Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 23.09.2026 *Version number 1* *Revision: 23.09.2026*

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

· **1.1 Product identifier**

· **Trade name:** **SiliconA 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
· **Distributor:**
Cavex Holland B.V.
Fustweg 5, 2031 CJ Haarlem, The Netherlands
+31 23 530 7700
dental@cavex.nl
www.cavex.nl

· **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 CLP regulation.
· **Additional information:**
As the product is a medical device within the meaning of Directive 93/42/EEC (MDD) or Regulation (EU) 2017/745 (MDR) that is intended for the end user and is used invasively or in contact with the body, it is exempt from the classification and labelling requirements of 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:**

CAS: 14464-46-1 EINECS: 238-455-4	cristobalite	STOT RE 1, H372	50-75%

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· **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.
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.

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· **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:**	
14464-46-1 cristobalite	
OEL (Ireland)	Long-term value: 0.1 mg/m³

· **DNELs**

556-67-2 octamethylcyclotetrasiloxane		
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.

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· **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

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Physical state**	Liquid
· **Colour:**	Violet
· **Smell:**	Characteristic
· **Odour threshold:**	Not determined
· **Melting point/freezing point:**	Not determined
· **Boiling point or initial boiling point and boiling range**	>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
· **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.

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· **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.

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

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· **Primary irritant effect:**
· **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**

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

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	
Bioconcentration 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.

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

· **European waste catalogue**	
10 13 01	waste preparation mixture before thermal processing
10 13 06	particulates and dust (except 10 13 12 and 10 13 13)

· **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
· **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 to IMO instruments**	Not applicable
· **Transport/Additional information:**	-
· **UN "Model Regulation":**	Void

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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.
· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 70

· **Regulation (EU) No 649/2012**
None of the ingredients are included.

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**
None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**
no information available

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**
no information available

· **Regulation (EC) No 273/2004 on drug precursors**
None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**
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**
H372 Causes damage to organs through prolonged or repeated exposure.
· **Date of previous version:** 11.05.2026
· **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 (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1
· *** Data compared to the previous version altered.**