



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

Printing date 25.11.2022

Version number 5 (replaces version 4)

Revision: 25.11.2022

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

· **1.1 Product identifier**

· Trade name: **Variotime 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](mailto:msds@kulzer-dental.com)

· **1.4 Emergency telephone number:** Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

**SECTION 2: Hazards identification**

· **2.1 Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008**

STOT RE 1      H372 Causes damage to the lung through prolonged or repeated exposure.  
Route of exposure: Inhalation.

Aquatic Chronic 3      H412 Harmful to aquatic life with long lasting effects.

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008**

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

· **Hazard pictograms**



GHS08

· **Signal word** Danger

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

crystalite

· **Hazard statements**

H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements**

P260 Do not breathe dust.

P264 Wash thoroughly after handling.

P273 Avoid release to the environment.

P280 Wear protective gloves / eye protection.

P280 Wear protective clothing.

P314 Get medical advice/attention if you feel unwell.

· **2.3 Other hazards -**

· **Results of PBT and vPvB assessment**

· **PBT:**

540-97-6 | Dodecamethylcyclohexasiloxane

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· **vPvB:**

540-97-6 | Dodecamethylcyclhexasiloxane

**SECTION 3: Composition/information on ingredients**

· **3.2 Mixtures**

· **Description:** -

· **Dangerous components:**

CAS: 14464-46-1 EINECS: 238-455-4	crystalite STOT RE 1, H372	25-50%
CAS: 13463-67-7 EINECS: 236-675-5	titanium dioxide substance with a Community workplace exposure limit	0-5%
CAS: 540-97-6 EINECS: 208-762-8 Reg.nr.: 01-2119717435-42-xxxx	Dodecamethylcyclhexasiloxane Non-classified vPvB substance. Non-classified PBT substance. Substance identified as having endocrine disrupting properties (II).	≥0-<1%
CAS: 556-67-2 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	≥0.025-<0.25%

· **SVHC**

540-97-6 | Dodecamethylcyclhexasiloxane

· **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**

CO<sub>2</sub>, 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.

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- **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.  
-

**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**

· **Components with critical values that require monitoring at the workplace:**

**13463-67-7 titanium dioxide**

WEL (Great Britain) Long-term value: 10\* 4\*\* mg/m<sup>3</sup>  
\*total inhalable \*\*respirable

· **DNELs**

**540-97-6 Dodecamethylcyclohexasiloxane**

Oral	general population, acute, systemic	1.7 mg/Kg (not defined)
	general population, long term, systemic	1.7 mg/Kg (not defined)
Inhalative	worker industrial, acute, local	6.1 mg/m <sup>3</sup> (not defined)
	worker industrial, long term, systemic	11 mg/m <sup>3</sup> (not defined)
	worker industrial, long term, local	1.22 mg/m <sup>3</sup> (not defined)
	general population, acute, local	1.5 mg/m <sup>3</sup> (not defined)
	general population, long term, systemic	2.7 mg/m <sup>3</sup> (not defined)
	general population, long term, local	0.3 mg/m <sup>3</sup> (not defined)

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**556-67-2 octamethylcyclotetrasiloxane**

Oral	general population, long term, systemic	3.7 mg/Kg (not defined)
Inhalative	worker industrial, long term, systemic	73 mg/m <sup>3</sup> (not defined)
	worker industrial, long term, local	73 mg/m <sup>3</sup> (not defined)
	general population, long term, systemic	13 mg/m <sup>3</sup> (not defined)
	general population, long term, local	13 mg/m <sup>3</sup> (not defined)

· **PNECs**

**540-97-6 Dodecamethylcyclohexasiloxane**

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)

**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 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/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

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· <b>Odour threshold:</b>	Not determined.
· <b>Melting point/freezing point:</b>	Not determined
· <b>Boiling point or initial boiling point and boiling range</b>	>300 °C
· <b>Flammability</b>	Not applicable.
· <b>Lower and upper explosion limit</b>	
· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.
· <b>Flash point:</b>	>130 °C
· <b>Decomposition temperature:</b>	Not determined.
· <b>SADT</b>	
· <b>pH</b>	Not determined.
· <b>Viscosity:</b>	
· <b>Kinematic viscosity</b>	Not determined.
· <b>dynamic:</b>	Not determined.
· <b>Solubility</b>	
· <b>Water:</b>	Not miscible or difficult to mix
· <b>Partition coefficient n-octanol/water (log value)</b>	Not determined.
· <b>Steam pressure:</b>	Not determined.
· <b>Density and/or relative density</b>	
· <b>Density</b>	Not determined
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.

· <b>9.2 Other information</b>	No further relevant information available.
· <b>Appearance:</b>	
· <b>Form:</b>	Pasty
· <b>Important information on protection of health and environment, and on safety.</b>	
· <b>Self-inflammability:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product is not explosive. Not determined.
· <b>Change in condition</b>	
· <b>Evaporation rate</b>	Not determined.

· <b>Information with regard to physical hazard classes</b>	
· <b>Explosives</b>	Void
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Void
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void

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· **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.

· **LD/LC50 values that are relevant for classification:**

**540-97-6 Dodecamethylcyclohexasiloxane**

Oral	LD50	>2,000 mg/kg (rat) (OECD 423)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)

**556-67-2 octamethylcyclotetrasiloxane**

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**  
Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
  - **Aspiration hazard** Based on available data, the classification criteria are not met.
- **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:**

**540-97-6 Dodecamethylcyclohexasiloxane**

NOEC / 91d	≥0.014 mg/l (fish) (OECD 210)
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NOEC / 21d	0.0046 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	>0.002 mg/l (algae) (OECD 201)
NOEC / 72h	≥0.002 mg/l (algae) (OECD 201)

**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**

**540-97-6 Dodecamethylcyclohexasiloxane**

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

**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.

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- **Uncleaned packagings:**
- **Recommendation:**  
Disposal must be made according to official regulations.  
Non contaminated packagings can be used for recycling.

**SECTION 14: Transport information**

- |   |                 |
|---|-----------------|
| · <b>14.1 UN number or ID number</b><br>· ADR, IMDG, IATA                     | Void            |
| · <b>14.2 UN proper shipping name</b><br>· ADR, IMDG, IATA                    | Void            |
| · <b>14.3 Transport hazard class(es)</b><br>· ADR, ADN, IMDG, IATA<br>· Class | Void            |
| · <b>14.4 Packing group</b><br>· ADR, IMDG, IATA                              | Void            |
| · <b>14.5 Environmental hazards:</b>  | Not applicable. |
| · <b>14.6 Special precautions for user</b>                                    | Not applicable. |
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b>         | Not applicable. |
| · <b>Transport/Additional information:</b>                                    | -               |
| · <b>UN "Model Regulation":</b>   | 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

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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  
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3  
\* **Data compared to the previous version altered.**

GB