

# Safety data sheet

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

Printing date 03.05.2018

Version number 7

Revision: 03.05.2018

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

- **1.1 Product identifier**
- **Trade name:** *Calibra Silane Coupling Agent*
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** *Silane Coupling Agent*
- **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**  
*Flam. Liq. 2 H225 Highly flammable liquid and vapour.*  
*Eye Irrit. 2 H319 Causes serious eye irritation.*
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
*The product is classified and labelled according to the CLP regulation.*
- **Hazard pictograms**



GHS02 GHS07

- **Signal word** *Danger*
- **Hazard statements**  
*H225 Highly flammable liquid and vapour.*  
*H319 Causes serious eye irritation.*
- **Precautionary statements**

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P241	Use explosion-proof [electrical/ventilating/lighting] equipment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
- **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.*

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· **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: 64-17-5 EINECS: 200-578-6	ethanol	Flam. Liq. 2, H225; Eye Irrit. 2, H319	50 – 100%
CAS: 67-64-1 EINECS: 200-662-2	acetone	Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	2.5 – 10%

· **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

· **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. If symptoms persist, consult a doctor.

· **After swallowing** 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

Wear protective equipment. Keep unprotected persons away.

Ensure adequate ventilation

#### · 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).

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

#### · 6.4 Reference to other sections

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

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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:**



Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Store away from oxidising agents.
- **Further information about storage conditions:** Store in cool, dry conditions in well sealed receptacles.
- **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: 64-17-5 ethanol

WEL Long-term value: 1920 mg/m<sup>3</sup>, 1000 ppm

CAS: 67-64-1 acetone

WEL Short-term value: 3620 mg/m<sup>3</sup>, 1500 ppmLong-term value: 1210 mg/m<sup>3</sup>, 500 ppm

- **Regulatory information** WEL: EH40/2011
- **Additional information:** The lists valid during the making were used as basis.

#### · 8.2 Exposure controls

##### · Personal protective equipment

##### · General protective and hygienic measures

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

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

##### · Protection of hands:



Protective gloves.

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.

Butyl rubber, BR

Recommended thickness of the material:  $\geq 0.7$  mm

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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:**

Tightly sealed goggles.

· **Body protection:** Protective work clothing.**SECTION 9: Physical and chemical properties**· **9.1 Information on basic physical and chemical properties**· **General Information**· **Appearance:**

Form:	Liquid
Colour:	Clear
Odour:	Alcohol-like
Odour threshold:	Not determined.

· **pH-value:** Not determined.· **Change in condition**

Melting point/freezing point:	undetermined
Initial boiling point and boiling range:	78 °C

· **Flash point:** 6 °C· **Flammability (solid, gaseous)** Not applicable.· **Ignition temperature:** 425 °C· **Decomposition temperature:** Not determined.· **Auto-ignition temperature:** Product is not selfigniting.· **Explosive properties:** Product is not explosive. However, formation of explosive air/vapour mixtures are possible.· **Explosion limits:**

Lower:	3.5 Vol %
Upper:	15 Vol %

· **Vapour pressure at 20 °C:** 59 hPa

Density at 20 °C:	0.8 g/cm <sup>3</sup>
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.

· **Solubility in / Miscibility with**

Water: Partly miscible

· **Partition coefficient: n-octanol/water:** Not determined.· **Viscosity:**

dynamic:	Not determined.
kinematic:	Not determined.

· **Solvent content:**

Organic solvents: 98.0 %

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## · 9.2 Other information

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: No further relevant information available.
- 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: 64-17-5 ethanol**

Oral	LD50	6,200 mg/kg (rat)
Inhalative	LC50/4 h	95.6 mg/l (rat)

**CAS: 67-64-1 acetone**

Oral	LD50	5,800 mg/kg (rat)
Dermal	LD50	20,000 mg/kg (rabbit)
Inhalative	LC50/4 h	76 mg/l (rat)

- Primary irritant effect:
- Skin corrosion/irritation Based on available data, the classification criteria are not met.
- Serious eye damage/irritation  
Causes serious eye irritation.
- 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: 64-17-5 ethanol**

LC50/48h	8,140 mg/l (Fish acute toxicity study)
EC50/48h	9,268 mg/L (daphnia magna)

**CAS: 67-64-1 acetone**

LC50/96h	5,540 mg/l (Fish acute toxicity study)
EC50/48h	6,100 mg/L (daphnia magna)

- 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.

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- **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**



Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- **European waste catalogue**

18 01 06*	chemicals consisting of or containing hazardous substances
HP 3	Flammable
HP 4	Irritant - skin irritation and eye damage

- **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, IMDG, IATA** UN1993
- **14.2 UN proper shipping name**  
· **ADR** 1993 FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL), ACETONE)  
· **IMDG** FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL), ACETONE)  
· **IATA** FLAMMABLE LIQUID, N.O.S. (ETHANOL, ACETONE)
- **14.3 Transport hazard class(es)**  
· **ADR**  
  - **Class** 3 (F1) Flammable liquids.
  - **Label** 3
- **IMDG, IATA**  
  - **Class** 3 Flammable liquids.
  - **Label** 3

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· <b>14.4 Packing group</b> · <b>ADR, IMDG, IATA</b>	II
· <b>14.5 Environmental hazards:</b>	Not applicable.
· <b>14.6 Special precautions for user</b> · <b>Danger code (Kemler):</b> · <b>EMS Number:</b> · <b>Stowage Category</b>	Warning: Flammable liquids. 33 F-E, S-E B
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	
· <b>ADR</b> · <b>Limited quantities (LQ)</b> · <b>Excepted quantities (EQ)</b>	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>Transport category</b> · <b>Tunnel restriction code</b>	2 D/E
· <b>IMDG</b> · <b>Limited quantities (LQ)</b> · <b>Excepted quantities (EQ)</b>	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>UN "Model Regulation":</b>	UN 1993 FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL), ACETONE), 3, II

\*

### 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.
- **Seveso category P5c** FLAMMABLE LIQUIDS
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5,000 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3, 40
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### 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.

- **Relevant phrases**  
H225 Highly flammable liquid and vapour.  
H319 Causes serious eye irritation.  
H336 May cause drowsiness or dizziness.
- **Department issuing SDS:** Research & Development
- **Contact:** HotLine for urgent technical support: +49-7531-583-350

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**· 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*

*Flam. Liq. 2: Flammable liquids – Category 2*

*Eye Irrit. 2: Serious eye damage/eye irritation – Category 2*

*STOT SE 3: Specific target organ toxicity (single exposure) – Category 3*

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

GB