



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

Printing date 06/03/2017

Reviewed on 06/03/2017

## 1 Identification

· **Product identifier**

· **Trade name:** **Flexitime Fast & Scan Easy Putty, ... Dynamix Putty, ...  
Dynamix Heavy Tray, ... Heavy Tray , ... Medium Flow, ...  
Light Flow**

· **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**

The product is not classified according to the Globally Harmonized System (GHS).

· **Label elements**

· **GHS label elements** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **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.

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### 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: Void**

### 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** If skin irritation continues, consult a doctor.

· **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**

CO<sub>2</sub>, 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** 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**

See Section 13 for disposal information.

See Section 8 for information on personal protection equipment.

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## 7 Handling and storage

- **Handling**
  - **Precautions for safe handling**  
Please observe the additional instructions in the product's instructions for use.
  - **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 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 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:** Not required.
    - **Protection of hands:**  
Not absolutely necessary.  
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

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- **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:**

Odorless

· **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:**

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.

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· **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:**

**Polydimethylsiloxan**

Oral	LD50	> 5000 mg/kg (rat)
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**Polydimethylsiloxan**

Oral	LD50	> 5000 mg/kg (rat)
Sensitization	Sensib.	nicht sensib. (guinea pig) (OECD 406; nach Magnusson-Kligman)

**13463-67-7 Titandioxid**

Oral	LD50	> 5000 mg/kg (rat) (OECD 425)
Dermal	LD50	> 5000 mg/kg (rabbit)
Inhalative	LC50/4 h	> 6.8 mg/l (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)**

13463-67-7	Titanium dioxide	2B
1318-02-1	Zeolith A	3
8007-18-9	C.I. Pigment Yellow 53	1

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· **NTP (National Toxicology Program)**

8007-18-9 C.I. Pigment Yellow 53

K

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

None of the ingredients is listed.

**12 Ecological information**

· **Toxicity**

· **Aquatic toxicity:**

No further relevant information available.

**13463-67-7 Titandioxid**

EC50/72h (static) 16 mg/l (algae) (EPA-600-9/78-018)

EC50/48h (static) > 100 mg/l (daphnia) (OECD 202)

LC50/96h (static) > 100 mg/l (fish) (OECD 203)

· **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:** Avoid transfer into the environment.

· **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**

Small quantities can be polymerized with the matching system component(s) and the cured solid material can be disposed of with the regular garbage.

· **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, ADN, IMDG, IATA**

Void

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· <b>ADR</b>	Void
· <b>Transport hazard class(es)</b>	
· <b>DOT, ADR, ADN, IMDG, IATA</b>	
· <b>Class</b>	Void
· <b>Packing group</b>	
· <b>DOT, ADR, IMDG, IATA</b>	Void
· <b>Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	-
· <b>UN "Model Regulation":</b>	Void

## 15 Regulatory information

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

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

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act)**

None of the ingredients is listed.

Medical devices are exempted from TSCA.

· **Carcinogenicity categories**

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

13463-67-7	Titanium dioxide	A4
8007-18-9	C.I. Pigment Yellow 53	A4

· **GHS label elements** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **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.

· **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)

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IMDG: International Maritime Code for Dangerous Goods  
DOT: US Department of Transportation  
IATA: International Air Transport Association  
ACGIH: American Conference of Governmental Industrial Hygienists  
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

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

USA