

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 24.03.2022

Version number 3 (replaces version 2)

Revision: 24.03.2022

Start

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:** Research and Development
- **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'-ethylenedioxydiethyl dimethacrylate
- **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.
P273 Avoid release to the environment.
P280 Wear protective gloves / eye protection / face protection.
P305+P351+P338 **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
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 regulation (EC) 2017/745 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.

(Contd. on page 2)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 24.03.2022

Version number 3 (replaces version 2)

Revision: 24.03.2022

Trade name: Calibra Ceram Catalyst

(Contd. of page 1)

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 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 Specific concentration limit: STOT SE 3; C ≥ 10 % | ≥ 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 | propylidynetrimehyl trimethacrylate Aquatic Chronic 2, H411 | ≥ 2.5 – < 10% |
| CAS: 109-16-0 EINECS: 203-652-6 | 2,2'-ethylenedioxydiethyl dimethacrylate 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 Specific concentration limits: Skin Corr. 1B; H314: C ≥ 10 % Skin Irrit. 2; H315: 3 % ≤ C < 10 % Eye Dam. 1; H318: C ≥ 3 % Eye Irrit. 2; H319: 1 % ≤ C < 3 % STOT SE 3; H335: C ≥ 10 % | ≥ 0.25 – < 1% |
| CAS: 79-10-7 EINECS: 201-177-9 | acrylic acid Flam. Liq. 3, H226; Skin Corr. 1A, H314; Eye Dam. 1, H318; Aquatic Acute 1, H400; Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332; STOT SE 3, H335 Specific concentration limit: STOT SE 3; H335: C ≥ 1 % | ≥ 0.25 – < 1% |
| CAS: 131-57-7 EINECS: 205-031-5 | oxybenzone Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 | ≤ 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**
- **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.
- **Information for doctor** No further relevant information available.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

(Contd. on page 3)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 24.03.2022

Version number 3 (replaces version 2)

Revision: 24.03.2022

Trade name: Calibra Ceram Catalyst

(Contd. of page 2)

- **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:** 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:**
Dispose contaminated material as waste according to item 13.
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.
- **Information about fire - and explosion protection:** No special measures required.
- **Handling** Product is intended for dental use only.
- **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 heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **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**
- **Appropriate engineering controls** No further data; see item 7.

(Contd. on page 4)

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

Printing date 24.03.2022

Version number 3 (replaces version 2)

Revision: 24.03.2022

Trade name: Calibra Ceram Catalyst

(Contd. of page 3)

- **Individual protection measures, such as 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.
- **Hand protection**



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: ≥ 0.12 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/face protection**

Safety glasses



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**

- **Physical state**

Fluid

- **Colour:**

According to product specification

- **Odour:**

Characteristic

- **Odour threshold:**

Not determined.

- **Melting point/freezing point:**

undetermined

- **Boiling point or initial boiling point and boiling range**

Undetermined.

- **Flammability**

Not applicable.

- **Lower and upper explosion limit**

- **Lower:**

Not determined.

- **Upper:**

Not determined.

- **Flash point:**

Not applicable

- **Ignition temperature:**

Not applicable

- **Decomposition temperature:**

Not determined.

- **pH**

Not determined.

- **Viscosity:**

- **Kinematic viscosity**

Not determined.

- **dynamic:**

Not determined.

(Contd. on page 5)

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

Printing date 24.03.2022

Version number 3 (replaces version 2)

Revision: 24.03.2022

Trade name: Calibra Ceram Catalyst

(Contd. of page 4)

| | |
|--|------------------------|
| · Solubility | |
| · Water: | <i>Insoluble</i> |
| · Partition coefficient n-octanol/water (log value) | <i>Not determined.</i> |
| · Vapour pressure: | <i>Not determined.</i> |
| · Density and/or relative density | |
| · Density: | <i>Not determined</i> |
| · Relative density | <i>Not determined.</i> |
| · Vapour density | <i>Not determined.</i> |

| | |
|--|--|
| · 9.2 Other information | |
| · Appearance: | |
| · Form: | <i>paste</i> |
| · Important information on protection of health and environment, and on safety. | |
| · Auto-ignition temperature: | <i>Product is not selfigniting.</i> |
| · Explosive properties: | <i>Product does not present an explosion hazard.</i> |
| · Solvent content: | |
| · Solids content: | <i>60.0 %</i> |
| · Change in condition | |
| · Evaporation rate | <i>Not determined.</i> |

| | |
|--|-------------|
| · Information with regard to physical hazard classes | |
| · Explosives | <i>Void</i> |
| · Flammable gases | <i>Void</i> |
| · Aerosols | <i>Void</i> |
| · Oxidising gases | <i>Void</i> |
| · Gases under pressure | <i>Void</i> |
| · Flammable liquids | <i>Void</i> |
| · Flammable solids | <i>Void</i> |
| · Self-reactive substances and mixtures | <i>Void</i> |
| · Pyrophoric liquids | <i>Void</i> |
| · Pyrophoric solids | <i>Void</i> |
| · Self-heating substances and mixtures | <i>Void</i> |
| · Substances and mixtures, which emit flammable gases in contact with water | <i>Void</i> |
| · Oxidising liquids | <i>Void</i> |
| · Oxidising solids | <i>Void</i> |
| · Organic peroxides | <i>Void</i> |
| · Corrosive to metals | <i>Void</i> |
| · Desensitised explosives | <i>Void</i> |

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

(Contd. on page 6)

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

Printing date 24.03.2022

Version number 3 (replaces version 2)

Revision: 24.03.2022

Trade name: Calibra Ceram Catalyst

(Contd. of page 5)

SECTION 11: Toxicological information

· **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

· **Acute toxicity**

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

CAS: 3290-92-4 propylidynetrimehyl trimethacrylate

| | | |
|------|------|---------------------|
| Oral | LD50 | > 2,000 mg/kg (rat) |
|------|------|---------------------|

CAS: 109-16-0 2,2'-ethylenedioxydiethyl dimetharcylate

| | | |
|------|------|---------------------|
| Oral | LD50 | > 5,000 mg/kg (rat) |
|------|------|---------------------|

| | | |
|--------|------|-----------------------|
| Dermal | LD50 | > 2,000 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 | 1,500 mg/kg (rat) |
|------|------|-------------------|

| | | |
|--------|------|------------------------|
| Dermal | LD50 | > 2,000 mg/kg (rabbit) |
|--------|------|------------------------|

| | | |
|------------|----------|---------------|
| Inhalative | LC50/4 h | 11 mg/l (ATE) |
|------------|----------|---------------|

CAS: 131-57-7 oxybenzone

| | | |
|------|------|-------------------|
| Oral | LD50 | 7,400 mg/kg (rat) |
|------|------|-------------------|

| | | |
|--------|------|-------------------------|
| Dermal | LD50 | > 16,000 mg/kg (rabbit) |
|--------|------|-------------------------|

· **Skin corrosion/irritation** Causes skin irritation.

· **Serious eye damage/irritation** Causes serious eye irritation.

· **Respiratory or skin sensitisation** May cause an allergic skin reaction.

· **11.2 Information on other hazards**

· **Endocrine disrupting properties**

| | | |
|---------------|------------|---------|
| CAS: 131-57-7 | oxybenzone | List II |
|---------------|------------|---------|

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

CAS: 3290-92-4 propylidynetrimehyl trimethacrylate

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

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

CAS: 109-16-0 2,2'-ethylenedioxydiethyl dimetharcylate

| | |
|----------|-------------------------------|
| LC50/96h | 16.4 mg/l (Brachydanio rerio) |
|----------|-------------------------------|

| | |
|----------|---|
| EC50/72h | > 100 mg/l (Pseudokirchnerella subcapitata) |
|----------|---|

CAS: 79-10-7 acrylic acid

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

| | |
|----------|-------------------------|
| EC50/48h | 95 mg/L (daphnia magna) |
|----------|-------------------------|

CAS: 131-57-7 oxybenzone

| | |
|----------|--------------------------------------|
| LC50/96h | 100 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.

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

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

(Contd. on page 7)

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

Printing date 24.03.2022

Version number 3 (replaces version 2)

Revision: 24.03.2022

Trade name: Calibra Ceram Catalyst

(Contd. of page 6)

- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**
Do not allow product to reach ground water, water course or sewage system.
Harmful to aquatic organisms

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.

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

SECTION 14: Transport information

- | | |
|---|-----------------|
| · 14.1 UN number or ID number · ADR, IMDG, IATA | Void |
| · 14.2 UN proper shipping name · ADR, 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 Maritime transport in bulk according to IMO instruments | 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.

(Contd. on page 8)

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

Printing date 24.03.2022

Version number 3 (replaces version 2)

Revision: 24.03.2022

Trade name: Calibra Ceram Catalyst

(Contd. of page 7)

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.
 H318 Causes serious eye damage.
 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 relatif au transport international 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. 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 Dam. 1: Serious eye damage/eye irritation – Category 1
 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.**

GB

Safety data sheet
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Version number 3 (replaces version 2)

Revision: 24.03.2022

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:** Research and Development
- **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'-ethylenedioxydiethyl dimethacrylate
- **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.
P273 Avoid release to the environment.
P280 Wear protective gloves / eye protection / face protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

(Contd. on page 2)

GB

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

Printing date 24.03.2022

Version number 3 (replaces version 2)

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Trade name: Calibra Ceram Base

(Contd. of page 1)

Additional information:

As this product is a medical device in the meaning of Directive 93/42/EEC and regulation (EC) 2017/745 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 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 | ≥ 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'-ethylenedioxydiethyl dimethacrylate 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% |
| CAS: 131-57-7 EINECS: 205-031-5 | oxybenzone Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 | ≤ 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.

· **Information for doctor** No further relevant information available.

· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media**Suitable extinguishing agents**

CO₂, 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.

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 24.03.2022

Version number 3 (replaces version 2)

Revision: 24.03.2022

Trade name: *Calibra Ceram Base*

(Contd. of page 2)

- **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 product to reach sewage system or any water course.*
- **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**
Ensure good ventilation/exhaustion at the workplace.
Observe normal care for working with chemicals.
- **Information about fire - and explosion protection:** *No special measures required.*
- **Handling** *Product is intended for dental use only.*
- **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 heat and direct sunlight.
- **7.3 Specific end use(s)** *No further relevant information available.*

SECTION 8: Exposure controls/personal protection

- **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**
- **Appropriate engineering controls** *No further data; see item 7.*
- **Individual protection measures, such as 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.*
- **Hand protection**



Protective gloves.

(Contd. on page 4)

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

Printing date 24.03.2022

Version number 3 (replaces version 2)

Revision: 24.03.2022

Trade name: Calibra Ceram Base

(Contd. of page 3)

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/face protection**

Safety glasses



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**

- **Physical state**

Fluid

- **Colour:**

According to product specification

- **Odour:**

Characteristic

- **Odour threshold:**

Not determined.

- **Melting point/freezing point:**

undetermined

- **Boiling point or initial boiling point and boiling range**

Undetermined.

- **Flammability**

Not applicable.

- **Lower and upper explosion limit**

- **Lower:**

Not determined.

- **Upper:**

Not determined.

- **Flash point:**

Not applicable

- **Ignition temperature:**

Not applicable

- **Decomposition temperature:**

Not determined.

- **pH**

Not determined.

- **Viscosity:**

- **Kinematic viscosity**

Not determined.

- **dynamic:**

Not determined.

- **Solubility**

- **Water:**

Not miscible or difficult to mix

- **Partition coefficient n-octanol/water (log value)**

Not determined.

- **Vapour pressure:**

Not determined.

- **Density and/or relative density**

- **Density:**

Not determined

- **Relative density**

Not determined.

- **Vapour density**

Not determined.

- **9.2 Other information**

- **Appearance:**

- **Form:**

paste

(Contd. on page 5)

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

Printing date 24.03.2022

Version number 3 (replaces version 2)

Revision: 24.03.2022

Trade name: Calibra Ceram Base

(Contd. of page 4)

- **Important information on protection of health and environment, and on safety.**
- **Auto-ignition temperature:** *Product is not selfigniting.*
- **Explosive properties:** *Product does not present an explosion hazard.*
- **Change in condition**
- **Evaporation rate** *Not determined.*

- **Information with regard to physical hazard classes**
- **Explosives** *Void*
- **Flammable gases** *Void*
- **Aerosols** *Void*
- **Oxidising gases** *Void*
- **Gases under pressure** *Void*
- **Flammable liquids** *Void*
- **Flammable solids** *Void*
- **Self-reactive substances and mixtures** *Void*
- **Pyrophoric liquids** *Void*
- **Pyrophoric solids** *Void*
- **Self-heating substances and mixtures** *Void*
- **Substances and mixtures, which emit flammable gases in contact with water** *Void*
- **Oxidising liquids** *Void*
- **Oxidising solids** *Void*
- **Organic peroxides** *Void*
- **Corrosive to metals** *Void*
- **Desensitised explosives** *Void*

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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity**

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

ATE (Acute Toxicity Estimate)

| | | |
|------|------|--------------------|
| Oral | LD50 | 20,000 mg/kg (rat) |
|------|------|--------------------|

CAS: 868-77-9 2-hydroxyethyl methacrylate

| | | |
|------|------|---------------------|
| Oral | LD50 | > 5,000 mg/kg (rat) |
|------|------|---------------------|

| | | |
|--------|------|------------------------|
| Dermal | LD50 | > 3,000 mg/kg (rabbit) |
|--------|------|------------------------|

CAS: 3290-92-4 propylidynetrimehyl trimethacrylate

| | | |
|------|------|---------------------|
| Oral | LD50 | > 2,000 mg/kg (rat) |
|------|------|---------------------|

CAS: 109-16-0 2,2'-ethylenedioxydiethyl dimethacrylate

| | | |
|------|------|---------------------|
| Oral | LD50 | > 5,000 mg/kg (rat) |
|------|------|---------------------|

| | | |
|--------|------|-----------------------|
| Dermal | LD50 | > 2,000 mg/kg (mouse) |
|--------|------|-----------------------|

(Contd. on page 6)

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

Printing date 24.03.2022

Version number 3 (replaces version 2)

Revision: 24.03.2022

Trade name: Calibra Ceram Base

(Contd. of page 5)

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

Oral LD50 500 mg/kg (ATE)

CAS: 131-57-7 oxybenzone

Oral LD50 7,400 mg/kg (rat)

Dermal LD50 > 16,000 mg/kg (rabbit)

- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **11.2 Information on other hazards**

· **Endocrine disrupting properties**

CAS: 131-57-7 oxybenzone

List II

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'-ethylenedioxydiethyl dimethacrylate

LC50/96h 16.4 mg/l (Brachydanio rerio)

EC50/72h > 100 mg/l (Pseudokirchnerella subcapitata)

CAS: 131-57-7 oxybenzone

LC50/96h 100 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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse 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

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.

(Contd. on page 7)

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

Printing date 24.03.2022

Version number 3 (replaces version 2)

Revision: 24.03.2022

Trade name: Calibra Ceram Base

(Contd. of page 6)

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

SECTION 14: Transport information

- | | |
|---|-----------------|
| · 14.1 UN number or ID number · ADR, IMDG, IATA | Void |
| · 14.2 UN proper shipping name · ADR, 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 Maritime transport in bulk according to IMO instruments | 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**
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 relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods

(Contd. on page 8)

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

Printing date 24.03.2022

Version number 3 (replaces version 2)

Revision: 24.03.2022

Trade name: Calibra Ceram Base

(Contd. of page 7)

*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**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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