



**Safety Data Sheet  
according to HPR, Schedule 1**

Printing date 11/22/2022

Reviewed on 11/22/2022

## 1 Identification

· **Product identifier**

· **Trade name:** **Flexitime Xtreme 2 Dynamix Heavy Tray Base**

· -

· **Application of the substance / the mixture** Dental impression material

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

· **Information department:**

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545

e-mail: [customer.servicehkna@kulzer-dental.com](mailto:customer.servicehkna@kulzer-dental.com)

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-Number)

ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

## 2 Hazard identification

· **Classification of the substance or mixture**

Carcinogenicity - Category 1A

H350 May cause cancer.

Specific Target Organ Toxicity - Repeated

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

Exposure - Category 1

· **Label elements**

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS08

· **Signal word** Danger

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

Cristobalite

· **Hazard statements**

May cause cancer.

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

· **Precautionary statements**

Do not breathe dust.

Wash thoroughly after handling.

Avoid release to the environment.

Wear protective gloves / eye protection.

Wear protective clothing.

Get medical advice/attention if you feel unwell.

· **Classification system**

· **NFPA ratings for USA (scale 0-4)**



Health = 0

Fire = 1

Reactivity = 0

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**HMIS-Ratings (Scale 0-4)**

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|            |    |                |
|------------|----|----------------|
| HEALTH     | *0 | Health = *0    |
| FIRE       | 1  | Fire = 1       |
| REACTIVITY | 0  | Reactivity = 0 |

Other hazards -

**3 Composition/Information on ingredients**

**Chemical characterization: Mixtures**

Description: -

**Dangerous components:**

|            |   |                |
|------------|---|----------------|
| 14464-46-1 | Cristobalite<br>Carcinogenicity - Category 1A, H350; Specific Target Organ Toxicity - Repeated Exposure - Category 1, H372                    | 50-75% w/w *   |
| 27306-78-1 | modified heptamethyltrisiloxane with polyalkylene oxide<br>Acute Toxicity (Inhalation) - Category 4, H332; Eye Irritation - Category 2A, H319 | ≥0-≤5% w/w *   |
| 540-97-6   | Dodecamethylcyclohexasiloxane<br>Flammable Liquids - Category 4, H227<br>PBT; vPvB  | ≥0-<0,2% w/w * |

\* Actual concentration ranges are withheld as a trade secret.

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

**4 First-aid measures**

**Description of first aid measures**

- After inhalation Supply fresh air; consult doctor in case of complaints.
- After skin contact If skin irritation continues, consult a doctor.
- After eye contact  
Rinse opened eye for several minutes under running water. Then consult a doctor.
- After swallowing  
Rinse out mouth and then drink plenty of water.  
If symptoms persist consult doctor.

**Information for doctor**

- Most important symptoms and effects, both acute and delayed  
No further relevant information available.
- Indication of any immediate medical attention and special treatment needed  
No further relevant information available.

**5 Fire-fighting measures**

**Extinguishing media**

- Suitable extinguishing agents  
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.  
Use fire fighting measures that suit the environment.

**Special hazards arising from the substance or mixture**

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

**Advice for firefighters**

- Protective equipment: Mount respiratory protective device.

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· **Additional information -**

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**6 Accidental release measures**

- **Personal precautions, protective equipment and emergency procedures**  
Ensure adequate ventilation  
Avoid contact with eyes and skin.
- **Environmental precautions:** Prevent seepage into sewage system, workpits and cellars.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).
- **Reference to other sections**  
No dangerous substances are released.  
See Section 7 for information on safe handling  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.  
-

**7 Handling and storage**

- **Handling**
  - **Precautions for safe handling**  
Keep receptacles tightly sealed.  
Ensure good ventilation/exhaustion at the workplace.
  - **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
  - **Storage**
    - **Requirements to be met by storerooms and receptacles:** No special requirements.
    - **Information about storage in one common storage facility:** Not required.
    - **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

**8 Exposure controls/ Personal protection**

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

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

**14464-46-1 Cristobalite**

|    |  |
|----|--|
| EL | TWA: 0,025 mg/m <sup>3</sup><br>respirable, ACGIH A2; IARC 1 |
| EV | TWA: 0,05* mg/m <sup>3</sup><br>*respirable fraction         |

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

- **Exposure controls**
  - **Personal protective equipment**
    - **General protective and hygienic measures**  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.
    - **Breathing equipment:** Not required.
    - **Protection of hands:**  
Check protective gloves prior to each use for their proper condition.

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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

**9 Physical and chemical properties**

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

· **General Information**

· **Appearance:**

- **Form:** Pasty
- **Color:** Violet
- **Odor:** Odorless
- **Odor threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

- **Melting point/Melting range:** undetermined
- **Boiling point/Boiling range:** 300 °C (572 °F)

· **Flash point:** >130 °C (>266 °F)

· **Flammability (solid, gaseous)** Not applicable.

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.  
Not determined.

· **Explosion limits:**

- **Lower:** Not determined.
- **Upper:** Not determined.

· **Vapor pressure:** Not determined.

· **Density:**

- **Relative density** Not determined.
- **Vapor 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.

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- **Viscosity:**
- **dynamic:** Not determined.
- **kinematic:** Not determined.

· **Other information** No further relevant information available.

**10 Stability and reactivity**

- **Reactivity** No further relevant information available.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** none
- **Additional information:** -

**11 Toxicological information**

· **Information on toxicological effects**

· **Acute toxicity:**

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

**68083-19-2 Silopren U 1 dental**

Oral LD50 >5.000 mg/kg (rat)

· **Primary irritant effect:**

- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.

· **Sensitization:** No sensitizing effects known.

· **Additional toxicological information:** Harmful

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

*Silicosis: Excessive inhalation of respirable crystalline silica dust may cause a progressive, disabling and sometimes fatal lung disease called silicosis. Symptoms include cough, shortness of breath, wheezing, non-specific chest illness and reduced pulmonary function. This disease is exacerbated by smoking. Individuals with silicosis are predisposed to develop mycobacterial infections (tuberculous and non-tuberculous) and fungal infections. Inhalation of air with a very high concentration of respirable silica dust can cause the most serious forms of silicosis in a matter of months or a few years. Some epidemiologic studies have concluded that there is significant risk of developing silicosis even at airborne exposure levels that are equal to the recommended NIOSH REL, the ACGIH TLV.*

*Cancer Status: The International Agency for Research on Cancer has determined that crystalline silica inhaled in the form of quartz or cristobalite from occupational sources is carcinogenic to humans (Group 1 - carcinogenic to humans). Refer to IARC Monograph 100C, A Review of Human Carcinogens: Arsenic, Fibres and Dusts (published in 2011) in conjunction with the use of these materials. The National Toxicology Program (NTP) classifies respirable crystalline silica as "known to be a human carcinogen". Refer to the Twelfth Report on Carcinogens (2011). The American Conference of Governmental Industrial Hygienists (ACGIH) classifies crystalline silica, quartz, as a suspected human carcinogen (A2).*

14464-46-1 Cristobalite

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1318-02-1 zeolites

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· **NTP (National Toxicology Program)**

14464-46-1 Cristobalite

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

**12 Ecological information**

- **Toxicity**
  - **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
  - **Bioaccumulative potential** No further relevant information available.
  - **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
  - **General notes:**  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**

|  |
|--|
| · <b>PBT:</b>                          |
| 540-97-6 Dodecamethylcyclohexasiloxane |
| · <b>vPvB:</b>                         |
| 540-97-6 Dodecamethylcyclohexasiloxane |
- **Other adverse effects** No further relevant information available.

**13 Disposal considerations**

- **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.

**14 Transport information**

- |   |      |
|---|------|
| · <b>UN-Number</b><br>· DOT/TDG, ADR, IMDG, IATA                              | Void |
| · <b>UN proper shipping name</b><br>· DOT/TDG, ADR, IMDG, IATA                | Void |
| · <b>Transport hazard class(es)</b><br>· DOT, ADR, ADN, IMDG, IATA<br>· Class | Void |
| · <b>Packing group</b><br>· DOT/TDG, ADR, IMDG, IATA                          | Void |

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- |  |                 |
|--|-----------------|
| · <b>Environmental hazards:</b>  |                 |
| · <b>Marine pollutant:</b>   | No              |
| · <b>Special precautions for user</b>  | Not applicable. |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable. |
| · <b>Transport/Additional information:</b>                                       | -               |
| · <b>UN "Model Regulation":</b>  | Void            |

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.
- **Sara**

· **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### 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**
  - H227 Combustible liquid.
  - H319 Causes serious eye irritation.
  - H332 Harmful if inhaled.
  - H350 May cause cancer.
  - H372 Causes damage to organs through prolonged or repeated exposure.
- **Date of the latest revision of the safety data sheet** 11/22/2022
- **Abbreviations and acronyms:**
  - IMDG: International Maritime Code for Dangerous Goods
  - DOT: US Department of Transportation
  - IATA: International Air Transport Association
  - 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)
  - NFPA: National Fire Protection Association (USA)
  - HMIS: Hazardous Materials Identification System (USA)
  - LC50: Lethal concentration, 50 percent
  - LD50: Lethal dose, 50 percent
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
- **\* Data compared to the previous version altered.**