

# Safety Data Sheet

acc. to OSHA HCS

Printing date 06/27/2014

Version number 6

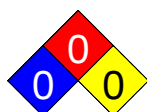
Reviewed on 06/26/2014

## 1 Identification

- **Product identifier**
- **Trade name:** ***Virtual 380 Heavy Fast / Regular Base***
- **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 MSDS Assistance:  
US: 1-800-533-6825  
Canada: 1-800-263-8182

## 2 Hazard(s) identification

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.
- **Classification system:**  
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
- **Label elements**
- **Labelling according to EU guidelines:**  
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 Dangerous Preparations Directive 1999/45/EC usually if they are in the finished state and intended for the final user.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



Health = 0  
Fire = 0  
Reactivity = 0

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### · 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:

|            |                                   |         |
|------------|-----------------------------------|---------|
| 14464-46-1 | cristobalite                      | 10-<25% |
| 9016-45-9  | 4-Nonylphenyl-polyethylene glycol | 0.1-<1% |

### · SVHC

|           |                                   |
|-----------|-----------------------------------|
| 9016-45-9 | 4-Nonylphenyl-polyethylene glycol |
|-----------|-----------------------------------|

## 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.
- **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.
- **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.

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See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

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### 7 Handling and storage

- **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.

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 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

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### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form: Viscous

Color: Blue

- **Odor:** like peppermint

- **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.

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

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### 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:**  
The product is not subject to classification according to internally approved calculation methods for preparations:
- **Carcinogenic categories**

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

14464-46-1 cristobalite

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- **NTP (National Toxicology Program)**

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### 12 Ecological information

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

### 14 Transport information

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

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|                                                                                      |                                                                                |
|--------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| · <b>UN proper shipping name</b><br>· DOT, ADR, ADN, IMDG, IATA                      | Void                                                                           |
| · <b>Transport hazard class(es)</b><br>· DOT, ADR, ADN, IMDG, IATA<br>· <b>Class</b> | Void                                                                           |
| · <b>Packing group</b><br>· DOT, ADR, IMDG, IATA                                     | Void                                                                           |
| · <b>Environmental hazards:</b><br>· <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). |

## 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:**

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· **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)**

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

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**· OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

**· Product related hazard 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 Dangerous Preparations Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

**· 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** 06/27/2014 / 5

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