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Revision: 08.02.2023

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

Printing date 08.02.2023

undertaking

Version number 6 (replaces version 5)

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

- · 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

The product is not classified, according to the GB CLP regulation.

· Additional information:

Since the product is a medical device in the sense of Directive 93/42/EEC (MDD) or the Regulation (EU) 2017/745 (MDR), that is intended for the end user and is used invasively or with physical contact, it is exempted from the classification and labeling obligation according to Regulation (EC) 1272/2008.

- · 2.2 Label elements
  - · Labelling according to Regulation (EC) No 1272/2008 Void
    - · Hazard pictograms Void
    - · **Signal word** Void
    - · Hazard statements Void
  - Additional information: see 2.1
- · 2.3 Other hazards -
  - Results of PBT and vPvB assessment
    - · PBT: Not applicable.
    - · vPvB: Not applicable.

### SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
  - · Description: -

· Dangerous components:		
	cristobalite STOT RE 1, H372	50-75%
EINECS: 209-136-7 Reg.nr.: 01-2119529238-36-xxxx	octamethylcyclotetrasiloxane Flam. Liq. 3, H226 Repr. 2, H361f Aquatic Chronic 1, H410 (M=10) PBT; vPvB	<i>≥</i> 0.025-<0.25%

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.

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### Trade name: Flexitime Bite Base

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- · After skin contact 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

No further relevant information available.

- · 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

Store in cool, dry place in tightly closed containers.

No special precautions necessary if used correctly.

- 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.

- GB



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

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Trade name: Flexitime Bite Base

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#### 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.

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#### 556-67-2 octamethylcyclotetrasiloxane

550-07-2 Octamethyleyelotetrashoxane						
Oral	general population, long term, systemic	3.7 mg/Kg (not defined)				
Inhalative	worker industrial, long term, systemic	73 mg/m3 (not defined)				
	worker industrial, long term, local	73 mg/m3 (not defined)				
	general population, long term, systemic	13 mg/m3 (not defined)				
	general population, long term, local	13 mg/m3 (not defined)				

#### · PNECs

### 556-67-2 octamethylcyclotetrasiloxane

freshwater 0.0015 mg/l (not defined)
marine water 0.00015 mg/l (not defined)
sewage treatment plant 10 mg/l (not defined)
sediment, dry weight, freshwater 3 mg/Kg (not defined)
sediment, dry weight, marine water 0.3 mg/Kg (not defined)

· Additional information: The lists that were valid during the compilation were used as basis.

#### 8.2 Exposure controls

- · Individual protection measures, such as personal protective equipment
  - General protective and hygienic measures

Wash hands during breaks and at the end of the work.

- · Breathing equipment: Not required.
- · Hand protection

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 trough 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/face protection Safety glasses

· Body protection: Light weight protective clothing

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Trade name: Flexitime Bite Base

Pyrophoric solids

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#### SECTION 9: Physical and chemical properties · 9.1 Information on basic physical and chemical properties **General Information** · Physical state Fluid · Colour: Violet · Smell: Characteristic Odour threshold: Not determined. · Melting point/freezing point: Not determined · Boiling point or initial boiling point and >300 °C boiling range · Flammability Not applicable. · Lower and upper explosion limit Not determined. Lower: Not determined. · Upper: >130 °C · Flash point: · Decomposition temperature: Not determined. SADT Not determined. Viscosity: · Kinematic viscosity Not determined. Not determined. · dynamic: Solubility Water: Not miscible or difficult to mix Partition coefficient n-octanol/water (log Not determined. value) Steam pressure: Not determined. Density and/or relative density Density Not determined Relative density Not determined. · Vapour density Not determined. · 9.2 Other information No further relevant information available. Appearance: Form: Pasty · Important information on protection of health and environment, and on safety. · Self-inflammability: Product is not selfigniting. · Explosive properties: Product is not explosive. Not determined. · Change in condition · Evaporation rate Not determined. · Information with regard to physical hazard classes · Explosives Void Flammable gases Void · Aerosols Void · Oxidising gases · Gases under pressure Void Void · Flammable liquids Void Flammable solids Void · Self-reactive substances and mixtures Void · Pyrophoric liquids Void

Void

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## Trade name: Flexitime Bite Base

		(Contd. of page
Self-heating substances and mixtures	Void	
· Substances and mixtures, which emit		
flammable gases in contact with water	Void	
· Oxidising liquids	Void	
Oxidising solids	Void	
· Organic peroxides	Void	
· Corrosive to metals	Void	
Desensitised explosives	Void	

### 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 hazard classes as defined in Regulation (EC) No 1272/2008
• Acute toxicity Based on available data, the classification criteria are not met.

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· LD/LC50 values that are relevant for classification:			
556-67-2	octamethy	rlcyclotetrasiloxane	
Oral	LD50	>4,800 mg/kg (rat) (OECD 401)	
Dermal	LD50	>2,375 mg/kg (rat) (OECD 402)	
Inhalative	LC50/4 h	36 mg/l (rat) (OECD 403)	

- · 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.
- 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.
- 11.2 Information on other hazards

· Endoc	rine disrupting properties	
556-67-2	octamethylcyclotetrasiloxane	List II, III
540-97-6	Dodecamethylcyclohexasiloxane	List II
541-02-6	Decamethylcyclopentasiloxane	List II

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### **SECTION 12: Ecological information**

#### · 12.1 Toxicity

## · Aquatic toxicity:

#### 556-67-2 octamethylcyclotetrasiloxane

EC50/21d >0.015 mg/L (daphnia) (EPA OTS 797.1330) EC50/48h >0.015 mg/l (daphnia) (EPA OTS 797.1300) LC50/96h >0.022 mg/l (fish) (EPA OTS 797.1400)

NOEC / 91d ≥0.0044 mg/l (fish)

NOEC / 21d ≥0.015 mg/l (daphnia) (EPA OTS 797.1330) NOEC / 96h <0.022 mg/l (algae) (EPA OTS 797.1050) ≥0.022 mg/l (fish) (EPA OTS 797.1400) NOEC / 48h ≥0.015 mg/l (daphnia) (EPA OTS 797.1300) ErC50/ 96h >0.022 mg/L (algae) (EPA OTS 797.1050)

#### 12.2 Persistence and degradability

#### 556-67-2 octamethylcyclotetrasiloxane

Biodegradation 3.7 % /29d (not defined) (OECD 310)

#### · 12.3 Bioaccumulative potential

#### 556-67-2 octamethylcyclotetrasiloxane

Bloconcentration factor (BCF) 12,400 (not defined)

- · 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 Endocrine disrupting properties

For information on endocrine disrupting properties see section 11.

- · 12.7 Other adverse effects
  - · Additional ecological information:
    - · General notes: Not known to be hazardous to water.

#### 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.

#### 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 or ID number

ADR, IMDG, IATA Void

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14.2 UN proper shipping name ADR, IMDG, IATA	Void	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	Void	
14.4 Packing group ADR, IMDG, IATA	Void	
· 14.5 Environmental hazards:	Not applicable.	
· 14.6 Special precautions for user	Not applicable.	
· 14.7 Maritime transport in bulk according IMO instruments	n <b>g to</b> 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
  - - 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.

H372 Causes damage to organs through prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Abbreviations and acronyms:

SADT: Self Accelerating Decomposition Temperature

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement

Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IMDG: International Mantime 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)
DNEL: Derived No-Effect Level (UK REACH)
PNEC: Predicted No-Effect Concentration (UK REACH)

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
STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

\* Data compared to the previous version altered.



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

- · 1.1 Product identifier
  - · Trade name: Flexitime Bite 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 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

The product is not classified, according to the GB CLP regulation.

· Additional information:

Since the product is a medical device in the sense of Directive 93/42/EEC (MDD) or the Regulation (EU) 2017/745 (MDR), that is intended for the end user and is used invasively or with physical contact, it is exempted from the classification and labeling obligation according to Regulation (EC) 1272/2008.

- · 2.2 Label elements
  - · Labelling according to Regulation (EC) No 1272/2008 Void
    - · Hazard pictograms Void
    - · **Signal word** Void
    - · Hazard statements Void
  - Additional information: see 2.1
- · 2.3 Other hazards ·
  - · Results of PBT and vPvB assessment

·PBT	•
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540-97-6 Dodecamethylcyclohexasiloxane

· vPvB:

540-97-6 Dodecamethylcyclohexasiloxane

### SECTION 3: Composition/information on ingredients

#### · 3.2 Mixtures

· Description: -

· Dangerous components:		
CAS: 14464-46-1	cristobalite	25-50%
	STOT RE 1, H372	0.50/
EINECS: 236-675-5	titanium dioxide substance with a Community workplace exposure limit	0-5%
EINECS: 208-762-8 Reg.nr.: 01-2119717435-42-xxxx	Dodecamethylcyclohexasiloxane Non-classified vPvB substance. Non-classified PBT substance. Substance identified as having endocrine disrupting properties (II).	≥0-<1%

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Trade name: Flexitime Bite Cat

CAS: 556-67-2 octamethylcyclotetrasiloxane ≥0.025-<0.25% EINECS: 209-136-7 Flam. Liq. 3, H226 Reg.nr.: 01-2119529238-36-xxxx Repr. 2, H361f

Aquatic Chronic 1, H410 (M=10)

PBT; vPvB

·SVHC

540-97-6 Dodecamethylcyclohexasiloxane

· 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 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

No further relevant information available.

- · 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.
- · 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.

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### SECTION 7: Handling and storage

7.1 Precautions for safe handling

Store in cool, dry place in tightly closed containers. No special precautions necessary if used correctly.

- · 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

· 8.1 Control parameters

· 8.7 Contro	•		
Compo	onents wi	th critical values that require	monitoring at the workplace:
13463-67-	7 titaniun	n dioxide	
WEL (Gre	at Britain)	Long-term value: 10* 4** mg/r *total inhalable **respirable	m³
· DNI	ELs		
540-97-6 I	Dodecam	ethylcyclohexasiloxane	
Oral	general p	opulation, acute, systemic	1.7 mg/Kg (not defined)
	general p	opulation, long term, systemic	1.7 mg/Kg (not defined)
Inhalative	worker in	dustrial, acute, local	6.1 mg/m3 (not defined)
	worker in	dustrial, long term, systemic	11 mg/m3 (not defined)
	worker in	dustrial, long term, local	1.22 mg/m3 (not defined)
	general p	opulation, acute, local	1.5 mg/m3 (not defined)
	general p	opulation, long term, systemic	2.7 mg/m3 (not defined)
	general p	opulation, long term, local	0.3 mg/m3 (not defined)
556-67-2	octameth	ylcyclotetrasiloxane	
Oral	general p	opulation, long term, systemic	3.7 mg/Kg (not defined)
Inhalative	worker in	dustrial, long term, systemic	73 mg/m3 (not defined)
	worker in	dustrial, long term, local	73 mg/m3 (not defined)

13 mg/m3 (not defined)

general population, long term, systemic 13 mg/m3 (not defined)

540-97-6 Dodecamethylcyclohexa	asiloxane

sewage treatment plant 1 mg/l (not defined) sediment, dry weight, freshwater 13.5 mg/Kg (not defined) sediment, dry weight, marine water 1.35 mg/Kg (not defined)

general population, long term, local

### 556-67-2 octamethylcyclotetrasiloxane

· PNECs

freshwater

marine water

sewage treatment plant

sediment, dry weight, freshwater

0.0015 mg/l (not defined)

10 mg/l (not defined)

3 mg/Kg (not defined)

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sediment, dry weight, marine water 0.3 mg/Kg (not defined)

Additional information: The lists that were valid during the compilation were used as basis.

· 8.2 Exposure controls

Individual protection measures, such as personal protective equipment

General protective and hygienic measures

Wash hands during breaks and at the end of the work.

· Breathing equipment: Not required.

· Hand protection

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 trough 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:

Not determined

Butyl rubber, BR Nitrile rubber, NBR

Eve/face 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** 

· Physical state Fluid · Colour: White

· Smell: Characteristic
· Odour threshold: Not determined.

· Melting point/freezing point: · Boiling point or initial boiling point and

boiling point or initial boiling point and >300 °C

Flammability Not applicable.

Lower and upper explosion limit
Lower: Not determined.

Upper: Not determined.
Flash point: >130 °C

Decomposition temperature: Not determined.
SADT

pH Not determined.

Viscosity:

· Kinematic viscosity Not determined. · dynamic: Not determined.

· Solubility
· Water:
· Not miscible or difficult to mix
· Partition coefficient n-octanol/water (log

value)
Not determined.
Steam pressure:
Not determined.

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(Conta.	ΟI	page	4

Density and/or relative density Density Relative density Vapour density	Not determined Not determined. Not determined.	
9.2 Other information Appearance:	No further relevant information available.	
· Form:	Pasty	

Important information on protection of health and environment, and on safety.

• Self-inflammability: Product is not selfigniting. Explosive properties: Product is not explosive.

Not determined.

· Change in condition · Evaporation rate Not determined.

· Information with regard to physical hazard classes

· Explosives	Void
Flammable gases	Void
Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
Flammable liquids	Void
Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
Substances and mixtures, which emit	
flammable gases in contact with water	Void
· Oxidising liquids	Void
Oxidising solids	Void
· Organic peroxides	Void
Corrosive to metals	Void
Desensitised explosives	Void

## 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 hazard classes as defined in Regulation (EC) No 1272/2008

· Acute toxicity Based on available data, the classification criteria are not met.

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## Trade name: Flexitime Bite Cat

			(Contd. of page 5)
· LD/	LC50 valu	es that are relevant for classification:	
540-97-6 I	Dodecame	ethylcyclohexasiloxane	
Oral	LD50	>2,000 mg/kg (rat) (OECD 423)	
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)	
556-67-2	octamethy	lcyclotetrasiloxane	
Oral	LD50	>4,800 mg/kg (rat) (OECD 401)	
Dermal	LD50	>2,375 mg/kg (rat) (OECD 402)	
Inhalative	LC50/4 h	36 mg/l (rat) (OECD 403)	

- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- Skin corrosion/intation 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.

  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.
- · 11.2 Information on other hazards

· Endocrine disrupting properties		
540-97-6	Dodecamethylcyclohexasiloxane	List II
556-67-2	octamethylcyclotetrasiloxane	List II, III
541-02-6	Decamethylcyclopentasiloxane	List II

## **SECTION 12: Ecological information**

#### · 12.1 Toxicity · Aquatic toxicity:

Aquatici	Aquatic toxicity.		
540-97-6 Do	540-97-6 Dodecamethylcyclohexasiloxane		
NOEC / 91d	≥0.014 mg/l (fish) (OECD 210)		
NOEC / 21d	0.0046 mg/l (daphnia) (OECD 211)		
ErC50 / 72 h	ErC50 / 72 h >0.002 mg/l (algae) (OECD 201)		
NOEC / 72h	NOEC / 72h ≥0.002 mg/l (algae) (OECD 201)		
556-67-2 oct	amethylcyclotetrasiloxane		
EC50/21d	>0.015 mg/L (daphnia) (EPA OTS 797.1330)		
EC50/48h	>0.015 mg/l (daphnia) (EPA OTS 797.1300)		
LC50/96h	>0.022 mg/l (fish) (EPA OTS 797.1400)		
NOEC / 91d ≥0.0044 mg/l (fish)			
NOEC / 21d	≥0.015 mg/l (daphnia) (EPA OTS 797.1330)		
NOEC / 96h	<0.022 mg/l (algae) (EPA OTS 797.1050)		
	≥0.022 mg/l (fish) (EPA OTS 797.1400)		
NOEC / 48h	≥0.015 mg/l (daphnia) (EPA OTS 797.1300)		
ErC50/ 96h	>0.022 mg/L (algae) (EPA OTS 797.1050)		
42.2 Davaict	and and developility		

#### · 12.2 Persistence and degradability

## 540-97-6 Dodecamethylcyclohexasiloxane

Biodegradation 4.47 % /28d (not defined) (OECD 310)

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556-67-2 octamethylcyclotetrasiloxane	,
Biodegradation 3.7 % /29d (not defined) (OECD 310)	
· 12.3 Bioaccumulative potential	
540-97-6 Dodecamethylcyclohexasiloxane	
Bloconcentration factor (BCF) 1,160 (not defined)	
556-67-2 octamethylcyclotetrasiloxane	
Bloconcentration factor (BCF)   12,400 (not defined)	

- 12.4 Mobility in soil No further relevant information available.
- 12.5 Results of PBT and vPvB assessment
  - · PBT:

540-97-6 Dodecamethylcyclohexasiloxane

· vPvB:

540-97-6 Dodecamethylcyclohexasiloxane

12.6 Endocrine disrupting properties

For information on endocrine disrupting properties see section 11.

- · 12.7 Other adverse effects
  - · Additional ecological information:
    - · General notes:

Do not allow product to reach ground water, water bodies or sewage system.

Danger to drinking water if even small quantities leak into soil.

## 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.

- · Uncleaned packagings:
  - Recommendation:

Disposal must be made according to official regulations.

Non contaminated packagings can be used for recycling.

14.1 UN number or ID number · ADR, IMDG, IATA	Void	
14.2 UN proper shipping name · ADR, IMDG, IATA	Void	
14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	Void	
14.4 Packing group ADR, IMDG, IATA	Void	
14.5 Environmental hazards:	Not applicable.	

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· 14.6 Special precautions for user	Not applicable.	
· 14.7 Maritime transport in bulk according IMO instruments	<b>g to</b> 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.
- 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.

H372 Causes damage to organs through prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Abbreviations and acronyms:

SADT: Self Accelerating Decomposition Temperature

ADR: Accord relatif au transport international 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)
DNEL: Derived No-Effect Level (UK REACH)
PNEC: Predicted No-Effect Concentration (UK REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

Repr. 2: Reproductive toxicity – Category 3

Repr. 2: Reproductive toxicity – Category 2

STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

\* Data compared to the previous version altered.