

## Safety Data Sheet according to WHS Regulations

Printing date 04.10.2021

Version number 8

Revision: 04.10.2021

Hazardous according to criteria of Australian Safety and Compensation Council.

### 1 Identification

· **Product identifier**

· **Trade name:** Virtual Light Body Regular / Fast Base, Virtual Extra Light Body Regular / Fast Base

· **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

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

· **Manufacturer/Supplier:**

Ivoclar Vivadent AG

Bendererstrasse 2

9494 Schaan

PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35 / Fax: +423 235 33 60

**Importer:**

Ivoclar Vivadent Pty. Ltd.

1- 5 Overseas Drive

Noble Park North VIC 3174

Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645

· **Further information obtainable from:**

Regulatory Affairs

sds@ivoclarvivadent.com

· **Emergency telephone number:** 131 126 (Poisons Information Centre - 24 hours / 7 days)

### 2 Hazard(s) Identification

· **Classification of the substance or mixture**

STOT RE 1 H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

· **Label elements**

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS08

· **Signal word** Danger

· **Hazard-determining components of labelling:**

cristobalite

Quartz (SiO<sub>2</sub>)

· **Hazard statements**

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

· **Precautionary statements**

Get medical advice/attention if you feel unwell.

Dispose of contents/container in accordance with local/regional/national/international regulations.

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· **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.

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

### 3 Composition and Information on Ingredients

· **Chemical characterisation: Mixtures**

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

· **Dangerous components:**

CAS: 14464-46-1	cristobalite	STOT RE 1, H372	10-25%
CAS: 14808-60-7	Quartz (SiO <sub>2</sub> )	STOT RE 1, H372	2.5-10%

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

### 4 First Aid Measures

· **Description of first aid measures**

· **After inhalation:**

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:** Rinse with water.

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

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

· **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

· **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

### 5 Fire Fighting Measures

· **Extinguishing media**

· **Suitable extinguishing agents:**

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

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

· **Advice for firefighters**

· **Protective equipment:** No special measures required.

### 6 Accidental Release Measures

· **Personal precautions, protective equipment and emergency procedures** Not required.

· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

· **Methods and material for containment and cleaning up:** Pick up mechanically.

· **Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

### 7 Handling and Storage

- **Handling:**
- **Precautions for safe handling**  
Only adequately trained personnel should handle this product.  
For use in dentistry only.
- **Information about fire - and explosion protection:** No special measures required.
- **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.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **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.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Usual hygienic measures for dental practice and dental laboratories.  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Protection of hands:**  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
After use of gloves apply skin-cleaning agents and skin cosmetics.
- **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

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### 9 Physical and Chemical Properties

· <b>Information on basic physical and chemical properties</b>	
· <b>General Information</b>	
· <b>Appearance:</b>	
Form:	Viscous
Colour:	Light blue
· Odour:	like peppermint
· Odour threshold:	Not determined.
· pH-value:	Not applicable.
· <b>Change in condition</b>	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gas):	Not applicable.
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not determined.
· 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.
· <b>Viscosity:</b>	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Other information	No further relevant information available.

### 10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

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### 11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity**
- **Specific symptoms in biological assay:**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitisation** No sensitising effects known.
- **Additional toxicological information:** No further relevant information available.

### 12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |                                     |      |
|-------------------------------------|------|
| · <b>UN-Number</b>                  |      |
| · <b>ADG, ADN, IMDG, IATA</b>       | Void |
| · <b>UN proper shipping name</b>    |      |
| · <b>ADG, ADN, IMDG, IATA</b>       | Void |
| · <b>Transport hazard class(es)</b> |      |
| · <b>ADG, ADN, IMDG, IATA</b>       |      |
| · <b>Class</b>                      | Void |
| · <b>Packing group</b>              |      |
| · <b>ADG, IMDG, IATA</b>            | Void |

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· <b>Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of Marpol 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).
· <b>UN "Model Regulation":</b>	Void

### 15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Australian Inventory of Industrial Chemicals**

All ingredients are listed.

· **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS08

· **Signal word** *Danger*

· **Hazard-determining components of labelling:**

cristobalite

Quartz (SiO<sub>2</sub>)

· **Hazard statements**

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

· **Precautionary statements**

Get medical advice/attention if you feel unwell.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to the Directive 93/42/EEC.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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### 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 organs through prolonged or repeated exposure.*

· **Contact:**

· **Abbreviations and acronyms:**

*ADR: Accord relatif au transport international 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*

*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)*

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*

*STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1*

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