

Safety Data Sheet
according to HPR, Schedule 1

Printing date 10/23/2019

Version number 8

Reviewed on 04/26/2019

1 Identification

- **Product identifier**
- **Trade name:** Virtual Light Body Regular / Fast Base, Virtual Extra Light Body Regular / Fast Base
- **Application of the substance / the mixture** Dental impression material
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285

Ivoclar Vivadent Inc.
1-6600 Dixie Road
Mississauga, Ontario
L5T 2Y2
Canada
Phone: +1 905 670 8499
Fax: +1 905 670 3102
- **Information department:** Quality Assurance / Regulatory Affairs
- **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666

General SDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard identification

- **Classification of the substance or mixture**
Carcinogenicity - Category 1A H350 May cause cancer.
Specific Target Organ Toxicity - Repeated Exposure - Category 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 labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



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- **Signal word** Danger
- **Hazard-determining components of labeling:**
cristobalite
Quartz (SiO₂)

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- **Hazard statements**

May cause cancer.

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

- **Precautionary statements**

Get medical advice/attention if you feel unwell.

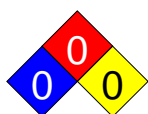
Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Additional information:**

Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



Health = *0

Fire = 0

Reactivity = 0

3 Composition/Information on ingredients

- **Chemical characterization: Mixtures**

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

- **Dangerous components:**

CAS: 14464-46-1	cristobalite	10-30% w/w *
CAS: 14808-60-7	Quartz (SiO ₂)	1-5% w/w *

* Actual concentration ranges are withheld as a trade secret.

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 Firefighting measures

- **Extinguishing media**

- **Suitable extinguishing agents:**

CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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- **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.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **Information about protection against explosions and fires:** 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 receptacle 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 systems:** No further data; see item 7.
- **Control parameters**
- **Components 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 that were valid during the creation 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.
- **Breathing equipment:** 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

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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
· Color:	Light blue
· Odor:	like peppermint
· Odor threshold:	Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not applicable.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapor pressure:** Not determined.

· **Density:** Not determined.

· **Relative density** Not determined.

· **Vapor 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.

· **Viscosity:**

· 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.

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- **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:**
 - **on the skin:** No irritant effect.
 - **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:** No further relevant information available.

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

CAS: 14464-46-1	crystalite	I
CAS: 14808-60-7	Quartz (SiO ₂)	I

- **NTP (National Toxicology Program)**

CAS: 14464-46-1	crystalite	K
CAS: 14808-60-7	Quartz (SiO ₂)	K

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior 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 (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.

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- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
· **DOT/TDG, ADR, ADN, IMDG, IATA** *Void*
- **UN proper shipping name**
· **DOT/TDG, ADR, ADN, IMDG, IATA** *Void*
- **Transport hazard class(es)**
· **DOT, ADR, ADN, IMDG, IATA**
· **Class** *Void*
- **Packing group**
· **DOT/TDG, ADR, IMDG, IATA** *Void*
- **Environmental hazards:**
· **Marine pollutant:** *No*
- **Special precautions for user** *Not applicable.*
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** *Not applicable.*
- **Transport/Additional information:** *Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).*
- **UN "Model Regulation":** *Void*

15 Regulatory information

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

- **Sara**

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

- **TSCA (Toxic Substances Control Act):**

CAS: 14464-46-1 *crystalite*

CAS: 14808-60-7 *Quartz (SiO₂)*

CAS: 9016-45-9 *Renex 678*

- **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



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- **Signal word** *Danger*
- **Hazard-determining components of labeling:**
*crystalite
Quartz (SiO₂)*
- **Hazard statements**
*May cause cancer.
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.*
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
*The product is a medical device according to the Directive 93/42/EEC.
This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.*
- **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.

- **Date of the latest revision of the safety data sheet** *10/23/2019 / 7*
- **Abbreviations and acronyms:**
*IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative*
- *** Data compared to the previous version altered.**

CA