

SAFETY DATA SHEETS

This SDS packet was issued with item:

074567822

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

070375022 070375899 074567814

Material Safety Data Sheet According to 91/155 EEC

Printing date 02.09.2004

Reviewed on 02.09.2004

1 Identification of substance

· **Product details**

· **Trade name:** **Flexitime Xtreme Heavy Tray base**

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

· **Manufacturer/Supplier:**

Heraeus Kulzer GmbH & Co. KG
Grüner Weg 11, D-63450 Hanau

Tel.: 0800 4372522

· **Informing department:** Dr. Palussek Tel.: +49 2133 51-4911 / Fax: +49 2133 51-5016

· **Emergency information:** Call +49 30 19240 (24 hours).

2 Composition/Data on components:

· **Chemical characterization**

· **Description:**

2-component material comprising base paste and matching catalyst paste for addition curing

· **Dangerous components:** Void

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

3 Hazards identification

· **Hazard designation:** void

· **Information pertaining to particular dangers for man and environment**

The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

· **Classification system**

The classification is in line with current EC lists. It is expanded, however, by information from technical literature and by information furnished by supplier companies.

4 First aid measures

· **General information** No special measures required.

· **After skin contact** The product is not skin irritating.

· **After eye contact** Rinse opened eye for several minutes under running water.

· **After swallowing** Initiate vomiting and consult a doctor.

5 Fire fighting measures

· **Suitable extinguishing agents** void

· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Person-related safety precautions:** Not required.

· **Measures for environmental protection:** No special measures required.

· **Measures for cleaning/collecting:**

Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

· **Additional information:** No dangerous materials are released.

GB

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**Material Safety Data Sheet
According to 91/155 EEC**

Printing date 02.09.2004

Reviewed on 02.09.2004

Trade name: Flexitime Xtreme Heavy Tray base

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7 Handling and storage

- **Handling**
 - **Information for safe handling:** No special measures required.
 - **Information about protection against explosions and fires:** No special measures required.
- **Storage**
 - **Requirements to be met by storerooms and containers:** No special requirements.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:** None.

8 Exposure controls and personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Components with critical values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
 - **Additional information:** The lists that were valid during the compilation were used as basis.
- **Personal protective equipment**
 - **General protective and hygienic measures**
The usual precautionary measures should be adhered to in handling the chemicals.
 - **Breathing equipment:** Not required.
 - **Protection of hands:** Not required.
 - **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.
 - **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 in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:**
PVC or PE gloves
 - **Eye protection:** not absolutely necessary
 - **Body protection:** Light weight protective clothing

9 Physical and chemical properties:

· General Information

- | | |
|------------------|-------------------------------|
| · Form: | Pasty |
| · Colour: | Different according to colour |
| · Smell: | Product specific |

· Change in condition

- | | |
|---------------------------------------|----------------|
| · Melting point/Melting range: | Not determined |
| · Boiling point/Boiling range: | Not determined |

- | | |
|-----------------------|----------------|
| · Flash point: | Not applicable |
|-----------------------|----------------|

- | | |
|-------------------------------|------------------------------|
| · Self-inflammability: | Product is not selfigniting. |
|-------------------------------|------------------------------|

- | | |
|-------------------------------|---------------------------|
| · Danger of explosion: | Product is not explosive. |
|-------------------------------|---------------------------|

- | | |
|--------------------------|-----------------------|
| · Density at 20°C | 1.5 g/cm ³ |
|--------------------------|-----------------------|

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Material Safety Data Sheet According to 91/155 EEC

Printing date 02.09.2004

Reviewed on 02.09.2004

Trade name: Flexitime Xtreme Heavy Tray base

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- **Solubility in / Miscibility with**
- **Water:** Not miscible or difficult to mix

10 Stability and reactivity

- **Conditions to be avoided:** No decomposition if used and stored according to specifications.
- **Dangerous reactions** No dangerous reactions known
- **Dangerous products of composition:** None

11 Toxicological information

- **Acute toxicity:**
 - **Primary irritant effect:**
 - **on the skin:** No irritant effect.
 - **on the eye:** No irritant effect.
 - **Sensitization:** No sensitizing effect known.
- **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EC 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.

12 Ecological information:

- **General notes:**
Water hazard class 1 (calculated according to VwVwS): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

13 Disposal considerations

- **Product:**
 - **Recommendation** Smaller quantities can be disposed with household garbage.
- **European waste catalogue**
18 01 06 | chemicals consisting of or containing dangerous substances
- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **Land transport ADR/RID and GGVS/GGVE (cross-border/domestic)**
 - **ADR/RID-GGVS/E Class:** -
- **Maritime transport IMDG/GGVSea:**
 - **IMDG/GGVSea Class:** -
 - **Marine pollutant:** No

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Material Safety Data Sheet According to 91/155 EEC

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Reviewed on 02.09.2004

Trade name: Flexitime Xtreme Heavy Tray base

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- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** -

15 Regulatory information

- **Designation according to EC guidelines:**
Observe the normal safety regulations when handling chemicals
The product is not subject to identification regulations under EC Directives and the Ordinance on Hazardous Materials (GefStoffV).
The product is not subject to classification according to the calculation methods of the "General Classification Guideline for Preparations of the EC" as issued in the last version.
- **National regulations**
 - **Water hazard class:**
Water hazard class 1 (calculated according to VwVwS): slightly hazardous for water.

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.
- **Contact:**
Dr. Tuchscherer Tel.: (49) 6081 959-287
christian.tuchscherer@heraeus.com
 - *** Data compared to the previous version altered.**

GB



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

1 Identification

· **Product identifier**

· **Trade name:** **Flexitime Xtreme 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

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-Number)

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

2 Hazard(s) identification

· **Classification of the substance or mixture**

Eye Irrit. 2A H319 Causes serious eye irritation.

· **Label elements**

· **GHS label elements**

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

· **Hazard pictograms**



GHS07

· **Signal word** Warning

· **Hazard statements**

Causes serious eye irritation.

· **Precautionary statements**

Wear eye protection / face protection.

Wash thoroughly after handling.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

· **Classification system**

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



Health = 1

Fire = 0

Reactivity = 0

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Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Flexitime Xtreme Heavy Tray base

· **HMIS-Ratings (Scale 0-4)**

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

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· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Description:**

2-component silicone impression material comprising base paste and matching catalyst paste for addition curing

· **Dangerous components:**

24938-91-8	poly(oxy-1,2-ethanediyl), α -tridecyl- ω -hydroxy-	Eye Dam. 1, H318	0-5%
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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**

- **After inhalation** Supply fresh air; consult doctor in case of complaints.
- **After skin contact** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact** Rinse opened eye for several minutes under running water.
- **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.

· **Special hazards arising from the substance or mixture** No further relevant information available.

· **Advice for firefighters**

· **Protective equipment:** No special measures required.

· **Additional information -**

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Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Flexitime Xtreme Heavy Tray base

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6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** No special measures required.
- **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.

7 Handling and storage

- **Handling**
 - **Precautions for safe handling** No special measures required.
 - **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:**

1317-65-3 Calciumcarbonat, nat., gem.

PEL	15*, 5** mg/m ³ *Total dust **Respirable fraction
REL	10*, 5** mg/m ³ *Total dust **Respirable fraction
TLV	10 mg/m ³ (e)

· **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 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.

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Trade name: Flexitime Xtreme Heavy Tray base

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- **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:** Not absolutely necessary.
- **Body protection:** Light weight protective clothing

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

· **Form:**

Pasty

· **Color:**

Different according to coloring

· **Odor:**

Product specific

· **Odor threshold:**

Not determined.

· **pH-value:**

Not determined.

· **Change in condition**

· **Melting point/Melting range:**

undetermined

· **Boiling point/Boiling range:**

undetermined

· **Flash point:**

Not applicable

· **Flammability (solid, gaseous)**

Not applicable.

· **Ignition temperature:**

· **Decomposition temperature:**

Not determined.

· **Auto igniting:**

Product is not selfigniting.

· **Danger of explosion:**

Product does not present an explosion hazard.

· **Explosion limits:**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Vapor pressure:**

Not determined.

· **Density at 20 °C (68 °F):**

1.5 g/cm³ (12.518 lbs/gal)

· **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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USA



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acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Flexitime Xtreme Heavy Tray base

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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

11 Toxicological information

- **Information on toxicological effects**
 - **Acute toxicity:**

· LD/LC50 values that are relevant for classification:		
Polydimethylsiloxan		
Oral	LD50	> 5000 mg/kg (rat)
Polydimethylsiloxan		
Oral	LD50	> 5000 mg/kg (rat)
Sensitization	Sensib.	nicht sensibil. (guinea pig) (OECD 406; nach Magnusson-Kligman)
24938-91-8 poly(oxy-1,2-ethanediyl), α-tridecyl-ω-hydroxy-		
Oral	LD50	7400 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:**

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)		
14808-60-7	Quartz (SiO ₂)	1
· NTP (National Toxicology Program)		
14808-60-7	Quartz (SiO ₂)	R

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Safety Data Sheet
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Reviewed on 06/03/2017

Trade name: Flexitime Xtreme Heavy Tray base

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· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

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**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
 - **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|---|-----------------|
| · UN-Number
· DOT, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name
· DOT, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es)
· DOT, ADR, ADN, IMDG, IATA
· Class | Void |
| · Packing group
· DOT, ADR, IMDG, IATA | Void |
| · Environmental hazards:
· Marine pollutant: | No |
| · Special precautions for user | Not applicable. |

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Reviewed on 06/03/2017

Trade name: Flexitime Xtreme Heavy Tray base

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· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

· **UN "Model Regulation":** Void

15 Regulatory information

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

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

None of the ingredients is listed.

· **Carcinogen categories**

· **TLV (Threshold Limit Value established by ACGIH)**

14808-60-7 | Quartz (SiO₂)

A2

· **GHS label elements**

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

· **Hazard pictograms**



GHS07

· **Signal word** Warning

· **Hazard statements**

Causes serious eye irritation.

· **Precautionary statements**

Wear eye protection / face protection.

Wash thoroughly after handling.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

· **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**

H318 Causes serious eye damage.

· **Date of preparation / last revision** 06/03/2017 / 2

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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Trade name: Flexitime Xtreme Heavy Tray base

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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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
*** Data compared to the previous version altered.**

USA