

**Safety Data Sheet**  
in accordance with HSNO

Printing date 12.12.2019

Version number 8

Revision: 12.12.2019


**1 Identification of the substance or mixture and of the supplier**

- **Product identifier**
- **Trade name:** Virtual Light Body Fast / Regular Catalyst , Virtual Extra Light Body Fast / Regular Catalyst
- **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 Ltd  
12 Omega St, Rosedale, Auckland  
New Zealand  
Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990
- **Further information obtainable from:**  
Regulatory Affairs  
sds@ivoclarvivadent.com
- **Emergency telephone number:** 0800 764 766 (National Poison Centre - 24 hours / 7 days)

**2 Hazards identification**

- **Classification of the substance or mixture**  
STOT RE 2 H373 May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

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  - **Label elements**
  - **GHS label elements**  
The product is classified and labelled according to the Globally Harmonised System (GHS).
  - **Hazard pictograms**
- 

GHS08
- **Signal word** Warning
  - **Hazard-determining components of labelling:**  
cristobalite  
Quartz (SiO<sub>2</sub>)
  - **Hazard statements**  
May cause 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.
  - **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.

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- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### 3 Composition/Information on ingredients

- **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	2.5-10%
CAS: 14808-60-7 EINECS: 238-878-4	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:** Use fire extinguishing methods suitable to surrounding conditions.
- **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.  
See Section 13 for disposal information.

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### 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/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*

### 9 Physical and chemical properties

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

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· <b>Colour:</b>	Light blue
· <b>Odour:</b>	Odourless
· <b>Odour threshold:</b>	Not determined.
· <b>pH-value:</b>	Not applicable.
· <b>Change in condition</b>	
<b>Melting point/freezing point:</b>	Undetermined.
<b>Initial boiling point and boiling range:</b>	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gas):</b>	Not applicable.
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapour pressure:</b>	Not determined.
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water:</b>	Not miscible or difficult to mix.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
· <b>Other information</b>	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.

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitisation** No sensitising effects known.

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· **Additional toxicological information:** No further relevant information available.

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### 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>ADR/RID/ADN, ADN, IMDG, IATA</b>                                       | Void                                                                           |
| · <b>UN proper shipping name</b>                                            |                                                                                |
| · <b>ADR/RID/ADN, ADN, IMDG, IATA</b>                                       | Void                                                                           |
| · <b>Transport hazard class(es)</b>                                         |                                                                                |
| · <b>ADR/RID/ADN, ADN, IMDG, IATA</b>                                       |                                                                                |
| · <b>Class</b>                                                              | Void                                                                           |
| · <b>Packing group</b>                                                      |                                                                                |
| · <b>ADR/RID/ADN, IMDG, IATA</b>                                            | Void                                                                           |
| · <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). |

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· UN "Model Regulation": Void

### 15 Regulatory information

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

· **New Zealand Inventory of Chemicals**

All ingredients are listed.

· **HSNO Approval numbers**

CAS: 14464-46-1 *cristobalite*

HSR003244

CAS: 14808-60-7 *Quartz (SiO<sub>2</sub>)*

HSR003125

· **GHS label elements**

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

· **Hazard pictograms**



GHS08

· **Signal word** *Warning*

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

*cristobalite*

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

· **Hazard statements**

*May cause 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.*

### 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: Inhalation.*

· **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*

*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*

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

vPvB: very Persistent and very Bioaccumulative

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

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

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