



Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
 - **Trade name:** **Flexitime Fast & Scan Easy Putty, ... Dynamix Putty, ... Dynamix Heavy Tray, ... Heavy Tray, ... Medium Flow, ... Light Flow**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**

No further relevant information available.

 - **Application of the substance / the mixture** Dental impression material
- **1.3 Details of the supplier of the safety data sheet**
 - **Manufacturer/Supplier:**
Kulzer GmbH
Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522
 - **Informing department:** E-Mail: msds@kulzer-dental.com
- **1.4 Emergency telephone number:** Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
 - **Classification according to Regulation (EC) No 1272/2008**
The product is not classified according to the CLP regulation.
- **2.2 Label elements**
 - **Labelling according to Regulation (EC) No 1272/2008** Void
 - **Hazard pictograms** Void
 - **Signal word** Void
 - **Hazard statements** Void
 - **Additional information:**
Safety data sheet available on request.
- **2.3 Other hazards -**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
 - **Description:**
2-component silicone impression material comprising base paste and matching catalyst paste for addition curing
 - **Dangerous components:** Void

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
 - **General information** No special measures required.
 - **After inhalation** Supply fresh air; consult doctor in case of symptoms.
 - **After skin contact** If skin irritation continues, consult a doctor.

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Flow**

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- **After eye contact** Rinse opened eye for several minutes under running water.
- **After swallowing**
Rinse out mouth and then drink plenty of water.
In case of persistent symptoms consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
 - **Suitable extinguishing agents**
CO₂, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.
Use fire fighting measures that suit the environment.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
 - **Protective equipment:** No special measures required.
 - **Additional information** -

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
- **6.4 Reference to other sections**
See Section 13 for information on disposal.
See Section 8 for information on personal protection equipment.

SECTION 7: Handling and storage

- **7.1 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.
- **7.2 Conditions for safe storage, including any incompatibilities**
 - **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.
- **7.3 Specific end use(s)** No further relevant information available.

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SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**

· **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.

· **DNELs**

13463-67-7 Titandioxid

Inhalative	worker industr., l.te., local	10 mg/m ³ (human)
	worker profess., l.te., local	10 mg/m ³ (human)

· **PNECs**

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freshwater	0.127 mg/l (nd)
marine water	1 mg/l (nd)
sedim., dw, fre.wat.	1000 mg/Kg (nd)
sedim., dw, mar.wat.	100 mg/Kg (nd)
soil,dw	100 mg/Kg (nd)

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

· **8.2 Exposure controls**

· **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 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

· **Eye protection:** not absolutely necessary

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· **Body protection:** Light weight protective clothing

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SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

· **Form:**

Pasty

· **Colour:**

Different according to colour

· **Smell:**

Odourless

· **Odour threshold:**

Not determined.

· **pH-value:**

Not determined.

· **Change in condition**

· **Melting point/Melting range:**

Not determined

· **Boiling point/Boiling range:**

Not determined

· **Flash point:**

Not applicable

· **Inflammability (solid, gaseous)**

Not applicable.

· **Ignition temperature:**

· **Decomposition temperature:**

Not determined.

· **Self-inflammability:**

Product is not selfigniting.

· **Danger of explosion:**

Product is not explosive.

· **Critical values for explosion:**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Steam pressure:**

Not determined.

· **Density**

Not determined

· **Relative density**

Not determined.

· **Vapour 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.

· **9.2 Other information**

No further relevant information available.



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SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
 - **Conditions to be avoided:** No decomposition if used and stored according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None
 - **Additional information:** -

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
 - **Acute toxicity** Based on available data, the classification criteria are not met.

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

Polydimethylsiloxan		
Oral	LD50	> 5000 mg/kg (rat)
Polydimethylsiloxan		
Oral	LD50	> 5000 mg/kg (rat)
Sensitisation	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:**
 - **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
 - **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - **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.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
 - **Aquatic toxicity:**
No further relevant information available.

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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)

- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
 - **Additional ecological information:**
 - **General notes:** Avoid transfer into the environment.
- **12.5 Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 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.

SECTION 14: Transport information

- **14.1 UN-Number**
 - **ADR, ADN, IMDG, IATA** Void
- **14.2 UN proper shipping name**
 - **ADR, ADN, IMDG, IATA** Void
- **14.3 Transport hazard class(es)**
 - **ADR, ADN, IMDG, IATA**
 - **Class** Void
- **14.4 Packing group**
 - **ADR, IMDG, IATA** Void
- **14.5 Environmental hazards:**
 - **Marine pollutant:** No
- **14.6 Special precautions for user** Not applicable.
- **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code** Not applicable.

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- | | |
|--|------|
| · Transport/Additional information: | - |
| · UN "Model Regulation": | Void |

SECTION 15: Regulatory information

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

SECTION 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.

· **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
- IATA: International Air Transport Association
- GHS: Globally Harmonised System of Classification and Labelling of Chemicals
- 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)
- DNEL: Derived No-Effect Level (REACH)
- PNEC: Predicted No-Effect Concentration (REACH)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative

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