

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

Printing date 04.05.2015

Version number 7

Revision: 27.04.2015


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

- **1.1 Product identifier**
- **Trade name:** *Virtual*
- **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 impression material
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent AG  
Bendererstrasse 2  
FL-9494 Schaan  
PRINCIPALITY OF LIECHTENSTEIN
- 
- Tel: +423 235 35 35  
Fax: +423 235 33 60
- **Further information obtainable from:**  
Regulatory Affairs  
sds@ivoclarvivadent.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
STOT RE 1 H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalative.

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- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**
- 

GHS08
- **Signal word** *Danger*
- **Hazard-determining components of labelling:**  
*cristobalite*  
*Quartz (SiO<sub>2</sub>)*
- **Hazard statements**  
H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalative.
- **Precautionary statements**  
P314 Get medical advice/attention if you feel unwell.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Additional information:**  
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.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.

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Trade name: **Virtual**· **vPvB:** Not applicable.

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### SECTION 3: Composition/information on ingredients

#### · 3.2 Chemical characterisation: Mixtures

· **Description:** Mixture of substances listed below with nonhazardous additions.

#### · **Dangerous components:**

CAS: 14464-46-1 EINECS: 238-455-4	crystalite	STOT RE 1, H372	50-100%
CAS: 14808-60-7 EINECS: 238-878-4	Quartz (SiO <sub>2</sub> )	STOT RE 1, H372	10-<25%

· **Additional information:** For the wording of the listed risk phrases refer to section 16.

### SECTION 4: First aid measures

#### · 4.1 Description of first aid measures

· **After inhalation:** Supply fresh air; consult doctor in case of complaints.

· **After skin contact:**

Immediately rinse with water.

If skin irritation continues, consult a doctor.

· **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

· **After swallowing:** Seek medical treatment.

· **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:**

CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· **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

Only adequately trained personnel should handle this product.

For use in dentistry only.

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- **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:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
Keep container tightly sealed.  
Protect from heat and direct sunlight.
- **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:**  
Usual hygienic measures for dental practice.  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes and skin.
- **Respiratory protection:** Not required.
- **Protection of hands:**  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **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.
- **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 protection:**  
Safety glasses  
Goggles recommended during refilling

### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

<b>Form:</b>	Viscous
<b>Colour:</b>	Different according to colouring

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· <b>Odour:</b>	<i>like peppermint</i>
· <b>Odour threshold:</b>	<i>Not determined.</i>
· <b>pH-value:</b>	<i>Not applicable.</i>
· <b>Change in condition</b>	
<b>Melting point/Melting range:</b>	<i>Undetermined.</i>
<b>Boiling point/Boiling range:</b>	<i>Undetermined.</i>
· <b>Flash point:</b>	<i>Not applicable.</i>
· <b>Flammability (solid, gaseous):</b>	<i>Not applicable.</i>
· <b>Self-igniting:</b>	<i>Product is not selfigniting.</i>
· <b>Danger of explosion:</b>	<i>Product does not present an explosion hazard.</i>
· <b>Explosion limits:</b>	
<b>Lower:</b>	<i>Not determined.</i>
<b>Upper:</b>	<i>Not determined.</i>
· <b>Vapour pressure:</b>	<i>Not determined.</i>
· <b>Density at 20 °C:</b>	<i>1.0 - 1.6 g/cm<sup>3</sup></i>
· <b>Relative density</b>	<i>Not determined.</i>
· <b>Vapour density</b>	<i>Not determined.</i>
· <b>Evaporation rate</b>	<i>Not determined.</i>
· <b>Solubility in / Miscibility with water:</b>	<i>Nearly insoluble.</i>
· <b>Partition coefficient (n-octanol/water):</b>	<i>Not determined.</i>
· <b>Viscosity:</b>	
<b>Dynamic:</b>	<i>Not determined.</i>
<b>Kinematic:</b>	<i>Not determined.</i>
· <b>9.2 Other information</b>	<i>No further relevant information available.</i>

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** *No further relevant information available.*
- **10.2 Chemical stability** *Stable under normal handling and storage conditions.*
- **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:** *None under normal conditions of storage and use.*

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** *No irritant effect.*
- **on the eye:** *No irritating effect.*
- **Sensitisation:** *No sensitising effects known.*

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### 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**  
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
  - **European waste catalogue**
- |           |                                                            |
|-----------|------------------------------------------------------------|
| 18 01 06* | chemicals consisting of or containing dangerous substances |
|-----------|------------------------------------------------------------|
- **Uncleaned packaging:**
  - **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |                                                                                       |                                                                                |
|---------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| · <b>14.1 UN-Number</b>                                                               |                                                                                |
| · <b>ADR, ADN, IMDG, IATA</b>                                                         | Void                                                                           |
| · <b>14.2 UN proper shipping name</b>                                                 |                                                                                |
| · <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>                                                  |                                                                                |
| · <b>Marine pollutant:</b>                                                            | No                                                                             |
| · <b>14.6 Special precautions for user</b>                                            | Not applicable.                                                                |
| · <b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable.                                                                |
| · <b>Transport/Additional information:</b>                                            | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |

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· UN "Model Regulation":

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**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
The product is a medical device according to the Directive 93/42/EEC.
- **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.

· **Relevant phrases**

H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalative.

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport 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)

STOT RE 1: Specific target organ toxicity - Repeated exposure, Hazard Category 1

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