

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

071294487

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

071294354 071294388 071294412 071294438 071294446 071294453 071294479 71294354 71294388 71294412

71294438 71294446 71294453 71294479 71294487

# Safety data sheet

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

Printing date 27.01.2021

Version number 2

Revision: 27.01.2021

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

- **1.1 Product identifier**
- **Trade name:** *VisCalor*
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** *Dental filling material*
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
*VOCO GmbH*  
*Anton-Flettner-Str. 1-3*  
*D-27472 Cuxhaven*
- **Further information obtainable from:** *Scientific department tel. +49 (0)4721-719-0*
- **1.4 Emergency telephone number:** *Poison Control Center Mainz +49 (0)6131-19240*

### 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**  
*As a medical device the product is not subject to labelling regulations under 1272/2008/EC.*
- **Hazard pictograms** *GHS07*
- **Signal word** *Warning*
- **Hazard statements**  
*Causes skin irritation.*  
*Causes serious eye irritation.*  
*May cause an allergic skin reaction.*  
*Harmful to aquatic life with long lasting effects.*
- **Precautionary statements**  
*Avoid breathing dust/fume/gas/mist/vapours/spray.*  
*Avoid release to the environment.*  
*Wear protective gloves / eye protection / face protection.*  
*IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*  
*If skin irritation or rash occurs: Get medical advice/attention.*  
*Dispose of contents/container in accordance with local/regional/national/international regulations.*
- **2.3 Other hazards** *Use only for intended scope of application*
- **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	BIS GMA <i>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317</i>	10-25%
	<i>aliphatic dimethacrylate</i> <i>Aquatic Chronic 2, H411</i> <i>Skin Sens. 1B, H317</i>	2.5-5%

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### 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.
- **After swallowing:** If symptoms persist consult doctor.
- **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:** Use fire extinguishing methods suitable to surrounding conditions.
- **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** 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:** 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** 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:** See storage instructions on package
- **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:**  
The usual precautionary measures are to be adhered to when handling chemicals.

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- **Respiratory protection:** Not required.
- **Protection of hands:**



Protective gloves

- **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.

- **Eye protection:** Safety glasses

### 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, gas):** Not determined.

- **Decomposition temperature:** Not determined.

- **Auto-ignition temperature:** Product is not selfigniting.

- **Explosive properties:** Product does not present an explosion hazard.

- **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.

- **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.

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- **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.
- **Primary irritant effect:**
- **Skin corrosion/irritation**  
Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured  
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.
- **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:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |                                       |      |
|---------------------------------------|------|
| · <b>14.1 UN-Number</b>               |      |
| · <b>ADR, IMDG, IATA</b>              | Void |
| · <b>ADN</b>                          | 1    |
| · <b>14.2 UN proper shipping name</b> | -    |

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· <b>ADR, ADN, IMDG, IATA</b>	Void
· <b>14.3 Transport hazard class(es)</b>	-
· <b>ADR, ADN, IMDG, IATA</b> · <b>Class</b>	Void
· <b>14.4 Packing group</b> · <b>ADR, IMDG, IATA</b>	- Void
· <b>14.5 Environmental hazards:</b>	Not applicable.
· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>UN "Model Regulation":</b>	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.

### **SECTION 16: Other information**

- **Department issuing SDS:** Scientific department
- **Contact:** Tel.: +49 (0)4721-719-0
- **Abbreviations and acronyms:**  
 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  
 Skin Sens. 1B: Skin sensitisation – Category 1B  
 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

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