

**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 10/23/2019

Version number 8

Reviewed on 04/26/2019


**1 Identification**

- **Product identifier**
- **Trade name:** **Virtual Heavy Body Fast / Regular Catalyst, Virtual Heavy Body Fast / Regular 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(s) identification**

- **Classification of the substance or mixture**  
Carc. 1A H350 May cause cancer.  
STOT RE 1 H372 Causes 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 labeled according to the Globally Harmonized System (GHS).
  - **Hazard pictograms**
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GHS08
- **Signal word** Danger
  - **Hazard-determining components of labeling:**  
cristobalite
  - **Hazard statements**  
May cause cancer.  
Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

(Contd. on page 2)

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(Contd. of page 1)

- **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

- **Other hazards**

- **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

### 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	25-50%
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### 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>, 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 acc. to OSHA HCS

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**Trade name: Virtual Heavy Body Fast / Regular Catalyst, Virtual Heavy Body Fast / Regular 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

acc. to OSHA HCS

Printing date 10/23/2019

Version number 8

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**Trade name: Virtual Heavy Body Fast / Regular Catalyst, Virtual Heavy Body Fast / Regular 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:**

Form:	Viscous
Color:	According to product specification
Odor:	Characteristic
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.

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

(Contd. on page 5)

## Safety Data Sheet

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Version number 8

Reviewed on 04/26/2019

**Trade name: Virtual Heavy Body Fast / Regular Catalyst, Virtual Heavy Body Fast / Regular 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
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- **NTP (National Toxicology Program)**

CAS: 14464-46-1	cristobalite	K
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- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

### 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.

US  
(Contd. on page 6)

## Safety Data Sheet

acc. to OSHA HCS

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Version number 8

Reviewed on 04/26/2019

**Trade name: Virtual Heavy Body Fast / Regular Catalyst, Virtual Heavy Body Fast / Regular Base**

(Contd. of page 5)

### 14 Transport information

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

**· Proposition 65**

**· Chemicals known to cause cancer:**

CAS: 14464-46-1 cristobalite

**· Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

**· Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

**· Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

(Contd. on page 7)

## Safety Data Sheet

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**Trade name: Virtual Heavy Body Fast / Regular Catalyst, Virtual Heavy Body Fast / Regular Base**

(Contd. of page 6)

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

CAS: 14464-46-1 cristobalite

A2

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

CAS: 14464-46-1 cristobalite

· **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.

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 preparation / last revision** 10/23/2019 / 7

· **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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

(Contd. on page 8)

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**Trade name: Virtual Heavy Body Fast / Regular Catalyst, Virtual Heavy Body Fast / Regular Base**

(Contd. of page 7)

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Carc. 1A: Carcinogenicity – Category 1A

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

· **\* Data compared to the previous version altered.**

US