

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

Printing date 06.07.2022

Version number 10 (replaces version 9)

Revision: 06.07.2022

Start

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

- **1.1 Product identifier**
- **Trade name:** *Calibra Base*
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** *Esthetic Resin Cement*
- **Uses advised against** *No further relevant information available.*
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Dentsply DeTrey GmbH
De-Trey-Str. 1
D-78467 Konstanz
GERMANY
Tel.: +49-(0)7531-583-0
Fax: +49-(0)7531-583-104
email: KonstanzDEU.info-sdb@dentsplysirona.com
- **Further information obtainable from:** *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.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB 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
(1-methylethylidene)bis(4,1-phenyleneoxy-2,1-ethanediyl)bismethacrylate
2,2'-ethylenedioxydiethyl dimethacrylate
2,2'-[(4-methylphenyl)imino]bisethanol
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
- **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
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.
P337+P313 If eye irritation persists: 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 06.07.2022

Version number 10 (replaces version 9)

Revision: 06.07.2022

Trade name: Calibra Base

(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: 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	(1-methylethylidene)bis(4,1-phenyleneoxy-2,1-ethanediyl)bismethacrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	≥ 10 – < 20%
CAS: 109-16-0 EINECS: 203-652-6	2,2'-ethylenedioxydiethyl dimethacrylate Skin Sens. 1, H317	≥ 2.5 – < 10%
CAS: 131-57-7 EINECS: 205-031-5	oxybenzone Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	≤ 2.5%
CAS: 3077-12-1 EINECS: 221-359-1	2,2'-[(4-methylphenyl)imino]bisethanol Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Sens. 1, H317; Aquatic Chronic 3, H412	≥ 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**
- **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.
- **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**
Formation of toxic gases is possible during heating or in case of fire.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

GB

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 06.07.2022

Version number 10 (replaces version 9)

Revision: 06.07.2022

Trade name: Calibra Base

(Contd. of page 2)

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **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** 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 exposure to the light.
- **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.

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

(Contd. on page 4)

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

Printing date 06.07.2022

Version number 10 (replaces version 9)

Revision: 06.07.2022

Trade name: Calibra Base

(Contd. of page 3)

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/face 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**

· **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:**

Insoluble

· **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:**

Pasty

· **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.

· **Solvent content:**

· **Solids content:**

67.0 %

· **Change in condition**

· **Evaporation rate**

Not determined.

· **Information with regard to physical hazard classes**

· **Explosives**

Void

· **Flammable gases**

Void

· **Aerosols**

Void

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

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Version number 10 (replaces version 9)

Revision: 06.07.2022

Trade name: Calibra Base

(Contd. of page 4)

· 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:**

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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CAS: 131-57-7 oxybenzone

Oral	LD50	7,400 mg/kg (rat)
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Dermal	LD50	> 16,000 mg/kg (rabbit)
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CAS: 3077-12-1 2,2'-[(4-methylphenyl)imino]bisethanol

Oral	LD50	500 mg/kg (ATE)
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- **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
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List II

GB

(Contd. on page 6)

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

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Version number 10 (replaces version 9)

Revision: 06.07.2022

Trade name: Calibra Base

(Contd. of page 5)

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

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

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**

· Additional ecological information:

· General notes:

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

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.

(Contd. on page 7)

Safety data sheet

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(Contd. of page 6)

· **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.
H412 Harmful 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
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 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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

GB