

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 16.05.2018

Version number 8

Revision: 16.05.2018

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

- **1.1 Product identifier**
- **Trade name: Calibra Try-In Paste**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** Esthetic Resin Cement
- **Uses advised against** No further relevant information available.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
DENTSPLY DeTrey GmbH  
De-Trey-Str. 1  
D-78467 Konstanz  
GERMANY  
Tel.: +49-(0)7531-583-0  
Fax: +49-(0)7531-583-104  
email: KonstanzDEU.info-sdb@dentsplysirona.com
- **Further information obtainable from:**
  - Departement Research & Development for technical information
  - Departement Marketing & Sales for distribution of the safety data sheets
- **1.4 Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

### 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:**  
As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation (EC) 1272/2008.
- **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:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 56-81-5	glycerol	substance with a Community workplace exposure limit	50 – 100%
EINECS: 200-289-5			

- **Additional information** For the wording of the listed hazard phrases refer to section 16.

### 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 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.

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- **After swallowing**  
If symptoms persist consult doctor.  
Rinse out mouth and then drink plenty of water.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Information for doctor** 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**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents** Water with full jet.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** Self-contained respiratory protective device.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:**  
Dilute with plenty of water.  
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 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.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Observe normal care for working with chemicals.
- **Handling** Product is intended for dental use only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **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.

### SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.

#### · 8.1 Control parameters

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

CAS: 56-81-5 glycerol

WEL Long-term value: 10 mg/m<sup>3</sup>

- **Regulatory information** WEL: EH40/2011

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

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· **8.2 Exposure controls**· **Personal protective equipment**· **General protective and hygienic measures**

The usual precautionary measures are to be adhered to when handling chemicals.

· **Respiratory protection:** Not necessary if room is well-ventilated.

· **Protection of hands:**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **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.

Nitrile rubber, NBR

Recommended thickness of the material:  $\geq 0.11$  mm

Permeation: Level  $\geq 6$

· **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.

· **Eye protection:** Goggles recommended during refilling.

· **Body protection:** Protective work clothing.

**SECTION 9: Physical and chemical properties**

· **9.1 Information on basic physical and chemical properties**· **General Information**· **Appearance:**

Form: paste

Colour: Different according to colouring

· **Odour:** Mild

· **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

Melting point/freezing point: undetermined

Initial boiling point and boiling range: Undetermined.

· **Flash point:** Not applicable

· **Flammability (solid, gaseous)** Not applicable.

· **Ignition temperature:** Not applicable

· **Decomposition temperature:** Not determined.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

· **Explosion limits:**

Lower: 2.6 Vol %

Upper: 11.3 Vol %

· **Vapour pressure:** Not determined.

· **Density at 20 °C:** 1.4 g/cm<sup>3</sup>

· **Relative density** Not determined.

· **Vapour density** Not determined.

· **Evaporation rate** Not determined.

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- |  |  |
|--|--|
| · <b>Solubility in / Miscibility with Water:</b> | Partly soluble                             |
| · <b>Partition coefficient: n-octanol/water:</b> | Not determined.                            |
| · <b>Viscosity:</b>                              |  |
| dynamic:   | Not determined.                            |
| kinematic:                                       | Not determined.                            |
| · <b>Solvent content:</b>                        |  |
| Organic solvents:                                | 85.0 %                                     |
| Solids content:                                  | 15.0 %                                     |
| · <b>9.2 Other information</b>                   | No further relevant information available. |

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used 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:**
  - strong oxidants
  - strong bases
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known

### 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 relevant for classification:**

**CAS: 56-81-5 glycerol**

Oral	LD50	12,600 mg/kg (rat)
Dermal	LD50	> 18,700 mg/kg (rabbit)

- **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:**

**CAS: 56-81-5 glycerol**

LC50/24h	> 5,000 mg/l (Fish acute toxicity study)
EC50/24h	> 10,000 mg/L (daphnia magna)

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- **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:**

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- **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**

Can be disposed of with household garbage after solidification following consultation with the waste disposal facility operator and the pertinent authorities and adhering to the necessary technical regulations.

- **European waste catalogue**

18 01 07	chemicals other than those mentioned in 18 01 06
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- **Uncleaned packaging:**

- **Recommendation:** Disposal must be made according to official regulations.

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

### 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:** Not applicable.

- **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.

- **UN "Model Regulation":** Void

### SECTION 15: Regulatory information

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

- **Directive 2012/18/EU**

- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

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

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**SECTION 16: Other information**

*This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.*

*The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.*

*For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.*

· **Department issuing SDS:** Research & Development

· **Contact:** HotLine for urgent technical support: +49-7531-583-350

· **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)*

*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.**

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