

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

Printing date 05/04/2015

Version number 7

Reviewed on 04/28/2015


**1 Identification**

- **Product identifier**
- **Trade name:** *Virtual CADbite Registration 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 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:  
Inhalative.

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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:**  
*crystalite*
  - **Hazard statements**  
*May cause cancer.*  
*Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalative.*

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- **Precautionary statements**

Get medical advice/attention if you feel unwell.

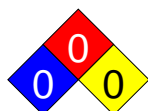
Dispose of contents/container in accordance with local/regional/national/international regulations.

- **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

- **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:**

14464-46-1	cristobalite	2.5-<10%
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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.

Generally the product does not irritate the skin.

- **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.

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- **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.
- **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.  
Wash hands before breaks and at the end of work.  
Keep away from foodstuffs, beverages and feed.
- **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 application.

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· **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:** Pasty

· **Color:** White

· **Odor:** Odorless

· **Odour 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.

· **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.

· **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.

· **Conditions to avoid** No further relevant information available.

· **Incompatible materials:** No further relevant information available.

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· **Hazardous decomposition products:** None under normal conditions of storage and use.

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **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)**

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· **NTP (National Toxicology Program)**

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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:** Generally not hazardous for water
- **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.

### 14 Transport information

- **UN-Number**
- **DOT, ADR, ADN, IMDG, IATA**                      Void

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

### 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):*

All ingredients are listed.

· *Proposition 65*

· *Chemicals known to cause cancer:*

All ingredients are listed.

· *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.

· *Carcinogenic categories*

· *EPA (Environmental Protection Agency)*

None of the ingredients is listed.

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

14464-46-1 | cristobalite

A2

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

All ingredients are listed.

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- **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: Inhalative.*

- **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** 05/04/2015 / 6

- **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)*

*Carc. 1A: Carcinogenicity, Hazard Category 1A*

*STOT RE 1: Specific target organ toxicity - Repeated exposure, Hazard Category 1*

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