



Safety Data Sheet
acc. to OSHA HCS

Printing date 12/17/2024

Reviewed on 10/08/2024

1 Identification

· **Product identifier**

· **Trade name:** **FLEXITIME Unlimited BASE 1:1**

· -

· **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

· **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:**

crystalite

· **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 breathe dust.

Wash thoroughly after handling.

Avoid release to the environment.

IF INHALED: Call a POISON CENTER/doctor if you feel unwell.

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)**



· **HMS-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	crystalite Carcinogenicity 1A, H350; Specific Target Organ Toxicity - Repeated Exposure 1, H372	≥10-≤25%
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.
In rare cases, intestinal blockage may arise.

· **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.

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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** No further relevant information available.
- **Advice for firefighters**
 - **Protective equipment:** No special measures required.
- **Additional information** -

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Avoid contact with eyes and skin.
Avoid formation of dust.
- **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**
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	crystalite	0.075 mg/m ³
65997-17-3	Glass Flake GF001-10	15 mg/m ³
65997-17-3	Glass Flake GF005-20	15 mg/m ³
68083-19-2	DIMETHYL POLYSILOXANE (VINYL TERMINATED)	48 mg/m ³
14464-46-1	crystalite	0.075 mg/m ³
556-67-2	octamethylcyclotetrasiloxane	30 ppm
540-97-6	Dodecamethylcyclohexasiloxane	150 mg/m ³
14808-60-7	Quartz (SiO ₂)	0.075 mg/m ³

· PAC-2:		
14464-46-1	crystalite	33 mg/m ³
65997-17-3	Glass Flake GF001-10	170 mg/m ³
65997-17-3	Glass Flake GF005-20	170 mg/m ³
68083-19-2	DIMETHYL POLYSILOXANE (VINYL TERMINATED)	530 mg/m ³
14464-46-1	crystalite	33 mg/m ³
556-67-2	octamethylcyclotetrasiloxane	68 ppm
540-97-6	Dodecamethylcyclohexasiloxane	1,700 mg/m ³
14808-60-7	Quartz (SiO ₂)	33 mg/m ³

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· PAC-3:		
14464-46-1	cristobalite	200 mg/m ³
65997-17-3	Glass Flake GF001-10	990 mg/m ³
65997-17-3	Glass Flake GF005-20	990 mg/m ³
68083-19-2	DIMETHYL POLYSILOXANE (VINYL TERMINATED)	3,200 mg/m ³
14464-46-1	cristobalite	200 mg/m ³
556-67-2	octamethylcyclotetrasiloxane	130 ppm
540-97-6	Dodecamethylcyclohexasiloxane	9,900 mg/m ³
14808-60-7	Quartz (SiO ₂)	200 mg/m ³

7 Handling and storage

- **Handling**
 - **Precautions for safe handling**
Store in cool, dry place in tightly closed receptacles.
No special precautions are necessary if used correctly.
 - **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

- **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 *respirable particulate matter, A2

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

- **Exposure controls**
 - **Personal protective equipment**
 - **General protective and hygienic measures** Wash hands before breaks and at the end of work.
 - **Breathing equipment:** Use a mask with particle filter in case of dust generation.

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- **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:**

White

· **Odor:**

Characteristic

· **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:**

>100 °C (>212 °F)

· **Flammability (solid, gaseous)**

Not applicable.

· **Auto igniting:**

470 °C (878 °F)

· **Decomposition temperature:**

Not determined.

· **Ignition temperature:**

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 at 1732 °C (3,149.6 °F):** 13.5 hPa (10.1 mm Hg)

· **Density:**

Not determined

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· 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 DIMETHYL POLYSILOXANE (VINYL TERMINATED)		
Oral	LD50	>5,000 mg/kg (rat)
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)

- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**

- **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.

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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
14808-60-7	Quartz (SiO ₂)	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)
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)
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· Behavior in environmental systems:

· Bioaccumulative potential

556-67-2 octamethylcyclotetrasiloxane

Bloconcentration factor (BCF)	12,400 (not defined)
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· Mobility in soil No further relevant information available.

· Additional ecological information:

· General notes:

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.

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- **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.
 - **Recommended cleansing agent:** Water, if necessary with cleansing agents.

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
· Environmental hazards:	Not applicable.
· 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

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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 the product matrix.

14464-46-1	cristobalite
14808-60-7	Quartz (SiO ₂)

· 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
14808-60-7 Quartz (SiO ₂)

- **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.

H332 Harmful if inhaled.

H350 May cause cancer.

H372 Causes damage to organs through prolonged or repeated exposure.

- **Date of preparation / last revision 12/17/2024**

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· **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)

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

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



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1 Identification

· **Product identifier**

· **Trade name:** **FLEXITIME Unlimited BASE 5:1**

· -

· **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

· **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:**

crystalite

· **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 breathe dust.

Wash thoroughly after handling.

Avoid release to the environment.

IF INHALED: Call a POISON CENTER/doctor if you feel unwell.

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)**



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



- **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	≥25-≤50%
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- **Additional information** For the wording of the listed hazard phrases refer to section 16.

4 First-aid measures

- **Description of first aid measures**
- **General information** No special measures required.
- **After inhalation** Supply fresh air; consult doctor in case of complaints.
- **After skin contact** Generally the product does not irritate the skin.
- **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.
In rare cases, intestinal blockage may arise.
- **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.

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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** No further relevant information available.
- **Advice for firefighters**
 - **Protective equipment:** No special measures required.
- **Additional information** -

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Avoid contact with eyes and skin.
Avoid formation of dust.
- **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**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
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- **Protective Action Criteria for Chemicals**

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65997-17-3	Glass Flake GF005-20	15 mg/m ³
68083-19-2	DIMETHYL POLYSILOXANE (VINYL TERMINATED)	48 mg/m ³
14464-46-1	crystalite	0.075 mg/m ³
556-67-2	octamethylcyclotetrasiloxane	30 ppm
540-97-6	Dodecamethylcyclohexasiloxane	150 mg/m ³
14808-60-7	Quartz (SiO ₂)	0.075 mg/m ³

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14464-46-1	crystalite	33 mg/m ³
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65997-17-3	Glass Flake GF005-20	170 mg/m ³
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14464-46-1	crystalite	33 mg/m ³
556-67-2	octamethylcyclotetrasiloxane	68 ppm
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7 Handling and storage

- **Handling**
 - **Precautions for safe handling**
Store in cool, dry place in tightly closed receptacles.
No special precautions are necessary if used correctly.
 - **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

· **Control parameters**

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

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 *respirable particulate matter, A2

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

· **Exposure controls**

- **Personal protective equipment**
 - **General protective and hygienic measures**
The usual precautionary measures for handling chemicals should be followed.
 - **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.

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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:**

White

· **Odor:**

Characteristic

· **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.

· **Auto igniting:**

470 °C (878 °F)

· **Decomposition temperature:**

Not determined.

· **Ignition temperature:**

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 at 1732 °C (3,149.6 °F):** 13.5 hPa (10.1 mm Hg)

· **Density:**

Not determined

· **Relative density**

Not determined.

· **Vapor density**

Not determined.

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· Evaporation rate	Not determined.
· Solubility in / Miscibility with · Water:	Not miscible or difficult to mix
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity: · dynamic: · kinematic:	Not determined. Not determined.
· Solvent content:	
· Solids content:	26.9-<28.7 %
· 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:**
- **Sensitization:** No sensitizing effects known.

· **Additional toxicological information:**

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **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,

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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
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· NTP (National Toxicology Program)

14464-46-1	cristobalite	K
------------	--------------	---

14808-60-7	Quartz (SiO ₂)	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:** 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 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.
- **Uncleaned packagings:**
 - **Recommendation:**
 - Disposal must be made according to official regulations.
 - Non contaminated packagings can be used for recycling.
 - **Recommended cleansing agent:** Water, if necessary with cleansing agents.



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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
· Environmental hazards:	Not applicable.
· 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 the product matrix.
14464-46-1 cristobalite
14808-60-7 Quartz (SiO ₂)
· 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.

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· **Carcinogeny 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
------------	--------------

14808-60-7	Quartz (SiO ₂)
------------	----------------------------

· **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**

H350 May cause cancer.

H372 Causes damage to organs through prolonged or repeated exposure.

· **Date of preparation / last revision** 12/17/2024

· **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)

HMIS: Hazardous Materials Identification System (USA)

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

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.**



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1 Identification

· **Product identifier**

· **Trade name:** **FLEXITIME Unlimited CAT 1:1**

· -

· **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

· **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:**

crystalite

· **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.

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Store locked up.

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

Classification system

NFPA ratings for USA (scale 0-4)



Health = 0
Fire = 1
Reactivity = 0

HMIS-Ratings (Scale 0-4)



Health = *0
Fire = 1
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	≥25-≤50%
	Carcinogenicity 1A, H350; Specific Target Organ Toxicity - Repeated Exposure 1, H372	

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.

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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** No further relevant information available.
- **Advice for firefighters**
 - **Protective equipment:** No special measures required.
- **Additional information** -

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Avoid formation of dust.
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**
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
65997-17-3	Glass Flake GF001-10	15 mg/m ³
65997-17-3	Glass Flake GF005-20	15 mg/m ³
14464-46-1	cristobalite	0.075 mg/m ³
1344-28-1	aluminium oxide	15 mg/m ³
556-67-2	octamethylcyclotetrasiloxane	30 ppm
540-97-6	Dodecamethylcyclohexasiloxane	150 mg/m ³
14808-60-7	Quartz (SiO ₂)	0.075 mg/m ³
67-63-0	propan-2-ol	400 ppm

· PAC-2:		
14464-46-1	cristobalite	33 mg/m ³
65997-17-3	Glass Flake GF001-10	170 mg/m ³
65997-17-3	Glass Flake GF005-20	170 mg/m ³
14464-46-1	cristobalite	33 mg/m ³
1344-28-1	aluminium oxide	170 mg/m ³
556-67-2	octamethylcyclotetrasiloxane	68 ppm
540-97-6	Dodecamethylcyclohexasiloxane	1,700 mg/m ³

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14808-60-7	Quartz (SiO ₂)	33 mg/m ³
67-63-0	propan-2-ol	2000* ppm
· PAC-3:		
14464-46-1	crystalobalite	200 mg/m ³
65997-17-3	Glass Flake GF001-10	990 mg/m ³
65997-17-3	Glass Flake GF005-20	990 mg/m ³
14464-46-1	crystalobalite	200 mg/m ³
1344-28-1	aluminium oxide	990 mg/m ³
556-67-2	octamethylcyclotetrasiloxane	130 ppm
540-97-6	Dodecamethylcyclohexasiloxane	9,900 mg/m ³
14808-60-7	Quartz (SiO ₂)	200 mg/m ³
67-63-0	propan-2-ol	12000** ppm

7 Handling and storage

- **Handling**
 - **Precautions for safe handling**
Store in cool, dry place in tightly closed receptacles.
No special precautions are necessary if used correctly.
 - **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

- **Control parameters**

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

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 *respirable particulate matter, A2

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

- **Exposure controls**

- **Personal protective equipment**
 - **General protective and hygienic measures** Wash hands before breaks and at the end of work.

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- **Breathing equipment:** Not necessary if room is well-ventilated.
- **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:** Grey

· **Odor:** Characteristic

· **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.

· **Auto igniting:** 470 °C (878 °F)

· **Decomposition temperature:** Not determined.

· **Ignition temperature:** 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 at 1732 °C (3,149.6 °F):** 13.5 hPa (10.1 mm Hg)

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· 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.
· Solvent content:	
· Solids content:	≥26.9-<28.8 %
· 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:** Based on available data, the classification criteria are not met.
 - **Primary irritant effect:**
 - **on the skin:**
No irritant effect.
Based on available data, the classification criteria are not met.
 - **on the eye:** No irritating effect.
 - **Sensitization:** No sensitizing effects known.
 - **Additional toxicological information:**
 - **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.

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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
14464-46-1	cristobalite	1
· NTP (National Toxicology Program)		
14464-46-1	cristobalite	K
14464-46-1	cristobalite	K
14808-60-7	Quartz (SiO ₂)	K

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

- **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.
- **Specific target organ toxicity - single exposure**
Based on available data, the classification criteria are not met.
- **Specific target organ toxicity - repeated exposure**
Based on available data, the classification criteria are not met.
- **Aspiration hazard** 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 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.

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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
· Environmental hazards:	Not applicable.
· 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)	
1344-28-1	aluminium oxide
67-63-0	propan-2-ol

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· 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 the product matrix.

The listing for titanium dioxide is as "airborne, unbound particles of respirable size". Titanium dioxide of this product is within the product matrix.

14464-46-1	cristobalite
14464-46-1	cristobalite
14808-60-7	Quartz (SiO ₂)

· 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.

· Cancerogenity categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value)

14464-46-1	cristobalite	A2
14464-46-1	cristobalite	A2
1344-28-1	aluminium oxide	A4

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

14464-46-1	cristobalite
14464-46-1	cristobalite
14808-60-7	Quartz (SiO ₂)

· 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

H350 May cause cancer.

H372 Causes damage to organs through prolonged or repeated exposure.

· Date of preparation / last revision 12/17/2024

· 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

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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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
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
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.**

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1 Identification

· **Product identifier**

· **Trade name:** **FLEXITIME Unlimited CAT 5:1**

· -

· **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

· **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.

Toxic to Reproduction 1B

H360 May damage fertility or the unborn child.

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:**

crystalite

Platinum divinyltetramethyldisiloxane complex

octamethylcyclotetrasiloxane

· **Hazard statements**

May cause cancer.

May damage fertility or the unborn child.

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.

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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.

· **Classification system**

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



· **HMIS-Ratings (Scale 0-4)**



· **Results of PBT and vPvB assessment**

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

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	≥10-≤25%
68478-92-2	Platinum divinyltetramethyldisiloxane complex Flammable Liquids 2, H225 Toxic to Reproduction 1B, H360	≥0.1-<1%
556-67-2	octamethylcyclotetrasiloxane Flammable Liquids 3, H226 Toxic to Reproduction 2, H361 PBT; vPvB	≥0.1-<1%

· **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.

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- **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** No further relevant information available.
- **Advice for firefighters**
 - **Protective equipment:** No special measures required.
- **Additional information** -

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Avoid formation of dust.
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**
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
65997-17-3	Glass Flake GF001-10	15 mg/m ³
65997-17-3	Glass Flake GF005-20	15 mg/m ³
556-67-2	octamethylcyclotetrasiloxane	30 ppm
540-97-6	Dodecamethylcyclohexasiloxane	150 mg/m ³
1344-28-1	aluminium oxide	15 mg/m ³
14464-46-1	cristobalite	0.075 mg/m ³
67-63-0	propan-2-ol	400 ppm

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14808-60-7	Quartz (SiO ₂)	0.075 mg/m ³
· PAC-2:		
14464-46-1	crystalite	33 mg/m ³
65997-17-3	Glass Flake GF001-10	170 mg/m ³
65997-17-3	Glass Flake GF005-20	170 mg/m ³
556-67-2	octamethylcyclotetrasiloxane	68 ppm
540-97-6	Dodecamethylcyclohexasiloxane	1,700 mg/m ³
1344-28-1	aluminium oxide	170 mg/m ³
14464-46-1	crystalite	33 mg/m ³
67-63-0	propan-2-ol	2000* ppm
14808-60-7	Quartz (SiO ₂)	33 mg/m ³
· PAC-3:		
14464-46-1	crystalite	200 mg/m ³
65997-17-3	Glass Flake GF001-10	990 mg/m ³
65997-17-3	Glass Flake GF005-20	990 mg/m ³
556-67-2	octamethylcyclotetrasiloxane	130 ppm
540-97-6	Dodecamethylcyclohexasiloxane	9,900 mg/m ³
1344-28-1	aluminium oxide	990 mg/m ³
14464-46-1	crystalite	200 mg/m ³
67-63-0	propan-2-ol	12000** ppm
14808-60-7	Quartz (SiO ₂)	200 mg/m ³

7 Handling and storage

· Handling

· Precautions for safe handling

Store in cool, dry place in tightly closed receptacles.
No special precautions are necessary if used correctly.

· **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

· Control parameters

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

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.

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

14464-46-1 cristobalite

PEL Long-term value: 0.05* mg/m³
*resp. dust; ½ value from resp.dust formulae Quartz

REL Long-term value: 0.05* mg/m³
*respirable dust; See Pocket Guide App. A

TLV Long-term value: 0.025* mg/m³
*respirable particulate matter, A2

556-67-2 octamethylcyclotetrasiloxane

WEEL Long-term value: 10* ppm
*OARS WEEL

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

· **Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures** Wash hands before breaks and at the end of work.

· **Breathing equipment:** Not necessary if room is well-ventilated.

· **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:**

Grey

· **Odor:**

Characteristic

· **Odor threshold:**

Not determined.

· **pH-value:**

Not determined.

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· 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.
· Auto igniting:	470 °C (878 °F)
· Decomposition temperature:	Not determined.
· Ignition temperature:	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 at 1732 °C (3,149.6 °F):	13.5 hPa (10.1 mm Hg)
· 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.
· Solvent content:	
· Solids content:	≥9-<11.2 %
· 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:** -

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11 Toxicological information

· **Information on toxicological effects**

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

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

68478-92-2 Platinum divinyltetramethyldisiloxane complex		
Oral	LD50	>5,000 mg/kg (rat) (OECD 425)
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.

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

· **on the eye:** No irritating effect.

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

· **Additional toxicological information:**

· **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
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· **NTP (National Toxicology Program)**

14464-46-1	cristobalite	K
14464-46-1	cristobalite	K
14808-60-7	Quartz (SiO2)	K

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

None of the ingredients is listed.

· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

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

· **Reproductive toxicity**

68478-92-2 Platinum divinyltetramethyldisiloxane complex

Oral | NOAEL (parental toxicity) | 125 mg/kg/d (rat) (OECD 422)

· **Specific target organ toxicity - single exposure**

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

· **Specific target organ toxicity - repeated exposure**

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

· **Aspiration hazard** 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)

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

Bloconcentration factor (BCF) | 12,400 (not defined)

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

· **Additional ecological information:**

· **General notes:**

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:**

556-67-2 | octamethylcyclotetrasiloxane

· **vPvB:**

556-67-2 | octamethylcyclotetrasiloxane

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

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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
· Environmental hazards:	Not applicable.
· 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)
1344-28-1 aluminium oxide

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67-63-0 | propan-2-ol

· 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 the product matrix.

The listing for titanium dioxide is as "airborne, unbound particles of respirable size". Titanium dioxide of this product is within the product matrix.

14464-46-1 | cristobalite

14464-46-1 | cristobalite

14808-60-7 | Quartz (SiO₂)

· 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.

· Cancerogenity 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

14464-46-1 | cristobalite

14808-60-7 | Quartz (SiO₂)

· 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

H225 Highly flammable liquid and vapor.

H226 Flammable liquid and vapor.

H350 May cause cancer.

H360 May damage fertility or the unborn child.

H361 Suspected of damaging fertility or the unborn child.

H372 Causes damage to organs through prolonged or repeated exposure.

· Date of preparation / last revision 12/17/2024

· 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)

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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
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Flammable Liquids 2: Flammable liquids – Category 2
Flammable Liquids 3: Flammable liquids – Category 3
Carcinogenicity 1A: Carcinogenicity – Category 1A
Toxic to Reproduction 1B: Reproductive toxicity – Category 1B
Toxic to Reproduction 2: Reproductive toxicity – Category 2
Specific Target Organ Toxicity - Repeated Exposure 1: Specific target organ toxicity (repeated exposure) – Category 1
* **Data compared to the previous version altered.**

US