

**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 Monophase Regular / Fast Base, Virtual Medium 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**  
  
GHS08
- **Signal word** Danger
- **Hazard-determining components of labeling:**  
cristobalite
- **Hazard statements**  
May cause cancer.

(Contd. on page 2)

## Safety Data Sheet according to HPR, Schedule 1

Printing date 10/23/2019

Version number 8

Reviewed on 04/26/2019

**Trade name: Virtual Monophase Regular / Fast Base, Virtual Medium Regular / Fast Base**

(Contd. of page 1)

*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)**



· **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = *0
FIRE	0	Fire = 0
REACTIVITY	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 *
-----------------	--------------	--------------

\* 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:**

*CO<sub>2</sub>, extinguishing 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.

(Contd. on page 3)

## Safety Data Sheet

### according to HPR, Schedule 1

Printing date 10/23/2019

Version number 8

Reviewed on 04/26/2019

**Trade name: Virtual Monophase Regular / Fast Base, Virtual Medium Regular / Fast Base**

(Contd. of page 2)

- **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 resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the

(Contd. on page 4)

## Safety Data Sheet

### according to HPR, Schedule 1

Printing date 10/23/2019

Version number 8

Reviewed on 04/26/2019

**Trade name: Virtual Monophase Regular / Fast Base, Virtual Medium Regular / Fast Base**

(Contd. of page 3)

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:**

· <b>Form:</b>	Viscous
· <b>Color:</b>	Light brown
· <b>Odor:</b>	like peppermint
· <b>Odor threshold:</b>	Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

· <b>Melting point/Melting range:</b>	Undetermined.
· <b>Boiling point/Boiling range:</b>	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:**

· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	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.

· **Possibility of hazardous reactions** No dangerous reactions known.

(Contd. on page 5)

CA

## Safety Data Sheet

### according to HPR, Schedule 1

Printing date 10/23/2019

Version number 8

Reviewed on 04/26/2019

**Trade name: Virtual Monophase Regular / Fast Base, Virtual Medium Regular / Fast Base**

(Contd. of page 4)

- **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 cristobalite

I

- **NTP (National Toxicology Program)**

CAS: 14464-46-1 cristobalite

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

CA

(Contd. on page 6)

## Safety Data Sheet

according to HPR, Schedule 1

Printing date 10/23/2019

Version number 8

Reviewed on 04/26/2019

**Trade name: Virtual Monophase Regular / Fast Base, Virtual Medium Regular / Fast Base**

(Contd. of page 5)

### 14 Transport information

<b>· UN-Number</b>	Void
<b>· DOT/TDG, ADR, ADN, IMDG, IATA</b>	Void
<b>· UN proper shipping name</b>	Void
<b>· DOT/TDG, ADR, ADN, IMDG, IATA</b>	Void
<b>· Transport hazard class(es)</b>	Void
<b>· DOT, ADR, ADN, IMDG, IATA</b>	Void
<b>· Class</b>	Void
<b>· Packing group</b>	Void
<b>· DOT/TDG, ADR, 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 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).
<b>· UN "Model Regulation":</b>	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 cristobalite

CAS: 9016-45-9 Renex 678

**· GHS label elements**

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

**· Hazard pictograms**



GHS08

**· Signal word** Danger

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

cristobalite

**· Hazard statements**

May cause cancer.

(Contd. on page 7)

CA

**Safety Data Sheet**  
according to HPR, Schedule 1

Printing date 10/23/2019

Version number 8

Reviewed on 04/26/2019

**Trade name: Virtual Monophase Regular / Fast Base, Virtual Medium Regular / Fast Base**

(Contd. of page 6)

*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