

# Safety Data Sheet

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

Date of issue: 28.02.2020  
 Printing date: 28.02.2020

Version: 2

### 1. Identification of the substance/mixture and of the company/undertaking

#### Product Identifier

**Trade name:** Oxford Cal VLC

**Use of the preparation:** Dental Product

**Details of the supplier of the safety data sheet:**

#### Manufacturer/supplier:

First Scientific Dental Materials GmbH

25335 Elmshorn

Germany

info@oxford-scientific.de

#### Emergency telephone number:

+49 4121 909508

#### 24 hour emergency telephone number for US:

1-800-255-3924

### 2. Hazards identification

#### Classification of the substance or mixture:

#### Classification according to Regulation (EC) No 1272/2008:

Eye Dam. 1, H318 Causes serious eye damage

Skin Sens. 1; H317 May cause allergic skin reaction

#### Information concerning particular hazards for human and environment:

The product has to be labeled due to calculation procedure for the "General Classification guideline for preparations of the EU" in the latest version.

#### Label elements

#### Labeling according to Regulation (EC) 1272/2008:

#### Hazard pictograms



#### Signal word

Danger

#### Hazard statements

H318 Causes serious eye damage

H317 May cause allergic skin reaction

#### Precautionary statements

P280 Wear protective gloves/protective clothing/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.

P302+P352 IF ON SKIN: Wash with plenty of soap and water

#### Labeling according to EU guidelines:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body; are exempted from the provisions of Regulation (EC) No. 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

#### Other hazards

#### Results of PBT and vPvB assessment

**PBT:** not applicable

**vPvB:** not applicable

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#### **3. Composition/Information on Ingredients**

**Chemical characterization:**

**Description:**

Dental material based on methacrylic esters, radiopaque fillers, calciumhydroxid, photoinitiators, stabilizers, and pigments

**Hazardous components:**

1305-62-0 (CAS No.)    Calcium hydroxide                    GHS05, H318

#### **4. First-aid measures**

**General information:** Seek medical advice, if symptoms occur, which can be caused by the product

**after skin contact:** wash with plenty of water

**after inhalation:** fresh air

**after eye contact:** rinse opened eye for several minutes under running water and consult a doctor

**after swallowing:** seek medical advice.

#### **5. Fire fighting measures**

**Extinguishing media:**

CO<sub>2</sub>, powder, water spray.

Use extinguishing method and media suitable to surrounding fire.

**Special hazards arising from the substance or mixture** No further relevant information available

**Protective equipment** Wear self-contained respiratory protective equipment

#### **6. Accidental release measures**

**Personal precautions, protective equipment and emergency procedures:**

Avoid contact with skin and eyes. Wear gloves and safety glasses

**Environmental precautions:**

Do not allow to enter drains/surface water/ ground-water.

**Methods for cleaning up:**

Wipe out with absorbent material. Forward for disposal. Clean up affected area.

**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

#### **7. Handling and storage**

**Handling:**

This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

**Precautions for safe handling:** Observe normal care for working with chemicals

**Information about fire and explosion protection:** -

**Storage:** Store at a dry place. Store tightly closed at room temperature.

**Requirements at storerooms and containers:** Store only in the original containers

**Further information on storage conditions:**

Store away from food stuffs.

**Specific end uses:** No further relevant information available

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### 8. Exposure controls/personal protection

#### Components with limits of values to be supervised at the workplace:

CAS-No.	name	art	value	unit
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The product contains no relevant quantities of components with limits of values to be supervised at the workplace.

**Additional information:** The lists valid during the making were used as basis

#### Personal protective equipment:

#### General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs and beverages. Avoid contact with eyes or skin

#### Hand protection

Protective gloves.

Due to missing tests no recommendation to the glove material can be given for the product.

**Eye protection:** Safety glasses

**Respiratory protection:** Required, when aerosols are generated

### 9. Physical and chemical properties

#### Information on basic physical and chemical properties

#### Appearance

<b>Form:</b>	paste		
<b>Color:</b>	slightly yellow		
<b>Odor:</b>	odourless		
	Value	Unit	Method

#### Safety relevant basic data

<b>Melting point/melting range:</b>	n.a.
<b>Boiling point/boiling range:</b>	n.a.
<b>Flash point:</b>	n.a.
<b>Ignition temperature:</b>	No information available
<b>Danger of explosion:</b>	
<b>Density:</b>	1.55 g/cm <sup>3</sup>
<b>Vapor pressure:</b>	n.d.
<b>pH:</b>	alkaline
<b>Solubility in/miscibility with:</b>	
<b>Water:</b>	insoluble
<b>Content of solvents:</b>	none
<b>Organic solvents:</b>	none

### 10. Stability and reactivity

#### Thermal decomposition / conditions to be avoided

**Possibility of hazardous reactions:** no information available

**Conditions to avoid:** Heat, direct sunlight and radical starters. Avoid contact with peroxides, metal powders, strong oxidizers, acids, free radical initiators

**Hazardous decomposition products:** No information available.

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### **11. Toxicological information**

**Acute toxicity:**

not determined

**Primary irritation:****skin:** skin absorption: n.d.**eye:** strong irritant with the danger of severe eye injury**Sensitization:** sensitization by skin contact possible**Additional toxicological information:**

Allergic reaction to methacrylate by chronic exposure to product are possible. When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

### **12. Ecological information**

**General information:** Do not allow undiluted product or large quantities of it into surface water or sanitary sewer system**Classification of water endangerment:** WGK=1 (slightly polluting substance)

### **13. Disposal considerations**

**Product:****Recommendation:**

Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

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

### **14. Transport information**

**Land transport ADR/RID and GGVS/GGVE (Germany):**

Not subject to transport regulations

**Sea transport IMDG:**

Not subject to transport regulations

**Air transport ICAO-TI and IATA-DGR:**

Not subject to transport regulations

### **15. Regulatory information**

**Classification according to EC-guidelines:**

The product is a medical device according to EC-directive 93/42 EEC.

**Chemical safety assessment:**

A Chemical Safety Assessment has not been carried out.

### **16. Other information:**

**Changes compared with the previous version:**

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to products properties. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.