

# Safety data sheet

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

Printing date 29.11.2016

Version number 8

Revision: 29.11.2016

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

- **1.1 Product identifier**
- **Trade name:** *Calibra Base*
- **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**  
*Skin Irrit. 2 H315 Causes skin irritation.*  
*Eye Irrit. 2 H319 Causes serious eye irritation.*  
*Skin Sens. 1 H317 May cause an allergic skin reaction.*

- **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**



GHS07

- **Signal word** *Warning*
- **Hazard-determining components of labelling:**  
*(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]bismethacrylate*  
*Ethoxylated Bisphenol A Dimethacrylate*  
*2,2'-Ethylendioxydiethyldimethacrylate*
- **Hazard statements**  
*H315 Causes skin irritation.*  
*H319 Causes serious eye irritation.*  
*H317 May cause an allergic skin reaction.*
- **Precautionary statements**

<i>P261</i>	<i>Avoid breathing dust/fume/gas/mist/vapours/spray.</i>
<i>P280</i>	<i>Wear protective gloves/protective clothing/eye protection/face protection.</i>
<i>P305+P351+P338</i>	<i>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</i>
<i>P333+P313</i>	<i>If skin irritation or rash occurs: Get medical advice/attention.</i>
<i>P337+P313</i>	<i>If eye irritation persists: Get medical advice/attention.</i>
<i>P501</i>	<i>Dispose of contents/container in accordance with local/regional/national/international regulations.</i>

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**Trade name: Calibra Base**

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**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 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: 1565-94-2 EINECS: 216-367-7	(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-<25%
CAS: 24448-20-2	Ethoxylated Bisphenol A Dimethacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	10-<25%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-Ethylendioxydiethyldimethacrylat ⚠ Skin Sens. 1, H317	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****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. Then consult a doctor.**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**

Formation of toxic gases is possible during heating or in case of fire.

**5.3 Advice for firefighters****Protective equipment:** No special measures required.

### SECTION 6: Accidental release measures

**6.1 Personal precautions, protective equipment and emergency procedures** Wear protective clothing.**6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

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- **6.3 Methods and material for containment and cleaning up:**  
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.  
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:**  
Keep receptacle tightly sealed.  
Protect from exposure to the light.
- **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:**  
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 valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures**  
Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing  
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.

Natural rubber, NR

Recommended thickness of the material:  $\geq 0.12$  mm

Permeation: Level  $\geq 1$

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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.
- **Eye protection:** Safety glasses
- **Body protection:** Protective work clothing.

## SECTION 9: Physical and chemical properties

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

#### · General Information

##### · Appearance:

Form:	Pasty
Colour:	According to product specification
Odour:	Characteristic
Odour threshold:	Not determined.

· **pH-value:** Not applicable.

#### · Change in condition

Melting point/Melting range:	undetermined
Boiling point/Boiling range:	Undetermined.

· **Flash point:** Not applicable

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

· **Ignition temperature:** Not applicable

· **Decomposition temperature:** Not determined.

· **Self-igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

#### · Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

· **Vapour pressure:** Not applicable.

Density:	Not determined
Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.

#### · Solubility in / Miscibility with

Water:	Insoluble
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· **Partition coefficient (n-octanol/water):** Not determined.

#### · Viscosity:

dynamic:	Not applicable.
kinematic:	Not applicable.

#### · Solvent content:

Organic solvents:	0.0 %
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Solids content:	67.0 %
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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.

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- **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: 1565-94-2 (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]bismethacrylate**

Oral	LD50	>5000 mg/kg (rat)
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**CAS: 109-16-0 2,2'-Ethylendioxydiethyldimethacrylat**

Oral	LD50	>5000 mg/kg (rat)
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Dermal	LD50	>2000 mg/kg (mouse)
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- **Primary irritant effect:**
- **Skin corrosion/irritation**  
The unpolymerized product may be irritant to the skin for susceptible persons.  
Causes skin irritation.
- **Serious eye damage/irritation**  
Causes serious eye irritation.
- **Respiratory or skin sensitisation**  
Repeated or prolonged contact with the not polymerized product may cause sensitization for acrylates / methacrylates.  
May cause an allergic skin reaction.
- **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: 109-16-0 2,2'-Ethylendioxydiethyldimethacrylat**

LC50/96h	16.4 mg/l (Fish acute toxicity study)
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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 product to reach ground water, water course or sewage system.  
Danger to drinking water if even small quantities leak into the ground.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

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### 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 4	Irritant - skin irritation and eye damage
HP 13	Sensitising

- Uncleaned packaging:
- 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:   | 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.

### 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.

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· **Relevant phrases***H315 Causes skin irritation.**H317 May cause an allergic skin reaction.**H319 Causes serious eye irritation.**H335 May cause respiratory irritation.*· **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**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Eye Irrit. 2: Serious eye damage/eye irritation – Category 2**Skin Sens. 1: Skin sensitisation – Category 1**STOT SE 3: Specific target organ toxicity (single exposure) – Category 3*· **\* Data compared to the previous version altered.**

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# Safety data sheet

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

Printing date 14.02.2017

Version number 7

Revision: 14.02.2017

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

- **1.1 Product identifier**
- **Trade name: Prime & Bond NT**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** Adhesive
- **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.
Skin Irrit. 2	H315 Causes skin irritation.
Eye Irrit. 2	H319 Causes serious eye irritation.
Skin Sens. 1	H317 May cause an allergic skin reaction.
STOT SE 3	H336 May cause drowsiness or dizziness.
Aquatic Chronic 3	H412 Harmful to aquatic life with long lasting effects.

- **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-determining components of labelling:**  
acetone  
Di(ethylene glycol) dimethacrylate
- **Hazard statements**
  - H225 Highly flammable liquid and vapour.
  - H315 Causes skin irritation.
  - H319 Causes serious eye irritation.
  - H317 May cause an allergic skin reaction.
  - H336 May cause drowsiness or dizziness.
  - H412 Harmful to aquatic life with long lasting effects.
- **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.

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**Trade name: Prime & Bond NT**

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P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/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.

P405 Store locked up.

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 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: 67-64-1 EINECS: 200-662-2	acetone ⚠ Flam. Liq. 2, H225; ⚠ Eye Irrit. 2, H319; STOT SE 3, H336	50-100%
CAS: 105883-40-7	Urethane Dimethacrylate Resin ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	10-25%
CAS: 87699-25-0	Dipentaerythritol pentaacrylate phosphate ⚠ Aquatic Chronic 2, H411; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	2.5-<10%
CAS: 2358-84-1	Di(ethylene glycol) dimethacrylate ⚠ Skin Sens. 1, H317	2.5-<10%
CAS: 3290-92-4	propylidynetrimethyl trimethacrylate ⚠ Aquatic Chronic 2, H411	0.25-<2.5%
CAS: 128-37-0 EINECS: 204-881-4	2,6-di-tert-butyl-p-cresol ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410	0.25-<2.5%

· **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** Immediately remove any clothing soiled by the product.

· **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** If symptoms persist consult doctor.

· **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.

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### 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.
- **6.2 Environmental precautions:**  
Inform respective authorities in case of seepage into water course or sewage system.  
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).  
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.  
See Section 13 for disposal information.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**  
Observe normal care for working with chemicals.  
Prevent formation of aerosols.  
Ensure good ventilation/exhaustion at the workplace.
- **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.  
Store only in the original receptacle.
- **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.

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### · 8.1 Control parameters

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

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

WEL	Short-term value: 3620 mg/m <sup>3</sup> , 1500 ppm Long-term value: 1210 mg/m <sup>3</sup> , 500 ppm
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#### · **Regulatory information WEL: EH40/2011**

#### · **DNELs**

##### **CAS: 128-37-0 2,6-di-tert-butyl-p-cresol**

Inhalative	DNEL Werte	3.5 mg/m <sup>3</sup> bw/day (rat)
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#### · **Additional information:** The lists valid during the making were used as basis.

### · 8.2 Exposure controls

#### · **Personal protective equipment**

##### · **General protective and hygienic measures**

Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing  
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.  
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

##### · **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.

Natural rubber, NR

Recommended thickness of the material:  $\geq 0.75$  mm

Permeation: Level  $\geq 2$

##### · **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:**

<b>Form:</b>	Fluid
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<b>Colour:</b>	Yellow
<b>· Odour:</b>	Characteristic
<b>· Odour threshold:</b>	Not determined.
<b>· pH-value:</b>	Not determined.
<b>· Change in condition</b>	
<b>Melting point/freezing point:</b>	undetermined
<b>Initial boiling point and boiling range:</b>	60 °C
<b>· Flash point:</b>	-19 °C (c.c. Abel)
<b>· Flammability (solid, gaseous)</b>	Not applicable.
<b>· Ignition temperature:</b>	465 °C
<b>· Decomposition temperature:</b>	Not determined.
<b>· Auto-ignition temperature:</b>	Product is not selfigniting.
<b>· Explosive properties:</b>	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
<b>· Explosion limits:</b>	
<b>Lower:</b>	2.6 Vol %
<b>Upper:</b>	12.8 Vol %
<b>· Vapour pressure at 20 °C:</b>	233 hPa
<b>· Density at 20 °C:</b>	0.9 g/cm <sup>3</sup>
<b>· Relative density</b>	Not determined.
<b>· Vapour density</b>	Not determined.
<b>· Evaporation rate</b>	Not determined.
<b>· Solubility in / Miscibility with</b>	
<b>Water:</b>	Partly miscible
<b>· Partition coefficient: n-octanol/water:</b>	Not determined.
<b>· Viscosity:</b>	
<b>dynamic:</b>	Not determined.
<b>kinematic:</b>	Not determined.
<b>· Solvent content:</b>	
<b>Organic solvents:</b>	67.0 %
<b>    Solids content:</b>	3.0 %
<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:** 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.

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**· LD/LC50 values relevant for classification:****CAS: 67-64-1 acetone**

Oral	LD50	5800 mg/kg (rat)
Dermal	LD50	20000 mg/kg (rabbit)
Inhalative	LC50/4 h	76 mg/l (rat)

**CAS: 3290-92-4 propylidynetrimethyl trimethacrylate**

Oral	LD50	>2000 mg/kg (rat)
------	------	-------------------

**CAS: 128-37-0 2,6-di-tert-butyl-p-cresol**

Oral	LD50	2930 mg/kg (rat)
Dermal	LD50	> 2000 mg/kg (rabbit)

**· Primary irritant effect:****· Skin corrosion/irritation**

Causes skin irritation.

**· Serious eye damage/irritation**

Causes serious eye irritation.

**· Respiratory or skin sensitisation**

Repeated or prolonged contact with the not polymerized product may cause sensitization for acrylates / methacrylates.

May cause an allergic skin reaction.

**· 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**

May cause drowsiness or dizziness.

**· 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: 67-64-1 acetone**

LC50/96h	5540 mg/l (Fish acute toxicity study)
EC50/48h	6100 mg/L (daphnia magna)

**CAS: 3290-92-4 propylidynetrimethyl trimethacrylate**

LC50/96h	2 mg/l (Fish acute toxicity study)
EC50/48h	>9.22 mg/L (daphnia magna)

**CAS: 128-37-0 2,6-di-tert-butyl-p-cresol**

LC50/48h	>0.57 mg/l (daphnia magna)
LC50/96h	>0.42 mg/l (Fish acute toxicity study)
EC50/72h	>0.42 mg/l (Algae, growth inhibition test)

**· 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.**· Ecotoxicological effects:****· Remark:** Harmful to fish**· Additional ecological information:****· General notes:**

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

Harmful to aquatic organisms

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- **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
HP 5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity
HP 13	Sensitising
HP 14	Ecotoxic

- **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** UN1090
- **14.2 UN proper shipping name**  
· **ADR** 1090 ACETONE mixture  
· **IMDG, IATA** ACETONE, MIXTURE
- **14.3 Transport hazard class(es)**  
· **ADR**  

  - **Class** 3 (F1) Flammable liquids.
  - **Label** 3
- **IMDG, IATA**  

  - **Class** 3 Flammable liquids.
  - **Label** 3
- **14.4 Packing group**  
· **ADR, IMDG, IATA** II

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· <b>14.5 Environmental hazards:</b>	Not applicable.
· <b>14.6 Special precautions for user</b>	Warning: Flammable liquids.
· <b>Danger code (Kemler):</b>	33
· <b>EMS Number:</b>	F-E,S-D
· <b>Stowage Category</b>	E
· <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>	1L
· <b>Excepted quantities (EQ)</b>	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>Transport category</b>	2
· <b>Tunnel restriction code</b>	D/E
· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	1L
· <b>Excepted quantities (EQ)</b>	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>UN "Model Regulation":</b>	UN 1090 ACETONE MIXTURE, 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
- **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.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H336 May cause drowsiness or dizziness.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.

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*H411 Toxic to aquatic life with long lasting effects.*

- **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)

DNEL: Derived No-Effect Level (REACH)

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

Skin Irrit. 2: Skin corrosion/irritation – Category 2

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

Skin Sens. 1: Skin sensitisation – Category 1

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

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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

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# Safety data sheet

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

Printing date 08.04.2015

Version number 3

Revision: 08.04.2015

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

- **1.1 Product identifier**
- **Trade name: Self Cure Activator**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** Activator
- **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@dentsply.com
- **Further information obtainable from:**
  - Departement Analytical Research / 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.  
 Skin Irrit. 2 H315 Causes skin irritation.  
 Eye Irrit. 2 H319 Causes serious eye irritation.  
 Skin Sens. 1 H317 May cause an allergic skin reaction.  
 STOT SE 3 H336 May cause drowsiness or dizziness.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
 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 1272/2008.  
 The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**  
  
GHS02 GHS07
- **Signal word** Danger
- **Hazard-determining components of labelling:**  
acetone  
2-hydroxyethyl methacrylate
- **Hazard statements**  
 H225 Highly flammable liquid and vapour.  
 H315 Causes skin irritation.  
 H319 Causes serious eye irritation.  
 H317 May cause an allergic skin reaction.  
 H336 May cause drowsiness or dizziness.

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

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**Trade name: Self Cure Activator**

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**· 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.
- P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/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.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

**· 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: 67-64-1 EINECS: 200-662-2	acetone ⚠ Flam. Liq. 2, H225; ⚠ Eye Irrit. 2, H319; STOT SE 3, H336	50-100%
CAS: 105883-40-7	Urethane Dimethacrylate Resin ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	10-<25%
CAS: 868-77-9 EINECS: 212-782-2	2-hydroxyethyl methacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	3-<10%
CAS: 75980-60-8 EINECS: 278-355-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide ⚠ Repr. 2, H361f; ⚠ Aquatic Chronic 2, H411	1-≤2.5%

- **Additional information** For the wording of the listed risk 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** If symptoms persist consult doctor.
- **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>, sand, extinguishing powder. Do not use water.
- **For safety reasons unsuitable extinguishing agents** Water.

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- **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.
- **6.2 Environmental precautions:**  
Prevent seepage into sewage system, workpits and cellars.  
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).  
Ensure adequate ventilation.  
Do not flush with water or aqueous cleansing agents
- **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**  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.  
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:**  
Keep receptacle tightly sealed.  
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.

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**Trade name: Self Cure Activator**

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### · 8.1 Control parameters

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

##### **67-64-1 acetone**

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

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

### · 8.2 Exposure controls

#### · **Personal protective equipment**

##### · **General protective and hygienic measures**

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

##### · **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

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**

Butyl rubber, BR

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

Permeation: Level  $\geq 6$

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.

##### · **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:**

<b>Form:</b>	Fluid
<b>Colour:</b>	Light yellow
<b>Odour:</b>	Acetone-like

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· <b>Odour threshold:</b>	Not determined.
· <b>pH-value at 20 °C:</b>	7
· <b>Change in condition</b>	
<b>Melting point/Melting range:</b>	undetermined
<b>Boiling point/Boiling range:</b>	56 °C (Aceton)
· <b>Flash point:</b>	2 °C (Pensky-Marten Closed Cup)
· <b>Flammability (solid, gaseous)</b>	Not applicable.
· <b>Ignition temperature:</b>	465 °C
· <b>Decomposition temperature:</b>	Not determined.
· <b>Self-igniting:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· <b>Explosion limits:</b>	
<b>Lower:</b>	2.6 Vol % (Aceton)
<b>Upper:</b>	12.8 Vol % (Aceton)
· <b>Vapour pressure at 20 °C:</b>	233 hPa
· <b>Density at 20 °C:</b>	0.9 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with Water:</b>	Partly miscible
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>dynamic:</b>	Not determined.
<b>kinematic:</b>	Not determined.
· <b>Solvent content:</b>	
<b>Organic solvents:</b>	61.0 %
<b>Water:</b>	16.0 %
<b>Solids content:</b>	4.0 %
· <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:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known

GB

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Trade name: Self Cure Activator

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### SECTION 11: Toxicological information

#### · 11.1 Information on toxicological effects

##### · Acute toxicity:

##### · LD/LC50 values relevant for classification:

##### ATE (Acute Toxicity Estimates)

Inhalative	LC50/4 h	125 mg/l
------------	----------	----------

##### 67-64-1 acetone

Oral	LD50	5800 mg/kg (rat)
Dermal	LD50	20000 mg/kg (rabbit)
Inhalative	LC50/4 h	76 mg/l (rat)

##### 868-77-9 2-hydroxyethyl methacrylate

Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	>3000 mg/kg (rabbit)

##### 75980-60-8 Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Oral	LD50	5000 mg/kg (rat)
------	------	------------------

##### · Primary irritant effect:

· **on the skin:** Irritant to skin and mucous membranes.

· **on the eye:** Irritating effect.

· **Sensitisation:** Sensitisation possible through skin contact.

##### · Additional toxicological information:

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

Irritant

### SECTION 12: Ecological information

#### · 12.1 Toxicity

##### · Aquatic toxicity:

##### 67-64-1 acetone

EC50/48h	6100 mg/L (daphnia magna)
LC50/96h	5540 mg/l (Fish acute toxicity study)

##### 868-77-9 2-hydroxyethyl methacrylate

EC50/48h	380 mg/L (daphnia magna)
LC50/96h	>100 mg/l (Fish acute toxicity study)

##### 75980-60-8 Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

LC50/48h	6.53 mg/l (Fish acute toxicity study)
----------	---------------------------------------

· **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 product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

##### · 12.5 Results of PBT and vPvB assessment

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

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· 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 dangerous substances

· Uncleaned packaging:

· Recommendation: Disposal must be made according to official regulations.

### SECTION 14: Transport information

· 14.1 UN-Number

· ADR, IMDG, IATA

UN1090

· 14.2 UN proper shipping name

· ADR

1090 ACETONE, mixture

· IMDG, IATA

ACETONE mixture

· 14.3 Transport hazard class(es)

· ADR



· Class

3 (F1) Flammable liquids.

· Label

3

· IMDG, IATA



· Class

3 Flammable liquids.

· Label

3

· 14.4 Packing group

· ADR, IMDG, IATA

II

· 14.5 Environmental hazards:

· Marine pollutant:

No

· 14.6 Special precautions for user

Warning: Flammable liquids.

· Danger code (Kemler):

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**Trade name: Self Cure Activator**

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· <b>EMS Number:</b>	<u>F-E,S-E</u>
· <b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	
· <b>ADR</b>	
· <b>Limited quantities (LQ)</b>	1L
· <b>Excepted quantities (EQ)</b>	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>Transport category</b>	2
· <b>Tunnel restriction code</b>	D/E
· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	1L
· <b>Excepted quantities (EQ)</b>	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>UN "Model Regulation":</b>	UN1090, ACETONE mixture, 3, II

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.
- **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.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H336 May cause drowsiness or dizziness.

H361f Suspected of damaging fertility.

H411 Toxic to aquatic life with long lasting effects.

- **Department issuing MSDS:** Analytical Research

- **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

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

Printing date 08.04.2015

Version number 3

Revision: 08.04.2015

**Trade name: Self Cure Activator**

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*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**Flam. Liq. 2: Flammable liquids, Hazard Category 2**Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2**Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2**Skin Sens. 1: Sensitisation - Skin, Hazard Category 1**Repr. 2: Reproductive toxicity, Hazard Category 2**STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3**Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2***. \* Data compared to the previous version altered.**

GB

# Safety data sheet

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

Printing date 05.08.2016

Version number 6

Revision: 05.08.2016

### 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.*
- **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

- **Signal word** *Danger*
- **Hazard statements**  
*H225 Highly flammable liquid and vapour.*
- **Precautionary statements**

<i>P210</i>	<i>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</i>
<i>P241</i>	<i>Use explosion-proof electrical/ventilating/lighting/equipment.</i>
<i>P280</i>	<i>Wear protective gloves/protective clothing/eye protection/face protection.</i>
<i>P303+P361+P353</i>	<i>IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.</i>
<i>P403+P235</i>	<i>Store in a well-ventilated place. Keep cool.</i>
<i>P501</i>	<i>Dispose of contents/container in accordance with local/regional/national/international regulations.</i>
- **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 1272/2008.*
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*

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# Safety data sheet

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

Printing date 05.08.2016

Version number 6

Revision: 05.08.2016

Trade name: Calibra Silane Coupling Agent

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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	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.· **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.

See Section 13 for disposal information.

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# Safety data sheet

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

Printing date 05.08.2016

Version number 6

Revision: 05.08.2016

Trade name: Calibra Silane Coupling Agent

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### 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.
- **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:  $\geq 0.7$  mmPermeation: 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.

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**Trade name: Calibra Silane Coupling Agent**

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· **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/Melting range:	undetermined
Boiling point/Boiling range:	78 °C

· **Flash point:** 6 °C (c.c. Abel)· **Flammability (solid, gaseous)** Not applicable.· **Ignition temperature:** 425 °C· **Decomposition temperature:** Not determined.· **Self-igniting:** Product is not selfigniting.· **Danger of explosion:** Product is not explosive. However, formation of explosive air/vapour mixtures are possible.· **Explosion limits:**

Lower:	3.5 Vol %
Upper:	15.0 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 %

· **9.2 Other information** No further relevant information available.

### SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.

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**Trade name: Calibra Silane Coupling Agent**

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- **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	6200 mg/kg (rat)
Inhalative	LC50/4 h	95.6 mg/l (rat)

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

Oral	LD50	5800 mg/kg (rat)
Dermal	LD50	20000 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** 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: 64-17-5 ethanol**

LC50/48h	8140 mg/l (Fish acute toxicity study)
EC50/48h	9268 mg/L (daphnia magna)

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

LC50/96h	5540 mg/l (Fish acute toxicity study)
EC50/48h	6100 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.
- **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.

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Trade name: Calibra Silane Coupling Agent

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· 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

- 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	UN1993
· ADR, IMDG, IATA	
· 14.2 UN proper shipping name	1993 FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL), ACETONE)
· ADR	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
· 14.4 Packing group	
· ADR, IMDG, IATA	II
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Warning: Flammable liquids.
· Danger code (Kemler):	33
· EMS Number:	F-E, <u>S-E</u>

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**Trade name: Calibra Silane Coupling Agent**

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· <b>Stowage Category</b>	<b>B</b>
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	<b>Not applicable.</b>
· <b>Transport/Additional information:</b>	
· <b>ADR</b>	
· <b>Limited quantities (LQ)</b>	<b>IL</b>
· <b>Excepted quantities (EQ)</b>	<b>Code: E2</b> <b>Maximum net quantity per inner packaging: 30 ml</b> <b>Maximum net quantity per outer packaging: 500 ml</b>
· <b>Transport category</b>	<b>2</b>
· <b>Tunnel restriction code</b>	<b>D/E</b>
· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	<b>IL</b>
· <b>Excepted quantities (EQ)</b>	<b>Code: E2</b> <b>Maximum net quantity per inner packaging: 30 ml</b> <b>Maximum net quantity per outer packaging: 500 ml</b>
· <b>UN "Model Regulation":</b>	<b>UN 1993 FLAMMABLE LIQUID, N.O.S. (ETHANOL (ETHYL ALCOHOL), ACETONE), 3, II</b>

\*

### 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
- **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

#### · **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

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CAS: Chemical Abstracts Service (division of the American Chemical Society)

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**Trade name: Calibra Silane Coupling Agent**

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*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