



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

Printing date 26.05.2020

Version number 4

Revision: 26.05.2020

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

· **1.1 Product identifier**

· Trade name: **Flexitime Fast & Scan Dynamix Heavy Tray Base (5:1)**

· **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.

· **2.2 Label elements**

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

The product is classified and labelled according to the 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.

· **Precautionary statements**

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P264 Wash thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P314 Get medical advice/attention if you feel unwell.

· **2.3 Other hazards -**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**

· **Description:** -

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· Dangerous components:

CAS: 14464-46-1 EINECS: 238-878-4	Cristobalite STOT RE 1, H372	50-75%
CAS: 540-97-6 EINECS: 208-762-8 Reg.nr.: 01-2119717435-42-xxxx	Dodecamethylcyclohexasiloxane Acute Tox. 4, H302; Acute Tox. 4, H312	<1%

· SVHC

540-97-6 | Dodecamethylcyclohexasiloxane

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

SECTION 4: First aid measures

· 4.1 Description of first aid measures

· After inhalation Supply fresh air; consult doctor in case of symptoms.

· After skin contact

Instantly rinse with water.

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

- **Additional information about design of technical systems:** No further data; see item 7.

· **8.1 Control parameters**

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

13463-67-7 Titandioxid

WEL (Great Britain)	Long-term value: 10* 4** mg/m ³ *total inhalable **respirable
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- **Additional information:** The lists that were valid during the compilation were used as basis.

· **8.2 Exposure controls**

· **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:** Use a mask with particle filter in case of dust generation.

· **Protection of hands:**

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 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**
 - **Appearance:**
 - **Form:** Pasty
 - **Colour:** Green
 - **Smell:** Characteristic
 - **Odour threshold:** Not determined.
 - **pH-value:** Not determined.
 - **Change in condition**
 - **Melting point/freezing point:** Not determined
 - **Initial boiling point and boiling range:** 300 °C
 - **Flash point:** >130 °C
 - **Inflammability (solid, gaseous)** Not applicable.
 - **Decomposition temperature:** Not determined.
 - **Self-inflammability:** Product is not selfigniting.
 - **Explosive properties:** Product is not explosive.
Not determined.
 - **Critical values for explosion:**
 - **Lower:** Not determined.
 - **Upper:** Not determined.
 - **Steam pressure:** Not determined.
 - **Density** Not determined
 - **Relative density** Not determined.
 - **Vapour density** Not determined.
 - **Evaporation rate** Not determined.
 - **Solubility in / Miscibility with**
 - **Water:** Not miscible or difficult to mix
 - **Partition coefficient: n-octanol/water:** Not determined.
 - **Viscosity:**
 - **dynamic:** Not determined.
 - **kinematic:** Not determined.
- **9.2 Other information** No further relevant information available.

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 toxicological effects**

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

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

68083-19-2 Polydimethylsiloxan

Oral	LD50	>5,000 mg/kg (rat)
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13463-67-7 Titandioxid

Oral	LD50	>5,000 mg/kg (rat)
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Dermal	LD50	>5,000 mg/kg (rabbit)
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Inhalative	LC50/4 h	>6.8 mg/l (rat)
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540-97-6 Dodecamethylcyclohexasiloxane

Oral	LD50	2,000 mg/kg (rat)
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Dermal	LD50	2,000 mg/kg (rat)
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· **Primary irritant effect:**

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

· **Serious eye damage/irritation**

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

· **Respiratory or skin sensitisation**

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

· **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**

· **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)	1,000 mg/kg (rat)
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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.

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

13463-67-7 Titandioxid

EC50/72h (static)	16 mg/l (algae) (EPA-600-9/78-018)
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EC50/48h (static)	>100 mg/l (daphnia) (OECD 202)
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LC50/96h (static)	>100 mg/l (fish) (OECD 203)
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540-97-6 Dodecamethylcyclohexasiloxane

EC50/72h	>0.002 mg/l (algae) (OECD 201)
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NOEC / 21d	0.0046 mg/l (daphnia)
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NOEC / 72h	>0.002 mg/l (algae) (OECD 201)
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· **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.

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- **Additional ecological information:**
- **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.
- **12.5 Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **12.6 Other adverse effects** *No further relevant information available.*

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
 - **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Disposal must be made according to official regulations.
- **European waste catalogue**

18 01 06*	chemicals consisting of or containing hazardous substances
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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
· 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 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · Transport/Additional information: | - |
| · UN "Model Regulation": | Void |

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SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- **Directive 2012/18/EU**
 - **Named dangerous substances - ANNEX I** None of the ingredients is listed.
 - **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **National regulations**
 - **Other regulations, limitations and prohibitive regulations**

· Substances of very high concern (SVHC) according to REACH, Article 57

540-97-6 Dodecamethylcyclohexasiloxane

· 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**
 - H302 Harmful if swallowed.
 - H312 Harmful in contact with skin.
 - H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- **Abbreviations and acronyms:**
 - ADR: Accord européen sur le transport 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
 - SVHC: Substances of Very High Concern
 - vPvB: very Persistent and very Bioaccumulative
 - Acute Tox. 4: Acute toxicity - oral – Category 4
 - STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1
- *** Data compared to the previous version altered.**