

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 12.06.2014

Version number 6

Revision: 12.06.2014

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

- **1.1 Product identifier**
- **Trade name:** Virtual Heavy Fast / Regular Catalyst
- **1.2 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
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent AG  
Bendererstrasse 2  
FL-9494 Schaan  
PRINCIPALITY OF LIECHTENSTEIN  
  
Tel: +423 235 35 35  
Fax: +423 235 33 60
- **Further information obtainable from:**  
Regulatory Affairs  
msds@ivoclarvivadent.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.
- **Classification system:**  
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
- **2.2 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.
- **Special labelling of certain preparations:**  
Safety data sheet available for professional user on request.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

**SECTION 3: Composition/information on ingredients**

- **3.2 Chemical characterization: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

• **Dangerous components:**

CAS: 14464-46-1 EINECS: 238-455-4	cristobalite	Xn R48/20	10-25%
CAS: 9016-45-9 NLP: 500-024-6	4-Nonylphenyl-polyethylene glycol	Xn R22; Xi R37-41; N R50	< 2.5%

• **SVHC**

9016-45-9	4-Nonylphenyl-polyethylene glycol
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**Trade name: Virtual Heavy Fast / Regular Catalyst**

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· **Additional information:** For the wording of the listed risk phrases refer to section 16.

#### **SECTION 4: First aid measures**

- **4.1 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.
- **4.2 Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

#### **SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

#### **SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 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.

#### **SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling**  
Only adequately trained personnel should handle this product.  
For use in dentistry only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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 container tightly sealed.  
Protect from heat and direct sunlight.

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- 7.3 **Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
  - **Ingredients 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 valid during the making were used as basis.
- **8.2 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.
    - **Respiratory protection:** 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

### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - Form:** Viscous
      - Colour:** White
      - Odour:** Odourless
      - 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.
  - **Self-igniting:** Product is not selfigniting.
  - **Danger of explosion:** Product does not present an explosion hazard.

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

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- |  |                 |
|--|-----------------|
| · <b>Explosion limits:</b>   |                 |
| <b>Lower:</b>  | Not determined. |
| <b>Upper:</b>  | Not determined. |
| · <b>Vapour pressure:</b> Not determined.  |                 |
| · <b>Density:</b> Not determined.  |                 |
| · <b>Relative density</b> Not determined.  |                 |
| · <b>Vapour density</b> Not determined.  |                 |
| · <b>Evaporation rate</b> Not determined.  |                 |
| · <b>Solubility in / Miscibility with water:</b> Not miscible or difficult to mix. |                 |
| · <b>Partition coefficient (n-octanol/water):</b> Not determined.                  |                 |
| · <b>Viscosity:</b>  |                 |
| <b>Dynamic:</b>  | Not determined. |
| <b>Kinematic:</b>  | Not determined. |
| · <b>9.2 Other information</b> No further relevant information available.          |                 |

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None under normal conditions of storage and use.

### SECTION 11: Toxicological information

- **11.1 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 the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.

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

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- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |   |  |
|---|--|
| · <b>14.1 UN-Number</b>   |  |
| · <b>ADR, ADN, IMDG, IATA</b>   | Void   |
| · <b>14.2 UN proper shipping name</b>   |  |
| · <b>ADR, ADN, IMDG, IATA</b>   | Void   |
| · <b>14.3 Transport hazard class(es)</b>  |  |
| · <b>ADR, ADN, IMDG, IATA</b>   |  |
| · <b>Class</b>  | Void   |
| · <b>14.4 Packing group</b>   |  |
| · <b>ADR, IMDG, IATA</b>  | Void   |
| · <b>14.5 Environmental hazards:</b>  |  |
| · <b>Marine pollutant:</b>  | No   |
| · <b>14.6 Special precautions for user</b>  | Not applicable.  |
| · <b>14.7 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). |

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
The product is a medical device according to the Directive 93/42/EEC.

**Substances of very high concern (SVHC) according to REACH, Article 57**

9016-45-9	4-Nonylphenyl-polyethylene glycol
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· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**SECTION 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.*

· **Relevant phrases**

R22 Harmful if swallowed.

R37 Irritating to respiratory system.

R41 Risk of serious damage to eyes.

R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation.

R50 Very toxic to aquatic organisms.

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**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

- **1.1 Product identifier**
- **Trade name:** **Virtual Heavy Regular / Fast Base**
- **1.2 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
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent AG  
Bendererstrasse 2  
FL-9494 Schaan  
PRINCIPALITY OF LIECHTENSTEIN  
  
Tel: +423 235 35 35  
Fax: +423 235 33 60
- **Further information obtainable from:**  
Regulatory Affairs  
msds@ivoclarvivadent.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.
- **Classification system:**  
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
- **2.2 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.
- **Special labelling of certain preparations:**  
Safety data sheet available for professional user on request.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

**SECTION 3: Composition/information on ingredients**

- **3.2 Chemical characterization: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 14464-46-1 EINECS: 238-455-4	cristobalite	Xn R48/20	10-25%
CAS: 9016-45-9 NLP: 500-024-6	4-Nonylphenyl-polyethylene glycol	Xn R22; Xi R37-41; N R50	< 2.5%

· **SVHC**

9016-45-9	4-Nonylphenyl-polyethylene glycol
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· **Additional information:** For the wording of the listed risk phrases refer to section 16.

#### **SECTION 4: First aid measures**

- **4.1 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.
- **4.2 Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

#### **SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

#### **SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 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.

#### **SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling**  
Only adequately trained personnel should handle this product.  
For use in dentistry only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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 container tightly sealed.  
Protect from heat and direct sunlight.

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- 7.3 Specific end use(s) No further relevant information available.

### SECTION 8: Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see item 7.
- 8.1 Control parameters
- Ingredients 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 valid during the making were used as basis.
- 8.2 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.
- Respiratory protection: 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

### SECTION 9: Physical and chemical properties

- 9.1 Information on basic physical and chemical properties
- General Information
- Appearance:
 

Form:	Viscous
Colour:	Blue
Odour:	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.
- Self-igniting: Product is not selfigniting.
- Danger of explosion: Product does not present an explosion hazard.

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Trade name: **Virtual Heavy Regular / Fast Base**

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- |  |                 |
|--|-----------------|
| · <b>Explosion limits:</b>   |                 |
| Lower:   | Not determined. |
| Upper:   | Not determined. |
| · <b>Vapour pressure:</b> Not determined.  |                 |
| · <b>Density:</b> Not determined.  |                 |
| · <b>Relative density</b> Not determined.  |                 |
| · <b>Vapour density</b> Not determined.  |                 |
| · <b>Evaporation rate</b> Not determined.  |                 |
| · <b>Solubility in / Miscibility with water:</b> Not miscible or difficult to mix. |                 |
| · <b>Partition coefficient (n-octanol/water):</b> Not determined.                  |                 |
| · <b>Viscosity:</b>  |                 |
| Dynamic:   | Not determined. |
| Kinematic:   | Not determined. |
| · <b>9.2 Other information</b> No further relevant information available.          |                 |

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None under normal conditions of storage and use.

**SECTION 11: Toxicological information**

- **11.1 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 the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

**SECTION 12: Ecological information**

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.

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- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |   |  |
|---|--|
| · <b>14.1 UN-Number</b>   |  |
| · <b>ADR, ADN, IMDG, IATA</b>   | Void   |
| · <b>14.2 UN proper shipping name</b>   |  |
| · <b>ADR, ADN, IMDG, IATA</b>   | Void   |
| · <b>14.3 Transport hazard class(es)</b>  |  |
| · <b>ADR, ADN, IMDG, IATA</b>   |  |
| · <b>Class</b>  | Void   |
| · <b>14.4 Packing group</b>   |  |
| · <b>ADR, IMDG, IATA</b>  | Void   |
| · <b>14.5 Environmental hazards:</b>  |  |
| · <b>Marine pollutant:</b>  | No   |
| · <b>14.6 Special precautions for user</b>  | Not applicable.  |
| · <b>14.7 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). |

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
The product is a medical device according to the Directive 93/42/EEC.

· **Substances of very high concern (SVHC) according to REACH, Article 57**

9016-45-9	4-Nonylphenyl-polyethylene glycol
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**Trade name: Virtual Heavy Regular / Fast Base**

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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**SECTION 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.*

**· Relevant phrases**

R22 Harmful if swallowed.

R37 Irritating to respiratory system.

R41 Risk of serious damage to eyes.

R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation.

R50 Very toxic to aquatic organisms.

GB