# **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

071294412

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 071294438 071294446 071294453 071294479 071294487 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.

Eve 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 eve 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 comp	ponents:	
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	

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Trade name: VisCalor

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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
- $\cdot$  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: CharacteristicOdour 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.

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 (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.

## SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- $\cdot$  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

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

Void 1

· ADN
· 14.2 UN proper shipping name

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· 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 Marpol and the IBC Code	: <b>II of</b> Not applicable.	
· UN ''Model Regulation'':	Void	

# **SECTION 15: Regulatory information**

- $\cdot$  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

GB