC.
This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.
- *Chemical safety assessment: A Chemical Safety Assessment has not been carried out.*

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- *Abbreviations and acronyms:*
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

(Contd. on page 7)
USA

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

Printing date 05/12/2015

Reviewed on 05/12/2015

Trade name: Flexitime Bite (base + cat)

See Section 8 for information on personal protection equipment.

(Contd. of page 2)

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 trough 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.

(Contd. on page 4)

USA

Safety Data Sheet
acc. to ISO/DIS 11014

Printing date 11/08/2012

Version number J

Reviewed on 11/08/2012

Trade name: IPS e.max CAD

(Contd of page 6)

*ICAO: International Civil Aviation Organization**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**CAS: Chemical Abstracts Service (division of the American Chemical Society)**NFPA: National Fire Protection Association (USA)**H.M.S.: Hazardous Materials Identification System (USA)*

13A

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/12/2015

Reviewed on 05/12/2015

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

(Contd. of page 3)

· Danger of explosion:	Product does not present an explosion hazard.
· Density at 20 °C (68 °F):	1.4-1.6 g/cm ³ (11.683-13.35 lbs/gal)
· Solubility in / Miscibility with	
· Water:	Not miscible or difficult to mix
· Other information	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
-----------------------------	---

· **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.

USA

(Contd. on page 5)

Safety Data Sheet
according to 29CFR1910/1200 and GHS Rev. 3

Effective date : 10.12.2015

Tufcrete Part A

PNEC Predicted No-Effect Concentration (REACH).
CFR Code of Federal Regulations (USA).
SARA Superfund Amendments and Reauthorization Act (USA).
RCRA Resource Conservation and Recovery Act (USA).
TSCA Toxic Substances Control Act (USA).
NPRI National Pollutant Release Inventory (Canada).
DOT US Department of Transportation.
IATA International Air Transport Association.
GHS Globally Harmonized System of Classification and Labelling of Chemicals.
ACGIH American Conference of Governmental Industrial Hygienists.
CAS Chemical Abstracts Service (division of the American Chemical Society).
NFPA National Fire Protection Association (USA).
HMIS Hazardous Materials Identification System (USA).
WHMIS Workplace Hazardous Materials Information System (Canada).
DNEL Derived No-Effect Level (REACH).

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/12/2015

Reviewed on 05/12/2015

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

(Contd. of page 4)

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

· 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	Void
	· 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":		-

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

GHS08
- **Signal word** Warning

(Contd. on page 6)

USA



Global Safety Management

Making Compliance Easy and Affordable

Authoring Intake Form

If this product is not manufactured by your company, STOP. You should complete the Private Label Intake Form.

Order Date: 10/6/2015

Company Name: Tufco International LLC Person Submitting Order: Kelly Hoyt

General Information	
<input checked="" type="checkbox"/> Use my company preferences	
<input type="checkbox"/> Sales Order Approval Required in Advance	
<input type="checkbox"/> Purchase Order Number Required, PO # (if available):	
Order Information	
SDS <input checked="" type="checkbox"/> North American GHS Only <input type="checkbox"/> Global GHS SDS <input type="checkbox"/> Extended Reach (EU) <input type="checkbox"/> Custom Format <input type="checkbox"/> Single Jurisdiction, specify: <input type="checkbox"/> Expanded Shipping Information <input type="checkbox"/> Certified for Turkey <input type="checkbox"/> Previously Authored by GSM	Labels <input checked="" type="checkbox"/> Industrial Use (GHS) <input type="checkbox"/> Consumer Safety Commission (CSC) <input type="checkbox"/> Secondary Container <input type="checkbox"/> Custom Label Typesetting <input type="checkbox"/> Custom Label Design <input type="checkbox"/> Other: _____ <input type="checkbox"/> Previously Authored by GSM
Countries Sold to <input checked="" type="checkbox"/> listed below or <input type="checkbox"/> list attached: Canada	
Translation required (Languages) <input type="checkbox"/> listed below or <input type="checkbox"/> list attached:	

Documentation Needed:
<input checked="" type="checkbox"/> Raw Material (M)SDS. (Check here <input type="checkbox"/> to have GSM contact the manufacturer for an updated version. Sourcing fees may apply.)
<input checked="" type="checkbox"/> Previous Product (M)SDS
<input type="checkbox"/> Formula Disclosure Form
<input type="checkbox"/> Test Data
<input type="checkbox"/> Other:

By submitting this form, you are acknowledging that you are authorized to make this purchase on behalf of the company, that you have received a copy of Global Safety Management's Terms of Service and that you accept these terms.

Safety Data Sheet
acc. to OSHA HCS

Printing date 05/12/2015

Reviewed on 05/12/2015

Trade name: Flexitime Bite (base + cat)

(Contd. of page 5)

- **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.

- **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



Global Safety Management

Making Compliance Easy and Affordable

Section 1			
<input checked="" type="checkbox"/> Use my company preferences			
Manufacturer		Supplier	
<input type="checkbox"/> Do Not Display on SDS or Label		Display as <input type="checkbox"/> Manufacturer <input type="checkbox"/> Supplier	
Name:	Tufco International LLC	Name:	
Address:	20811 Arkotex Rd Silcam Springs AR 72761	Address:	
Phone:	1-800-364-0836	Phone:	
Emergency Information Number			
<i>If you are using a provider, such as ChemTel or CHEMTREC for your emergency response, you must provide the contract number.</i>			
Provider Name:	ChemTrec	Contract #:	22907
Phone # within US:	1-800-424-9300	International #:	

Product Information			
<input type="checkbox"/> Multiple Products (See Attached Product List Form)			
Trade Name (required):	Tufcrete Part A	Product Number (required):	none
Synonyms:	Castor Oil	Application of the substance / Mixture (product use): 1 to 1 By Volume with Tufcrete Part B	
Other Identifier (ex. SAP #)		Product related to:	

Special Instructions:



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)

USA



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)

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 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)

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 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