



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

Printing date 24.06.2024

Version number 4 (replaces version 3)

Revision: 24.06.2024

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

· **1.1 Product identifier**

· Trade name: **Universal Adhesive**

· **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** Tray adhesive for use with silicone impression materials

· **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**

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Skin Irrit. 2 H315 Causes skin irritation.

Eye Dam. 1 H318 Causes serious eye damage.

STOT SE 3 H336 May cause drowsiness or dizziness.

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**



GHS02 GHS05 GHS07

· **Signal word** Danger

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

tetra-n-butoxytitanium

ethyl acetate

· **Hazard statements**

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H336 May cause drowsiness or dizziness.

H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements**

P210

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P273

Avoid release to the environment.

P280

Wear protective gloves / eye protection.

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P280 Wear protective clothing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P309+P311 IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.

2.3 Other hazards -

Results of PBT and vPvB assessment

PBT:

556-67-2 octamethylcyclotetrasiloxane

vPvB:

556-67-2 octamethylcyclotetrasiloxane

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description: -

Dangerous components:

CAS: 141-78-6 EINECS: 205-500-4 Index number: 607-022-00-5 Reg.nr.: 01-2119475103-46-xxxx	ethyl acetate Flam. Liq. 2, H225 Eye Irrit. 2, H319; STOT SE 3, H336 EUH066	≥10-≤25%
CAS: 1330-20-7 EINECS: 215-535-7 Index number: 601-022-00-9 Reg.nr.: 2119488216-32-xxxx	xylene, mixed isomers, pure Flam. Liq. 3, H226 Acute Tox. 4, H312; Acute Tox. 4, H332; Skin Irrit. 2, H315	≥0-<10%
CAS: 5593-70-4 EINECS: 227-006-8	tetra-n-butoxytitanium Flam. Liq. 3, H226 Eye Dam. 1, H318 Skin Irrit. 2, H315; STOT SE 3, H335-H336	≥3-≤5%
CAS: 100-41-4 EINECS: 202-849-4 Index number: 601-023-00-4	ethylbenzene Flam. Liq. 2, H225 STOT RE 2, H373; Asp. Tox. 1, H304 Acute Tox. 4, H332	≥0-≤5%
CAS: 556-67-2 EINECS: 209-136-7 Index number: 014-018-00-1 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.

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- **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 fire with alcohol-resistant foam.
 - **For safety reasons unsuitable extinguishing agents** Water with a full water jet.
- **5.2 Special hazards arising from the substance or mixture**
Can form explosive gas-air mixtures.
Formation of toxic gases is possible during heating or in case of fire.
- **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**
Wear protective equipment. Keep unprotected persons away.
- **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).
Do not flush with water or aqueous cleansing agents
- **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.
Prevent formation of aerosols.
- **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.

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- **7.2 Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and containers:** Store in cool location.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:**
Store in cool, dry conditions in well sealed containers.
- **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:**

141-78-6 ethyl acetate

WEL (Great Britain)	Short-term value: 1468 mg/m ³ , 400 ppm Long-term value: 734 mg/m ³ , 200 ppm
IOELV (European Union)	Short-term value: 1468 mg/m ³ , 400 ppm Long-term value: 734 mg/m ³ , 200 ppm

1330-20-7 xylene, mixed isomers, pure

WEL (Great Britain)	Short-term value: 441 mg/m ³ , 100 ppm Long-term value: 220 mg/m ³ , 50 ppm Sk; BMGV
IOELV (European Union)	Short-term value: 442 mg/m ³ , 100 ppm Long-term value: 221 mg/m ³ , 50 ppm Skin

100-41-4 ethylbenzene

WEL (Great Britain)	Short-term value: 552 mg/m ³ , 125 ppm Long-term value: 441 mg/m ³ , 100 ppm Sk
IOELV (European Union)	Short-term value: 884 mg/m ³ , 200 ppm Long-term value: 442 mg/m ³ , 100 ppm Skin

· **DNELs**

141-78-6 ethyl acetate

Oral	general population, long term, systemic	4.5 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	63 mg/Kg/d (not defined)
	general population, long term, systemic	37 mg/Kg/d (not defined)
Inhalative	worker industrial, acute, systemic	1,468 mg/m ³ (not defined)
	worker industrial, acute, local	1,468 mg/m ³ (not defined)
	worker industrial, long term, systemic	734 mg/m ³ (not defined)
	worker industrial, long term, local	734 mg/m ³ (not defined)
	general population, acute, systemic	734 mg/m ³ (not defined)
	general population, acute, local	734 mg/m ³ (not defined)
	general population, long term, systemic	367 mg/m ³ (not defined)

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	general population, long term, local	367 mg/m3 (not defined)
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

141-78-6 ethyl acetate

freshwater	0.24 mg/l (not defined)
marine water	0.024 mg/l (not defined)
sewage treatment plant	650 mg/l (not defined)
sediment, dry weight, freshwater	1.15 mg/Kg (not defined)
sediment, dry weight, marine water	0.115 mg/Kg (not defined)
soil, dry weight	0.148 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)

· Ingredients with biological limit values:

1330-20-7 xylene, mixed isomers, pure

BMGV (Great Britain)	650 mmol/mol creatinine
	Medium: urine
	Sampling time: post shift
	Parameter: methyl hippuric acid

· 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 section 7.

· Individual protection measures, such as personal protective equipment

· General protective and hygienic measures

Avoid contact with the eyes.

Keep away from foodstuffs, beverages and food.

Instantly remove any soiled and impregnated garments.

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

Avoid contact with the eyes and skin.

· Breathing equipment:

Not necessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).

· Hand protection

Check protective gloves prior to each use for their proper condition.
recommended

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- **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** *Tightly sealed 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:** *Blue*
 - **Smell:** *Ester-like*
 - **Odour threshold:** *Not determined.*
 - **Melting point/freezing point:** *Not determined*
 - **Boiling point or initial boiling point and boiling range** *77 °C*
 - **Flammability** *Not applicable.*
 - **Lower and upper explosion limit**
 - **Lower:** *2.1 Vol %*
 - **Upper:** *11.5 Vol %*
 - **Flash point:** *3 °C*
 - **Auto-ignition temperature:** *460 °C*
 - **Decomposition temperature:** *Not determined.*
 - **SADT** *Not determined.*
 - **pH** *Not determined.*
 - **Viscosity:**
 - **Kinematic viscosity** *Not determined.*
 - **Kinematic viscosity**
 - **dynamic:** *Not determined.*
 - **Solubility**
 - **Water:** *Not miscible or difficult to mix*
 - **Partition coefficient n-octanol/water (log value)** *Not determined.*
 - **Steam pressure at 20 °C:** *102 hPa*
 - **Vapour pressure:**
 - **Density and/or relative density**
 - **Density at 20 °C** *1.20169 g/cm³*
 - **Relative density** *Not determined.*

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· Vapour density	Not determined.
· 9.2 Other information	No further relevant information available.
· Appearance:	
· Form:	Fluid
· Important information on protection of health and environment, and on safety.	
· Self-inflammability:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures is possible.
· Solvent content:	
· Solids content:	0.0 %
· 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	Highly flammable liquid and vapour.
· 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:**

141-78-6 ethyl acetate

Dermal	LD50	>20,000 mg/kg (rabbit)
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1330-20-7 xylene, mixed isomers, pure

Oral	LD50	8,700 mg/kg (rat)
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Dermal	LD50	2,000 mg/kg (rabbit)
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Inhalative	LC50/4 h	6,350 mg/l (rat)
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100-41-4 ethylbenzene

Oral	LD50	3,500 mg/kg (rat)
------	------	-------------------

Dermal	LD50	17,800 mg/kg (rabbit)
--------	------	-----------------------

556-67-2 octamethylcyclotetrasiloxane

Oral	LD50	>4,800 mg/kg (rat) (OECD 401)
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Dermal	LD50	>2,375 mg/kg (rat) (OECD 402)
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Inhalative	LC50/4 h	36 mg/l (rat) (OECD 403)
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· **Skin corrosion/irritation**

Causes skin irritation.

· **Serious eye damage/irritation**

Causes serious eye damage.

· **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**

May cause drowsiness or dizziness.

· **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; III
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540-97-6	Dodecamethylcyclohexasiloxane	List II
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541-02-6	Decamethylcyclopentasiloxane	List II
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SECTION 12: Ecological information

12.1 Toxicity

· **Aquatic toxicity:**

141-78-6 ethyl acetate

LC50/96h	230 mg/l (fish)
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NOEC / 21d	2.4 mg/l (daphnia) (OECD 211)
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NOEC / 72h >100 mg/l (algae) (OECD 201)

1330-20-7 xylene, mixed isomers, pure

LC50/96h 13.4 mg/l (fish)

EC50 165 mg/l (daphnia)

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

141-78-6 ethyl acetate

Biodegradation 69 % /20d (not defined)

100-41-4 ethylbenzene

Biodegradation 68 % (not defined)

556-67-2 octamethylcyclotetrasiloxane

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

· 12.3 Bioaccumulative potential

141-78-6 ethyl acetate

Bloconcentration factor (BCF) 30 (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:

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

· 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.

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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**

UN1866

· **14.2 UN proper shipping name**

· **ADR**

1866 RESIN SOLUTION, special provision 640D

· **IMDG, IATA**

RESIN SOLUTION

· **14.3 Transport hazard class(es)**

· **ADR**



· **Class**

3 (F1) Flammable liquids.

· **Label**

3

· **IMDG, IATA**



· **Class**

3 Flammable liquids.

· **Label**

3

· **14.4 Packing group**

· **ADR, IMDG, IATA**

II

· **14.5 Environmental hazards:**

· **Marine pollutant:**

No

· **14.6 Special precautions for user**

Warning: Flammable liquids.

· **Kemler Number:**

33

· **EMS Number:**

F-E, S-E

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· Stowage Category	B
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	-
· ADR	
· Limited quantities (LQ)	5L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category	2
· Tunnel restriction code	D/E
· IMDG	
· Limited quantities (LQ)	5L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1866 RESIN SOLUTION, SPECIAL PROVISION 640D, 3, II

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.

· **Seveso category P5c** FLAMMABLE LIQUIDS

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5.000 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50.000 t

· **LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (UK ANNEX XIV)**

· **Substances of very high concern (SVHC) according to UK REACH**

556-67-2 octamethylcyclotetrasiloxane

· **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**

H225 Highly flammable liquid and vapour.

H226 Flammable liquid and vapour.

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- H304 May be fatal if swallowed and enters airways.
H312 Harmful in contact with skin.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H332 Harmful if inhaled.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.
H361f Suspected of damaging fertility.
H373 May cause damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.
EUH066 Repeated exposure may cause skin dryness or cracking.

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. 2: Flammable liquids – Category 2
Flam. Liq. 3: Flammable liquids – Category 3
Acute Tox. 4: Acute toxicity – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Repr. 2: Reproductive toxicity – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
Asp. Tox. 1: Aspiration hazard – 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.**



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Printing date 07.02.2023

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Revision: 07.02.2023

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

· **1.1 Product identifier**

· Trade name: **Flexitime Heavy Tray 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

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:**

CAS: 14464-46-1 EINECS: 238-878-4	Cristobalite STOT RE 1, H372	50-75%
CAS: 78330-21-9	Alkohole, C11-14-iso-, C13-reich, ethoxyliert Eye Dam. 1, H318	≥1-<3%
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%

· **Additional information** For the wording of the listed hazard phrases refer to section 16.



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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.
 - **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.

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· **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.

· **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 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** Tightly sealed 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:**

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

· **Ignition temperature:**

>500 °C

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· 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/cm ³
· 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	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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- **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:**

78330-21-9 Alkohole, C11-14-iso-, C13-reich, ethoxyliert

Oral	LD50	7,400 mg/kg (rat)
------	------	-------------------

- **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**

None of the ingredients is listed.

SECTION 12: Ecological information

- **12.1 Toxicity**

- **Aquatic toxicity:**

78330-21-9 Alkohole, C11-14-iso-, C13-reich, ethoxyliert

EC50/72h	2-10 mg/l (algae)
EC50/48h	2-10 mg/l (daphnia)
LC50/96h	5.6 mg/l (fish)

- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **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:**

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

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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:

-

· 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.

H318 Causes serious eye damage.

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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)

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

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

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 Heavy Tray 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**

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:**

556-67-2 | octamethylcyclotetrasiloxane

· **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	50-75%
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

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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**
Formation of toxic gases is possible during heating or in case of fire.
- **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.

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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:**
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)
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 through time has to be found out by the manufacturer of the protective gloves and has to be observed.

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- **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: | 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: | >500 °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/cm ³ |
| · 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

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· 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	>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** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

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11.2 Information on other hazards**Endocrine disrupting properties**

None of the ingredients is listed.

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) 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**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.

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

Printing date 07.02.2023

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Trade name: Flexitime Heavy Tray Cat (1:1)

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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

· 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:	-
· 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

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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.**

GB



**Safety data sheet
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Printing date 07.02.2023

Version number 6 (replaces version 5)

Revision: 07.02.2023

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

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:**

556-67-2 | octamethylcyclotetrasiloxane

· **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%

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

CAS: 27306-78-1	modified heptamethyltrisiloxane with polyalkylene oxide Aquatic Chronic 2, H411 Acute Tox. 4, H332; Eye Irrit. 2, H319	(Contd. of page 1) ≥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.
 - **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

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

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**

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.

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/m ³ (not defined)
	worker industrial, long term, local	73 mg/m ³ (not defined)
	general population, long term, systemic	13 mg/m ³ (not defined)
	general population, long term, local	13 mg/m ³ (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**

· **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.

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· **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:**

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.

· **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.

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- | | |
|--|--|
| · 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
- **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 Light Flow Base (1:1), Flexitime Medium Flow Base (1:1)

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· 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** 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**

List I: Substances identified as endocrine disruptors at EU level.

List II: Substances under evaluation for endocrine disruption under an EU legislation.

List III: Substances considered, by the evaluating National Authority, to have endocrine disrupting properties.

556-67-2	octamethylcyclotetrasiloxane	List II, III
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	
Bloconcentration factor (BCF)	12400 (not defined)

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- **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

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

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· **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
 - 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
- *** Data compared to the previous version altered.**



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Version number 6 (replaces version 5)

Revision: 07.02.2023

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**

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:**

556-67-2 octamethylcyclotetrasiloxane

540-97-6 Dodecamethylcyclohexasiloxane

· **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%

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

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).

(Contd. of page 1)

≥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**

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.

· **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.

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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)
	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)

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540-97-6 Dodecamethylcyclotrihexasiloxane

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 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:**

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.

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· Viscosity: · Kinematic viscosity · dynamic: · Solubility · Water: · Partition coefficient n-octanol/water (log value) · Steam pressure: · Density and/or relative density · Density at 20 °C · Relative density · Vapour density	Not determined. Not determined. Not miscible or difficult to mix Not determined. Not determined. 1.6 g/cm³ Not determined. Not determined.
· 9.2 Other information · Appearance: · Form: · Important information on protection of health and environment, and on safety. · Self-inflammability: · Explosive properties: · Solvent content: · Solids content: · Change in condition · Evaporation rate	No further relevant information available. Pasty Product is not selfigniting. Product is not explosive. Not determined. 47.3 % Not determined.
· Information with regard to physical hazard classes · Explosives · Flammable gases · Aerosols · Oxidising gases · Gases under pressure · Flammable liquids · Flammable solids · Self-reactive substances and mixtures · Pyrophoric liquids · Pyrophoric solids · Self-heating substances and mixtures · Substances and mixtures, which emit flammable gases in contact with water · Oxidising liquids · Oxidising solids · Organic peroxides · Corrosive to metals · Desensitised explosives	Void Void Void Void Void Void Void Void Void Void Void Void Void Void Void Void Void Void Void 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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- **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)
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556-67-2 octamethylcyclotetrasiloxane

Oral	LD50	>4800 mg/kg (rat) (OECD 401)
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Dermal	LD50	>2375 mg/kg (rat) (OECD 402)
--------	------	------------------------------

Inhalative	LC50/4 h	36 mg/l (rat) (OECD 403)
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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.
- **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**

List I: Substances identified as endocrine disruptors at EU level.

List II: Substances under evaluation for endocrine disruption under an EU legislation.

List III: Substances considered, by the evaluating National Authority, to have endocrine disrupting properties.

556-67-2	octamethylcyclotetrasiloxane	List II, III
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)
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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)
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540-97-6 Dodecamethylcyclohexasiloxane

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

12.3 Bioaccumulative potential

556-67-2 octamethylcyclotetrasiloxane

Bloconcentration factor (BCF)	12400 (not defined)
-------------------------------	---------------------

540-97-6 Dodecamethylcyclohexasiloxane

Bloconcentration factor (BCF)	1160 (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
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.

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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

- | | |
|---|-----------------|
| · 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: | - |
| · 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)

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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
· *** Data compared to the previous version altered.**

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