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

Printing date 23.11.2022 *Version number 5 (replaces version 4)* *Revision: 23.11.2022*

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

· **1.1 Product identifier**

· **Trade name:** **Flexitime Light Flow Base (1:1), Flexitime Medium Flow Base (1:1)**

· **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

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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:**
Cristobalite

· **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:**	
556-67-2	octamethylcyclotetrasiloxane

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Trade name: Flexitime Light Flow Base (1:1), Flexitime Medium Flow Base (1:1)

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· **vPvB:**	
556-67-2	octamethylcyclotetrasiloxane

*

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**
· **Description:** -

· **Dangerous components:**		
CAS: 14464-46-1 EINECS: 238-878-4	Cristobalite STOT RE 1, H372	25-50%
CAS: 27306-78-1	modified heptamethyltrisiloxane with polyalkylene oxide Aquatic Chronic 2, H411 Acute Tox. 4, H332; Eye Irrit. 2, H319	≥2.5-≤5%
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**	
556-67-2	octamethylcyclotetrasiloxane

· **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**
Formation of toxic gases is possible during heating or in case of fire.
· **5.3 Advice for firefighters**
· **Protective equipment:** Put on breathing apparatus.

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Trade name: Flexitime Light Flow Base (1:1), Flexitime Medium Flow Base (1:1)

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· **Additional information -**

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures**
Ensure adequate ventilation
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**
No dangerous materials are released.
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**
Please observe the additional instructions in the product's instructions for use.
Keep containers tightly sealed.
Ensure good ventilation/exhaustion at the workplace.
· **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.

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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.

· **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)

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Trade name: Flexitime Light Flow Base (1:1), Flexitime Medium Flow Base (1:1)

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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**
· **Appropriate engineering controls** No further data; see item 7.
· **Individual protection measures, such as personal protective equipment**
· **General protective and hygienic measures**
Keep away from foodstuffs, beverages and food.
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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SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**
· **General Information**

· **Physical state**	Fluid
· **Colour:**	Green
· **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
· **Ignition temperature:**	430 °C
· **Decomposition temperature:**	Not determined.
· **SADT**	
· **pH**	Not determined.

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Trade name: Flexitime Light Flow Base (1:1), Flexitime Medium Flow Base (1:1)

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· **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 at 20 °C**	1.6 g/cm³
· **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.
· **Solvent content:**	
· **Solids content:**	47.3 %
· **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

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Trade name: Flexitime Light Flow Base (1:1), Flexitime Medium Flow Base (1:1)

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· **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:**		
68083-19-2 Silopren U 1 dental		
Oral	LD50	>5000 mg/kg (rat)
556-67-2 octamethylcyclotetrasiloxane		
Oral	LD50	>4800 mg/kg (rat) (OECD 401)
Dermal	LD50	>2375 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**
List I: Substances identified as endocrine disruptors at EU level.
List II: Substances under evaluation for endocrine distruption under an EU legislation.
List III: Substances considered, by the evaluating National Authority, to have endocrine disrupting propertied.

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)

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Trade name: Flexitime Light Flow Base (1:1), Flexitime Medium Flow Base (1:1)

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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)	12400 (not defined)

· **12.4 Mobility in soil** No further relevant information available.

· **12.5 Results of PBT and vPvB assessment**

· **PBT:**	
556-67-2	octamethylcyclotetrasiloxane

· **vPvB:**	
556-67-2	octamethylcyclotetrasiloxane

· **12.6 Endocrine disrupting properties**
For information on endocrine disrupting properties see section 11.

· **12.7 Other adverse effects**
· **Remark:** Harmful to fish
· **Additional ecological information:**
· **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.
Harmful to aquatic organisms

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

· **14.2 UN proper shipping name**
· **ADR, IMDG, IATA** Void

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Trade name: Flexitime Light Flow Base (1:1), Flexitime Medium Flow Base (1:1)

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· **14.3 Transport hazard class(es)**	
· **ADR, ADN, IMDG, IATA**	
· **Class**	Void
· **14.4 Packing group**	
· **ADR, IMDG, IATA**	Void
· **14.5 Environmental hazards:**	
· **Marine pollutant:**	No
· **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

*

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.
H319 Causes serious eye irritation.
H332 Harmful if inhaled.
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.
H411 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
Flam. Liq. 3: Flammable liquids – Category 3

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Trade name: **Flexitime Light Flow Base (1:1), Flexitime Medium Flow Base (1:1)**

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Acute Tox. 4: Acute toxicity – Category 4
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
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 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
· **** 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 Light Flow Cat. (1:1), Flexitime Medium Flow Cat. (1:1)**

· **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**

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:**
Cristobalite

· **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:**	
556-67-2	octamethylcyclotetrasiloxane
540-97-6	Dodecamethylcyclohexasiloxane

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Trade name: Flexitime Light Flow Cat. (1:1), Flexitime Medium Flow Cat. (1:1)

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· **vPvB:**	
556-67-2	octamethylcyclotetrasiloxane
540-97-6	Dodecamethylcyclohexasiloxane

*

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**
· **Description:** -

· **Dangerous components:**		
CAS: 14464-46-1 EINECS: 238-878-4	Cristobalite STOT RE 1, H372	25-50%
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%
CAS: 540-97-6 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%

· **SVHC**	
556-67-2	octamethylcyclotetrasiloxane
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**
CO_2, 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**
Formation of toxic gases is possible during heating or in case of fire.

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Trade name: Flexitime Light Flow Cat. (1:1), Flexitime Medium Flow Cat. (1:1)

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· **5.3 Advice for firefighters**
· **Protective equipment:** Put on breathing apparatus.
· **Additional information** -

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures**
Ensure adequate ventilation
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**
No dangerous materials are released.
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**
Keep containers tightly sealed.
Ensure good ventilation/exhaustion at the workplace.
· **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:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
Not required.

· **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)
540-97-6 Dodecamethylcyclohexasiloxane		
Oral	general population, acute, systemic	1.7 mg/Kg (not defined)

(Contd. on page 4)

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Trade name: Flexitime Light Flow Cat. (1:1), Flexitime Medium Flow Cat. (1:1)

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	general population, long term, systemic	1.7 mg/Kg (not defined)
Inhalative	worker industrial, acute, local	6.1 mg/m3 (not defined)
	worker industrial, long term, systemic	11 mg/m3 (not defined)
	worker industrial, long term, local	1.22 mg/m3 (not defined)
	general population, acute, local	1.5 mg/m3 (not defined)
	general population, long term, systemic	2.7 mg/m3 (not defined)
	general population, long term, local	0.3 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)
540-97-6 Dodecamethylcyclohexasiloxane	
sewage treatment plant	1 mg/l (not defined)
sediment, dry weight, freshwater	13 mg/Kg (not defined)
sediment, dry weight, marine water	1.3 mg/Kg (not defined)

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

· **8.2 Exposure controls**
· **Appropriate engineering controls** No further data; see item 7.
· **Individual protection measures, such as personal protective equipment**
· **General protective and hygienic measures**
Keep away from foodstuffs, beverages and food.
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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SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Physical state**	Fluid
· **Colour:**	Light grey
· **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
· **Ignition temperature:**	430 °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 at 20 °C**	1.6 g/cm³
· **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.
· **Solvent content:**	
· **Solids content:**	47.3 %
· **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

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· **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:** -

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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:**		
68083-19-2 Silopren U 1 dental		
Oral	LD50	>5000 mg/kg (rat)
556-67-2 octamethylcyclotetrasiloxane		
Oral	LD50	>4800 mg/kg (rat) (OECD 401)
Dermal	LD50	>2375 mg/kg (rat) (OECD 402)
Inhalative	LC50/4 h	36 mg/l (rat) (OECD 403)
540-97-6 Dodecamethylcyclohexasiloxane		
Oral	LD50	>2000 mg/kg (rat) (OECD 423)
Dermal	LD50	>2000 mg/kg (rat) (OECD 402)

· **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**		
540-97-6 Dodecamethylcyclohexasiloxane		
Oral	NOAEL(C)	1000 mg/kg (rat)

· **STOT-single exposure** Based on available data, the classification criteria are not met.

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· ***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***
List I: Substances identified as endocrine disruptors at EU level.
List II: Substances under evaluation for endocrine distruption under an EU legislation.
List III: Substances considered, by the evaluating National Authority, to have endocrine disrupting propertied.

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)
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	>0.002 mg/l (algae) (OECD 201)
NOEC / 72h	≥0.002 mg/l (algae) (OECD 201)

· ***12.2 Persistence and degradability***	
556-67-2 octamethylcyclotetrasiloxane	
Biodegradation	3.7 % /29d (not defined) (OECD 310)
540-97-6 Dodecamethylcyclohexasiloxane	
Biodegradation	4.47 % /28d (not defined) (OECD 310)

· ***12.3 Bioaccumulative potential***	
556-67-2 octamethylcyclotetrasiloxane	
Bioconcentration factor (BCF)	12400 (not defined)
540-97-6 Dodecamethylcyclohexasiloxane	
Bioconcentration factor (BCF)	1160 (not defined)

· ***12.4 Mobility in soil*** *No further relevant information available.*

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· **12.5 Results of PBT and vPvB assessment**

· **PBT:**	
556-67-2	octamethylcyclotetrasiloxane
540-97-6	Dodecamethylcyclohexasiloxane

· **vPvB:**	
556-67-2	octamethylcyclotetrasiloxane
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 undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

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
· **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:**	
· **Marine pollutant:**	No
· **14.6 Special precautions for user**	Not applicable.
· **14.7 Maritime transport in bulk according to IMO instruments**	Not applicable.
· **Transport/Additional information:**	-

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· **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.

· **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
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.**