

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 16.05.2018

Version number 2

Revision: 16.05.2018

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

- **1.1 Product identifier**
- **Trade name:** *Calibra Veneer*
- **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'-ethylenedioxydiethyl dimethacrylate
- **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 / 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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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: 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'-ethylenedioxydiethyl dimethacrylate 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. If symptoms persist, 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**CO₂, 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.

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- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
 Dispose contaminated material as waste according to item 13.
 Ensure adequate ventilation.
 Pick up mechanically.
- **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

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*Recommended thickness of the material: ≥ 0.12 mm**Permeation: Level ≥ 1* **· 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/freezing point:** undetermined**Initial boiling point and boiling range:** Undetermined.**· Flash point:** Not applicable**· Flammability (solid, gaseous)** Not determined.**· 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:** 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**· Partition coefficient: n-octanol/water:** Not determined.**· Viscosity:****dynamic:** Not applicable.**kinematic:** Not applicable.**· Solvent content:****Organic solvents:** 0.0 %**Solids content:** 67.0 %**· 9.2 Other information** No further relevant information available.

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SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **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	> 5,000 mg/kg (rat)
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CAS: 109-16-0 2,2'-ethylenedioxydiethyl dimethacrylate

Oral	LD50	> 5,000 mg/kg (rat)
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Dermal	LD50	> 2,000 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'-ethylenedioxydiethyl dimethacrylate

LC50/96h	16.4 mg/l (Fish acute toxicity study)
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EC50/72h	> 100 mg/l (Pseudokirchnerella subcapitata)
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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.

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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 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 | Void |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | Void |
| · 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.

- **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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Printing date 25.08.2016

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Revision: 25.08.2016

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

- **1.1 Product identifier**
- **Trade name:** *Calibra Ceram Catalyst*
- **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.
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**



GHS07

- **Signal word** *Warning*
- **Hazard-determining components of labelling:**
Urethane modified Bis-GMA dimethacrylate resin
2,2'-Ethylendioxydiethylidimethacrylat
- **Hazard statements**
 - H315 Causes skin irritation.*
 - H319 Causes serious eye irritation.*
 - H317 May cause an allergic skin reaction.*
 - H412 Harmful to aquatic life with long lasting effects.*
- **Precautionary statements**

P261	<i>Avoid breathing dust/fume/gas/mist/vapours/spray.</i>
P280	<i>Wear protective gloves/protective clothing/eye protection/face protection.</i>
P273	<i>Avoid release to the environment.</i>
P305+P351+P338	<i>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</i>
P321	<i>Specific treatment (see on this label).</i>
P501	<i>Dispose of contents/container in accordance with local/regional/national/international regulations.</i>

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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: 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: 105883-40-7	Urethane Dimethacrylate Resin ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	2.5-<10%
CAS: 41637-38-1	Urethane modified Bis-GMA dimethacrylate resin ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	2.5-<10%
CAS: 3290-92-4	propylidynetrimethyl trimethacrylate ⚠ Aquatic Chronic 2, H411	2.5-<10%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-Ethylendioxydiethyldimethacrylat ⚠ Skin Sens. 1, H317	2.5-<10%
CAS: 80-15-9 EINECS: 201-254-7	α,α -dimethylbenzyl hydroperoxide ⚠ Org. Perox. E, H242; ⚠ Acute Tox. 3, H331; ⚠ STOT RE 2, H373; ⚠ Skin Corr. 1B, H314; ⚠ Aquatic Chronic 2, H411; ⚠ Acute Tox. 4, H302; Acute Tox. 4, H312	0.1-<1%
CAS: 79-10-7 EINECS: 201-177-9	acrylic acid ⚠ Flam. Liq. 3, H226; ⚠ Skin Corr. 1A, H314; ⚠ Aquatic Acute 1, H400; ⚠ Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; STOT SE 3, H335	0.1-<1%

• **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** 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**

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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- **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 clothing.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** 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**
Ensure good ventilation/exhaustion at the workplace.
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:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep receptacle tightly sealed.
Protect from heat and direct sunlight.
- **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.

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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**

Natural rubber, NR

Recommended thickness of the material: ≥ 0.12 mm

Permeation: Level ≥ 1

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:**

Form: paste

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:** 360 °C

· **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 %
- **Solids content:** 60.0 %
- **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: 3290-92-4 propylidynetrimethyl trimethacrylate

Oral	LD50	>2000 mg/kg (rat)
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CAS: 109-16-0 2,2'-Ethylendioxydiethyldimethacrylat

Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (mouse)

CAS: 80-15-9 α,α -dimethylbenzyl hydroperoxide

Oral	LD50	382 mg/kg (rat)
Dermal	LD50	500 mg/kg (rat)
Inhalative	LC50/4 h	220 mg/l (rat)

CAS: 79-10-7 acrylic acid

Oral	LD50	1500 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (rabbit)
Inhalative	LC50/4 h	1.5 mg/l (ATE)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation**
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.

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· **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· **12.1 Toxicity**· **Aquatic toxicity:****CAS: 3290-92-4 propylidynetrimethyl trimethacrylate**

LC50/96h 2 mg/l (Fish acute toxicity study)

EC50/48h >9.22 mg/L (daphnia magna)

CAS: 109-16-0 2,2'-Ethylendioxydiethyldimethacrylat

LC50/96h 16.4 mg/l (Fish acute toxicity study)

CAS: 79-10-7 acrylic acid

LC50/96h 27 mg/l (Fish acute toxicity study)

EC50/48h 95 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.· **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

· **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 4 Irritant - skin irritation and eye damage

HP 14 Ecotoxic

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

SECTION 14: Transport information

· **14.1 UN-Number**· **ADR, ADN, IMDG, IATA**

Void

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- | | |
|---|-----------------|
| · 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.*

- **Relevant phrases**
H226 Flammable liquid and vapour.
H242 Heating may cause a fire.
H302 Harmful if swallowed.
H312 Harmful in contact with skin.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H331 Toxic if inhaled.
H332 Harmful if inhaled.
H335 May cause respiratory irritation.
H373 May cause damage to organs through prolonged or repeated exposure.
H400 Very toxic to aquatic life.
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

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*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. 3: Flammable liquids – Category 3**Org. Perox. E: Organic peroxides – Type E/F**Acute Tox. 4: Acute toxicity – Category 4**Acute Tox. 3: Acute toxicity – Category 3**Skin Corr. 1A: Skin corrosion/irritation – Category 1A**Skin Corr. 1B: Skin corrosion/irritation – Category 1B**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**STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2**Aquatic Acute 1: Hazardous to the aquatic environment - acute 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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SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
 - **Trade name:** *Calibra Ceram 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.
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**



GHS07

- **Signal word** *Warning*
- **Hazard-determining components of labelling:**
 - 2-hydroxyethyl methacrylate*
 - Urethane modified Bis-GMA dimethacrylate resin*
 - 3-(Acryloyloxy)-2-hydroxypropyl methacrylate*
 - 2,2'-Ethylenedioxydiethyldimethacrylat*
- **Hazard statements**
 - H315 Causes skin irritation.*
 - H319 Causes serious eye irritation.*
 - H317 May cause an allergic skin reaction.*
 - H412 Harmful to aquatic life with long lasting effects.*
- **Precautionary statements**
 - P261 Avoid breathing dust/fume/gas/mist/vapours/spray.*
 - P280 Wear protective gloves/protective clothing/eye protection/face protection.*
 - P273 Avoid release to the environment.*
 - P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*
 - P321 Specific treatment (see on this label).*

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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: 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	2.5- <10%
CAS: 41637-38-1	Urethane modified Bis-GMA dimethacrylate resin ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	2.5- <10%
CAS: 105883-40-7	Urethane Dimethacrylate Resin ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	2.5- <10%
CAS: 3290-92-4	propylidynetrimethyl trimethacrylate ⚠ Aquatic Chronic 2, H411	2.5- <10%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-Ethylendioxydiethyldimethacrylat ⚠ Skin Sens. 1, H317	2.5- <10%
CAS: 1709-71-3	3-(Acryloyloxy)-2-hydroxypropyl methacrylate ⚠ Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; Skin Sens. 1, H317	1- ≤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.

SECTION 5: Firefighting measures

· **5.1 Extinguishing media**

· **Suitable extinguishing agents**

CO₂, 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.

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- **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 clothing.
- **6.2 Environmental precautions:** 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).
Pick up mechanically.
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**
Ensure good ventilation/exhaustion at the workplace.
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:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep receptacle tightly sealed.
Protect from heat and direct sunlight.
- **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.

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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: ≥ 0.12 mm

Permeation: Level ≥ 1

· **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: paste

Colour: According to product specification

· **Odour:** Characteristic

· **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

Melting point/Melting range: undetermined

Boiling point/Boiling range: Undetermined.

· **Flash point:** Not applicable

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

· **Ignition temperature:** 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 determined.

· **Density:** Not determined

· **Relative density** Not determined.

· **Vapour density** Not determined.

· **Evaporation rate** Not determined.

· **Solubility in / Miscibility with**

Water: Not miscible or difficult to mix

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- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
 - dynamic:** Not determined.
 - kinematic:** Not determined.
- **Solvent content:**
 - Organic solvents:** 0.0 %
- **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: 868-77-9 2-hydroxyethyl methacrylate

Oral LD50 >5000 mg/kg (rat)

Dermal LD50 >3000 mg/kg (rabbit)

CAS: 3290-92-4 propylidynetrimethyl trimethacrylate

Oral LD50 >2000 mg/kg (rat)

CAS: 109-16-0 2,2'-Ethylendioxydiethyldimethacrylat

Oral LD50 >5000 mg/kg (rat)

Dermal LD50 >2000 mg/kg (mouse)

CAS: 1709-71-3 3-(Acryloyloxy)-2-hydroxypropyl methacrylate

Oral LD50 500 mg/kg (ATE)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **CMR effects (carcinogenity, 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.

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Trade name: Calibra Ceram Base

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SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

CAS: 868-77-9 2-hydroxyethyl methacrylate

LC50/96h >100 mg/l (Fish acute toxicity study)

EC50/48h 380 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: 109-16-0 2,2'-Ethylendioxydiethyldimethacrylat

LC50/96h 16.4 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.

· Ecotoxicological effects:

· **Remark:** Harmful to fish

· Additional ecological information:

· General notes:

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

Harmful to aquatic organisms

· 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 4 Irritant - skin irritation and eye damage

HP 14 Ecotoxic

· 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

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· 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.
- **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**
H302 Harmful if swallowed.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 4: Acute toxicity – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

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*Skin Sens. 1: Skin sensitisation – Category 1**STOT SE 3: Specific target organ toxicity (single exposure) – Category 3**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.**

GB

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Printing date 29.03.2018

Version number 4

Revision: 29.03.2018

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

- **1.1 Product identifier**
- **Trade name:** *De Trey Conditioner 36 / De Trey Etch*
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** *Discharging 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**
*Skin Corr. 1B H314 Causes severe skin burns and eye damage.
 Eye Dam. 1 H318 Causes serious eye damage.*
- **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**



GHS05

- **Signal word** *Danger*
- **Hazard-determining components of labelling:**
phosphoric acid
- **Hazard statements**
H314 Causes severe skin burns and eye damage.
- **Precautionary statements**
 - P260 Do not breathe dusts or mists.*
 - 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.*
 - P310 Immediately call a POISON CENTER/doctor.*
 - 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 (EC) 1272/2008.

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Trade name: De Trey Conditioner 36 / De Trey Etch

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- **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: 7664-38-2	phosphoric acid	Met. Corr.1, H290; Skin Corr. 1B, H314	25 – 50%
EINECS: 231-633-2			

- **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. Then consult a doctor.
- **After swallowing**
 Drink plenty of water and provide fresh air. Call for a doctor immediately.
 Do not induce vomiting; call for medical help immediately.
- **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**
 CO₂, 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:** No special measures required.

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:** 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).
 Use neutralising agent.
 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.
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
- **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.
Store receptacle in a well ventilated area.
- **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: 7664-38-2 phosphoric acid

WEL	Short-term value: 2 mg/m ³ Long-term value: 1 mg/m ³
-----	---

- **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

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: ≥ 0.6 mmPermeation: Level ≥ 6

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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:**



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: Viscous

Colour: Blue

· **Odour:** Odourless

· **Odour threshold:** Not determined.

· **pH-value at 20 °C:** < 2

· **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: Not determined.

Upper: Not determined.

· **Vapour pressure at 20 °C:** 23 hPa

· **Density at 20 °C:** 1.2 g/cm³

· **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: 0.0 %

Water: 51.0 %

Solids content: 6.0 %

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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:****ATE (Acute Toxicity Estimate)**

Oral	LD50	3,612 mg/kg (rat)
------	------	-------------------

CAS: 7664-38-2 phosphoric acid

Oral	LD50	1,530 mg/kg (rat)
------	------	-------------------

Dermal	LD50	2,740 mg/kg (rabbit)
--------	------	----------------------

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
- **Serious eye damage/irritation**
Causes serious eye damage.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **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.
Must not reach sewage water or drainage ditch undiluted or unneutralised.
- **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 hazardous substances
HP 8	Corrosive

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

SECTION 14: Transport information

- 14.1 UN-Number
- ADR, IMDG, IATA

UN1805

- 14.2 UN proper shipping name

- ADR
- IMDG, IATA

1805 PHOSPHORIC ACID, SOLUTION
PHOSPHORIC ACID, SOLUTION

- 14.3 Transport hazard class(es)

- ADR



- Class
- Label

8 (C1) Corrosive substances.
8

- IMDG, IATA



- Class
- Label

8 Corrosive substances.
8

- 14.4 Packing group

- ADR, IMDG, IATA

III

- 14.5 Environmental hazards:

Not applicable.

- 14.6 Special precautions for user

Warning: Corrosive substances.

- Danger code (Kemler):

80

- EMS Number:

F-A,S-B

- Segregation groups

Acids

- Stowage Category

A

- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable.

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· Transport/Additional information:**· ADR****· Limited quantities (LQ)**

5L

· Excepted quantities (EQ)

Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000 ml

· Transport category

3

· Tunnel restriction code

E

· IMDG**· Limited quantities (LQ)**

5L

· Excepted quantities (EQ)

Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000 ml

· UN "Model Regulation":

UN 1805 PHOSPHORIC ACID, SOLUTION, 8, III

*

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.**· 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

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage.

· 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

Met. Corr. 1: Corrosive to metals – Category 1

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

· * Data compared to the previous version altered.

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

- **1.1 Product identifier**
- **Trade name: Prime & Bond XP**
- **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	H335 May cause respiratory irritation.
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:**
 - 2-hydroxyethyl methacrylate
 - tert-butyl alcohol
 - Butanedioic acid, 1,4-bis[2-[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethyl] ester 2,3 dicarboxylic acid
 - Dipentaerythritol pentaacrylate phosphate
 - 2,2'-Ethylendioxydiethyldimethacrylat
- **Hazard statements**
 - H225 Highly flammable liquid and vapour.
 - H315 Causes skin irritation.
 - H319 Causes serious eye irritation.
 - H317 May cause an allergic skin reaction.
 - H335 May cause respiratory irritation.
 - H412 Harmful to aquatic life with long lasting effects.

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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 [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.
- 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: 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	25-50%
CAS: 75-65-0 EINECS: 200-889-7	tert-butyl alcohol ⚠ Flam. Liq. 2, H225; ⚠ Acute Tox. 4, H332; Eye Irrit. 2, H319; STOT SE 3, H335	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	10-<25%
CAS: 144144-04-7	Butanedioic acid, 1,4-bis[2-[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethyl] ester 2,3 dicarboxylic acid ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	2.5-<10%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-Ethylendioxydiethyldimethacrylat ⚠ Skin Sens. 1, H317	2.5-<10%
CAS: 105883-40-7	Urethane Dimethacrylate Resin ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	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** 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.

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- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents** CO2, sand, extinguishing powder. Do not use water.
- **For safety reasons unsuitable extinguishing agents** Water.
- **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.
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**
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.
Protect from heat.

- **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:** Store away from oxidising agents.
- **Further information about storage conditions:**
Keep receptacle tightly sealed.
Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

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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: 75-65-0 tert-butyl alcohol

WEL	Short-term value: 462 mg/m ³ , 150 ppm
	Long-term value: 308 mg/m ³ , 100 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

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.

Nitrile rubber, NBR

Recommended thickness of the material: ≥ 0.4 mm

Permeation: Level ≥ 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:

Fluid

Colour:

Light yellow

· Odour:

Characteristic

· Odour threshold:

Not determined.

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· pH-value:	Not determined.
· Change in condition Melting point/freezing point:	undetermined
Initial boiling point and boiling range:	111 °C
· Flash point:	21 °C (c.c. Abel)
· Flammability (solid, gaseous)	Not applicable.
· Ignition temperature:	470 °C (tert-Butanol)
· 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:	2.4 Vol % (tert-Butanol)
Upper:	8.0 Vol % (tert-Butanol)
· Vapour pressure at 20 °C:	41 hPa
· Density at 20 °C:	1.044 g/cm ³
· 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:	0.0 %
Solids content:	8.0 %
· 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.

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· LD/LC50 values relevant for classification:		
ATE (Acute Toxicity Estimate)		
Dermal	LD50	>7,257 mg/kg
Inhalative	LC50/4 h	44.9 mg/l
CAS: 868-77-9 2-hydroxyethyl methacrylate		
Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>3,000 mg/kg (rabbit)
CAS: 75-65-0 tert-butyl alcohol		
Oral	LD50	2,743 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rabbit)
Inhalative	LC50/4 h	11 mg/l (ATE)
CAS: 109-16-0 2,2'-Ethylendioxydiethyldimethacrylat		
Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (mouse)

- **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 respiratory irritation.
- **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: 868-77-9 2-hydroxyethyl methacrylate	
LC50/96h	>100 mg/l (Fish acute toxicity study)
EC50/48h	380 mg/L (daphnia magna)
CAS: 75-65-0 tert-butyl alcohol	
LC50/96h	6,140 mg/l (Fish acute toxicity study)
EC50/48h	933 mg/L (daphnia magna)
CAS: 109-16-0 2,2'-Ethylendioxydiethyldimethacrylat	
LC50/96h	16.4 mg/l (Fish acute toxicity study)
EC50/72h	>100 mg/l (Pseudokirchnerella subcapitata)

- **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

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GB

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

Printing date 14.09.2017

Version number 5

Revision: 14.09.2017

Trade name: Prime & Bond XP

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- **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*
- **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.

*

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, IMDG, IATA** UN1120
- **14.2 UN proper shipping name**
- **ADR** 1120 BUTANOLS mixture
- **IMDG, IATA** BUTANOLS mixture

- **14.3 Transport hazard class(es)**

- **ADR**



- **Class** 3 (F1) Flammable liquids.
- **Label** 3

- **IMDG, IATA**



- **Class** 3 Flammable liquids.

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· 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,S-D
· Stowage Category	B
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category	2
· Tunnel restriction code	D/E
· IMDG	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1120 BUTANOLS 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.
- H332 Harmful if inhaled.

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H335 May cause respiratory irritation.

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)

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

Acute Tox. 4: Acute toxicity – Category 4

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 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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