



**Safety Data Sheet
acc. to OSHA HCS**

Printing date 11/17/2022

Reviewed on 11/17/2022

1 Identification

· **Product identifier**

· **Trade name:** **Flexitime Xtreme 2 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.servicehksa@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(s) identification

· **Classification of the substance or mixture**

Carcinogenicity 1A

H350 May cause cancer.

Specific Target Organ Toxicity - Repeated
Exposure 1

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

· **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**

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Do not breathe dust/fume/gas/mist/vapors/spray.

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

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

IF exposed or concerned: Get medical advice/attention.

Get medical advice/attention if you feel unwell.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

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- **Classification system**
- **NFPA ratings for USA (scale 0-4)**



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

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

- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description: -**

- **Dangerous components:**

| | | |
|------------|-------------------------------------------------------------------------------------------------------------------------|--------|
| 14464-46-1 | Cristobalite Carcinogenicity 1A, H350; Specific Target Organ Toxicity - Repeated Exposure 1, H372 | 50-75% |
| 27306-78-1 | modified heptamethyltrisiloxane with polyalkylene oxide Acute Toxicity - Inhalation 4, H332; Eye Irritation 2A, H319 | 0-5% |

- **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.

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- **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.
- **Additional information -**

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.

- **Protective Action Criteria for Chemicals**

| | | |
|-----------------|-------------------------------|-------------------------|
| · PAC-1: | | |
| 14464-46-1 | Cristobalite | 0.075 mg/m ³ |
| 68083-19-2 | Polydimethylsiloxan | 48 mg/m ³ |
| 540-97-6 | Dodecamethylcyclohexasiloxane | 150 mg/m ³ |
| 556-67-2 | octamethylcyclotetrasiloxane | 30 ppm |
| · PAC-2: | | |
| 14464-46-1 | Cristobalite | 33 mg/m ³ |
| 68083-19-2 | Polydimethylsiloxan | 530 mg/m ³ |
| 540-97-6 | Dodecamethylcyclohexasiloxane | 1,700 mg/m ³ |
| 556-67-2 | octamethylcyclotetrasiloxane | 68 ppm |
| · PAC-3: | | |
| 14464-46-1 | Cristobalite | 200 mg/m ³ |
| 68083-19-2 | Polydimethylsiloxan | 3,200 mg/m ³ |
| 540-97-6 | Dodecamethylcyclohexasiloxane | 9,900 mg/m ³ |
| 556-67-2 | octamethylcyclotetrasiloxane | 130 ppm |

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.

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· **Specific end use(s)** No further relevant information available.

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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:**

The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

At this time, the remaining constituent has no known exposure limits.

14464-46-1 Cristobalite

| | |
|-----|-------------------------------------------------------------------------------------------------|
| PEL | Long-term value: 0.05* mg/m ³ *resp. dust; ½ value from resp.dust formulae Quartz |
| REL | Long-term value: 0.05* mg/m ³ *respirable dust; See Pocket Guide App. A |
| TLV | Long-term value: 0.025* mg/m ³ *as 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.
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:**

Characteristic

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| | |
|---------------------------------------------------|------------------------------------------------------------------|
| · 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: | Not determined |
| · 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. |
| · 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 Polydimethylsiloxan | | |
| Oral | LD50 | >5,000 mg/kg (rat) |

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556-67-2 octamethylcyclotetrasiloxane

| | | |
|------------|----------|-------------------------------|
| Oral | LD50 | >4,800 mg/kg (rat) (OECD 401) |
| Dermal | LD50 | >2,375 mg/kg (rat) (OECD 402) |
| Inhalative | LC50/4 h | 36 mg/l (rat) (OECD 403) |

- **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 | 1 |
|------------|--------------|---|

· **NTP (National Toxicology Program)**

| | | |
|------------|--------------|---|
| 14464-46-1 | Cristobalite | K |
|------------|--------------|---|

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

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

12 Ecological information

· **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) |

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| | |
|------------|------------------------------------------|
| NOEC / 48h | ≥0.015 mg/l (daphnia) (EPA OTS 797.1300) |
| ErC50/ 96h | >0.022 mg/L (algae) (EPA OTS 797.1050) |

· **Persistence and degradability**

556-67-2 octamethylcyclotetrasiloxane

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

· **Behavior in environmental systems:**

· **Bioaccumulative potential**

556-67-2 octamethylcyclotetrasiloxane

Biokonzentrationsfaktor (BCF) 12,400 (not defined)

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

· **Ecotoxicological 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 course or sewage system.

Harmful to aquatic organisms

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **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

· **UN-Number**

· DOT, ADR, IMDG, IATA

Void

· **UN proper shipping name**

· DOT, ADR, IMDG, IATA

Void

· **Transport hazard class(es)**

· DOT, ADR, ADN, IMDG, IATA

· Class

Void

· **Packing group**

· DOT, ADR, IMDG, IATA

Void

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

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **Sara**

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

None of the ingredients is listed.

· **SARA Section 313 (specific toxic chemical listings)**

None of the ingredients is listed.

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **Proposition 65**

· **Prop 65 - Chemicals known to cause cancer**

The listing is for silica, crystalline as "airborne particles of respirable size". Silica, crystalline of this product is within a product matrix.

14464-46-1 Cristobalite

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogen categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value)**

14464-46-1 Cristobalite

A2

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

14464-46-1 Cristobalite

- **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**

H319 Causes serious eye irritation.

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H332 Harmful if inhaled.

H350 May cause cancer.

H372 Causes damage to organs through prolonged or repeated exposure.

· **Date of preparation / last revision 11/17/2022**

· **Abbreviations and acronyms:**

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

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)

HMS: 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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Acute Toxicity - Inhalation 4: Acute toxicity – Category 4

Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A

Carcinogenicity 1A: Carcinogenicity – Category 1A

Specific Target Organ Toxicity - Repeated Exposure 1: Specific target organ toxicity (repeated exposure) – Category 1

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

US