

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

- **1.1 Product identifier**
 - **Trade name:** VisCalor bulk
- **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 Sens. 1 H317 May cause an allergic skin reaction.
- **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
 - **Hazard statements**

May cause an allergic skin reaction.
 - **Precautionary statements**

Wear protective gloves / protective clothing.
IF ON SKIN: Wash with plenty of water.
If skin irritation 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	10-25%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
	aliphatic dimethacrylate	2.5-5%
	Aquatic Chronic 2, H411	
	Skin Sens. 1B, H317	

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
 - **General information:** No special measures required.
 - **After inhalation:** Seek medical treatment 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.

(Contd. on page 2)

Trade name: VisCalor bulk

(Contd. of page 1)

- **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:** *No special measures required.*
- **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:** *See storage instructions on package*
- **Information about storage in one common storage facility:** *Not required.*
- **Further information about storage conditions:** *None.*
- **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.
- **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.

(Contd. on page 3)

Trade name: VisCalor bulk

· **Eye protection:** Safety glasses

(Contd. of page 2)

SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

· Form:	Pasty
· Colour:	Light beige
· Odour:	Characteristic
· Odour threshold:	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· Melting point/freezing point:	Undetermined.
· Initial boiling point and boiling range:	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gas):** Not applicable.

· **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 determined.

· **Evaporation rate** Not determined.

· **Solubility in / Miscibility with water:** Not miscible or difficult to mix.

· **Partition coefficient: n-octanol/water:** Not determined.

· **Viscosity:**

· **Dynamic:** Not determined.

· **Kinematic:** Not determined.

· **Solids content:** 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.

(Contd. on page 4)

Trade name: VisCalor bulk

(Contd. of page 3)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **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 product to reach ground water, water course or sewage system, even in small quantities.
- **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

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|--|-----------------|
| · 14.1 UN-Number | |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | - |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) | - |
| · ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · 14.4 Packing group | - |
| · ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | Not applicable. |

(Contd. on page 5)

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

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Trade name: VisCalor bulk

(Contd. of page 4)

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|---|-----------------|
| · 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

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

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